

LEGISLATURE OF NEBRASKA
ONE HUNDRED NINTH LEGISLATURE
FIRST SESSION

LEGISLATIVE BILL 253

Introduced by Bostar, 29.

Read first time January 14, 2025

Committee:

- 1 A BILL FOR AN ACT relating to public health and welfare; to provide for
- 2 biomarker testing as prescribed.
- 3 Be it enacted by the people of the State of Nebraska,

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

2 (1) Biomarker means a characteristic that is objectively measured
3 and evaluated as an indicator of normal biological processes, pathogenic
4 processes, or pharmacologic responses to a specific therapeutic
5 intervention, including known gene-drug interactions for medications
6 being considered for use or already being administered. Biomarkers
7 include, but are not limited to, gene mutations, characteristics of
8 genes, or protein expression;

9 (2) Biomarker testing means the analysis of tissue, blood, or other
10 biospecimen for the presence of a biomarker. Biomarker testing includes,
11 but is not limited to, single-analyte tests, multi-plex panel tests,
12 protein expression, and whole exome, whole genome, and whole
13 transcriptome sequencing;

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

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

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

1 under subsection (2) of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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