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2025

LEGISLATURE OF NEBRASKA

ONE HUNDRED NINTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 253

Introduced by Bostar, 29.

Read first time January 14, 2025

Committee: Banking, Commerce and Insurance

A BILL FOR AN ACT relating to public health and welfare; to provide for biomarker testing as prescribed.

Be it enacted by the people of the State of Nebraska,

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Section 1. For purposes of sections 1 to 3 of this act:

(1) Biomarker means 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 medications being considered for use or already being administered. Biomarkers include, but are not limited to, gene mutations, characteristics of genes, or protein expression;

(2) Biomarker testing means the analysis of 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;

(3) Consensus statements means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care; and

(4) Nationally recognized clinical practice guidelines means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

Sec. 2. (1) Health insurers, nonprofit health service plans, and health maintenance organizations issuing, amending, delivering, or renewing a health insurance contract on or after January 1, 2026, shall include coverage for biomarker testing pursuant to criteria established

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under subsection (2) of this section.

(2) Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(a) Labeled indications for a test approved or cleared by the federal Food and Drug Administration;

(b) Indicated tests for a drug approved by the federal Food and Drug Administration;

(c) Warnings and precautions on drug labels approved by the federal Food and Drug Administration;

(d) National coverage determinations by the federal Centers for Medicare and Medicaid Services or local coverage determinations by the medicare administrative contractor; or

(e) Nationally recognized clinical practice guidelines and consensus statements.

(3) Health insurers, nonprofit health service plans, and health maintenance organizations shall ensure that coverage, as specified in subsection (2) of this section, is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(4) If prior authorization is required, the health insurer, nonprofit health service plan, health maintenance organization, prior authorization entity, or any third party acting on behalf of an organization or entity subject to this section shall approve or deny a prior authorization request and notify the patient, the patient's health care provider, and any entity requesting authorization of the service within seventy-two hours for nonurgent requests or within twenty-four hours for urgent requests.

(5) The patient and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception

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to a coverage policy or an adverse prior authorization determination. The process shall be made readily accessible on the health insurer's, nonprofit health service plan's, or health maintenance organization's website.

Sec. 3. (1) The medical assistance program shall cover biomarker testing no later than January 1, 2026.

(2) Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(a) Labeled indications for a test approved or cleared by the federal Food and Drug Administration;

(b) Indicated tests for a drug approved by the federal Food and Drug Administration;

(c) Warnings and precautions on drug labels approved by the federal Food and Drug Administration;

(d) National coverage determinations by the federal Centers for Medicare and Medicaid Services or local coverage determinations by the medicare administrative contractor; or

(e) Nationally recognized clinical practice guidelines and consensus statements.

(3) Entities contracting with the medical assistance program to deliver services to program recipients shall provide biomarker testing at the same scope, duration, and frequency as the medical assistance program otherwise provides to recipients.

(4) If prior authorization is required, the medical assistance program or any third party acting on behalf of the medical assistance program shall approve or deny a prior authorization request and notify the recipient, the recipient's health care provider, and any entity requesting authorization of the service within seventy-two hours for nonurgent requests or within twenty-four hours for urgent requests.

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(5) The recipient and participating medical assistance program provider shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy of the medical assistance program or an adverse prior authorization determination. The process shall be made readily accessible on the Department of Health and Human Services' website.