

**House File 2492 - Introduced**

HOUSE FILE 2492  
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HF 2157)

**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 a  
15 disease or condition in a covered person when the biomarker  
16 testing has demonstrated clinical utility, including but not  
17 limited to any 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 a disease or condition in a covered  
11 person when the test has demonstrated clinical utility as  
12 detailed in the bill. "Clinical utility" is defined in the  
13 bill. Coverage shall be provided in a manner which limits  
14 disruptions in a person's care. The bill requires a health  
15 carrier to provide a process on its internet site for a person  
16 and the person's health care professional to seek an exception  
17 to coverage required under 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.