

House File 2157 - Introduced

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BY LOHSE, YOUNG, and LUNDGREN

A BILL FOR

1 An Act relating to insurance coverage for biomarker testing.

2 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 514C.36 Biomarker testing —
2 coverage.

3 1. As used in this section, unless the context otherwise
4 requires:

5 a. "*Biomarker*" means a characteristic that is objectively
6 measured and evaluated as an indicator of normal biological
7 processes, pathogenic processes, or pharmacologic responses to
8 a specific therapeutic intervention, including but not limited
9 to genetic mutations or protein expression.

10 b. "*Biomarker testing*" means the analysis of an individual's
11 tissue, blood, or other biospecimen for the presence of a
12 biomarker, including but not limited to single-analyte tests,
13 multiplex panel tests, or whole genome sequencing.

14 c. "*Clinical utility*" means sufficient medical and
15 scientific evidence indicating the use of a specific biomarker
16 test will provide meaningful information that will affect
17 treatment decisions and improve a covered person's outcome.

18 d. "*Consensus statement*" means a statement developed by
19 an independent, multidisciplinary panel of experts, none of
20 whom have a conflict of interest, who utilize a transparent
21 methodology and reporting structure. A consensus statement
22 concerns specific clinical circumstances and is based on the
23 best available evidence for the purpose of optimizing the
24 outcomes of clinical care.

25 e. "*Covered person*" means a policyholder, subscriber, or
26 other person participating in a policy, contract, or plan that
27 provides for third-party payment or prepayment of health or
28 medical expenses.

29 f. "*Health care professional*" means the same as defined in
30 section 514J.102.

31 g. "*Local coverage determinations*" means the same as defined
32 in section 1869(f)(2)(B) of the federal Social Security Act.

33 h. "*National coverage determinations*" means the same as
34 defined in section 1869(f)(1)(B) of the federal Social Security
35 Act.

1 *i. "Nationally recognized clinical practice guidelines"*
2 means evidence-based clinical practice guidelines developed by
3 independent organizations or medical professional societies,
4 none of which have a conflict of interest, that utilize a
5 transparent methodology and reporting structure. Clinical
6 practice guidelines establish standards of care informed
7 by a systematic review of evidence and assessment of the
8 costs and benefits of alternative care options and include
9 recommendations intended to optimize patient care.

10 2. Notwithstanding the uniformity of treatment requirements
11 of section 514C.6, a policy, contract, or plan providing for
12 third-party payment or prepayment of medical expenses shall
13 provide coverage for biomarker testing for the purposes of
14 diagnosing, treating, appropriately managing, or monitoring
15 cancer in a covered person when the biomarker testing has
16 demonstrated clinical utility, including but not limited to any
17 of the following:

18 *a.* Labeled indications for a test approved or cleared by
19 the United States food and drug administration or indicated
20 tests for a drug approved by the United States food and drug
21 administration.

22 *b.* Centers for Medicare and Medicaid services of the
23 United States department of health and human services national
24 coverage determinations or Medicare administrative contractor
25 local coverage determinations.

26 *c.* Nationally recognized clinical practice guidelines and
27 consensus statements.

28 3. Coverage required under this section shall limit
29 disruptions in care, including mitigating the need for a
30 covered person to undergo multiple biopsies or to provide
31 multiple biospecimen samples.

32 4. A covered person and the covered person's health care
33 professional shall have access to a clear and convenient
34 process available on the health carrier's internet site to
35 request an exception to coverage provided under this section.

1 5. *a.* This section applies to the following classes of
2 third-party payment provider policies, contracts, or plans
3 delivered, issued for delivery, continued, or renewed in this
4 state on or after January 1, 2025:

5 (1) Individual or group accident and sickness insurance
6 providing coverage on an expense-incurred basis.

7 (2) An individual or group hospital or medical service
8 contract issued pursuant to chapter 509, 514, or 514A.

9 (3) An individual or group health maintenance organization
10 contract regulated under chapter 514B.

11 (4) A plan established pursuant to chapter 509A for public
12 employees.

13 *b.* This section shall apply to all of the following:

14 (1) The medical assistance program under chapter 249A.

15 (2) The healthy and well kids in Iowa (Hawki) program under
16 chapter 514I.

17 (3) A managed care organization acting pursuant to a
18 contract with the department of health and human services under
19 chapter 249A, or with the healthy and well kids in Iowa (Hawki)
20 program under chapter 514I.

21 *c.* This section shall not apply to accident-only,
22 specified disease, short-term hospital or medical, hospital
23 confinement indemnity, credit, dental, vision, Medicare
24 supplement, long-term care, basic hospital and medical-surgical
25 expense coverage as defined by the commissioner, disability
26 income insurance coverage, coverage issued as a supplement
27 to liability insurance, workers' compensation or similar
28 insurance, or automobile medical payment insurance.

29 6. The commissioner of insurance may adopt rules pursuant to
30 chapter 17A to administer this section.

31

EXPLANATION

32 The inclusion of this explanation does not constitute agreement with
33 the explanation's substance by the members of the general assembly.

34 This bill relates to health insurance coverage for biomarker
35 testing.

1 The bill defines "biomarker testing" as an analysis of
2 an individual's tissue, blood, or other biospecimen for the
3 presence of a biomarker. "Biomarker" is also defined in the
4 bill.

5 The bill requires a health carrier that offers individual,
6 group, or small group contracts, policies, or plans in this
7 state that provide for third-party payment or prepayment of
8 health or medical expenses to offer coverage for biomarker
9 testing for purposes of diagnosing, treating, appropriately
10 managing, or monitoring cancer in a covered person when the
11 test has demonstrated clinical utility as detailed in the bill.
12 "Clinical utility" is defined in the bill. Coverage shall be
13 provided in a manner which limits disruptions in a person's
14 care. The bill requires a health carrier to provide a process
15 on its internet site for a person and the person's health care
16 professional to seek an exception to coverage required under
17 the bill.

18 The bill applies to third-party payment provider contracts,
19 policies, or plans delivered, issued for delivery, continued,
20 or renewed in this state on or after January 1, 2025, by the
21 third-party payment providers enumerated in the bill. The bill
22 specifies the types of specialized health-related insurance
23 which are not subject to the bill's coverage requirements.

24 The bill applies to the medical assistance program
25 under Code chapter 249A, the healthy and well kids in Iowa
26 (Hawki) program under Code chapter 514I, and a managed care
27 organization acting pursuant to a contract with the department
28 of health and human services to administer either the medical
29 assistance program or the Hawki program.

30 The commissioner of insurance may adopt rules to administer
31 the bill.