

**Senate File 2159 - Introduced**

SENATE FILE 2159  
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO SSB 3001)

**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 a biomarker test result  
15 provides information used in the formulation of a treatment or  
16 monitoring strategy that informs a covered person's outcomes  
17 and impacts clinical decisions. The most appropriate biomarker  
18 test may include both information that is actionable and  
19 information that cannot be immediately used in the formulation  
20 of a clinical decision.

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

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

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

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

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

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

13     2. Notwithstanding the uniformity of treatment requirements  
14 of section 514C.6, a policy, contract, or plan providing for  
15 third-party payment or prepayment of medical expenses shall  
16 provide coverage for biomarker testing for the purposes of  
17 diagnosis, treatment, appropriate management, or ongoing  
18 monitoring of a covered person's disease or condition when the  
19 test provides clinical utility as demonstrated by medical and  
20 scientific evidence, including but not limited to any of the  
21 following:

22     *a.* Labeled indications for a test approved or cleared by  
23 the United States food and drug administration or indicated  
24 tests for a drug approved by the United States food and drug  
25 administration.

26     *b.* Centers for Medicare and Medicaid services of the  
27 United States department of health and human services national  
28 coverage determinations or Medicare administrative contractor  
29 local coverage determinations.

30     *c.* Nationally recognized clinical practice guidelines and  
31 consensus statements.

32     3. Coverage required under this section shall limit  
33 disruptions in care, including mitigating the need for a  
34 covered person to undergo multiple biopsies or to provide  
35 multiple biospecimen samples.

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

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

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

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

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

15 (4) A plan established pursuant to chapter 509A for public  
16 employees.

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

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

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

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

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

33 6. The commissioner of insurance shall adopt rules pursuant  
34 to chapter 17A to administer this section.

35

EXPLANATION

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

3       This bill relates to health insurance coverage for biomarker  
4 testing.

5       The bill defines "biomarker testing" as an analysis of  
6 an individual's tissue, blood, or other biospecimen for the  
7 presence of a biomarker. "Biomarker" is also defined in the  
8 bill.

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

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

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

33       The commissioner of insurance is required to adopt rules to  
34 administer the bill.