

COMMITTEE ON COMMERCE  
SENATE AMENDMENTS TO S.B. 1052  
(Reference to printed bill)

1 Strike everything after the enacting clause and insert:

2 "Section 1. Section 20-1376.10, Arizona Revised Statutes, is amended  
3 to read:

4 20-1376.10. Biomarker testing; coverage; definitions

5 A. A disability insurer that issues, amends, delivers or renews a  
6 policy on or after January 1, 2023 shall provide coverage for biomarker  
7 testing.

8 B. A policy shall cover biomarker testing for the purposes of  
9 diagnosis, treatment, appropriate management or ongoing monitoring of an  
10 insured's disease or condition to guide treatment decisions when the test  
11 provides clinical utility as demonstrated by medical and scientific  
12 evidence, including any of the following:

13 1. Labeled indications for tests that are approved or cleared by the  
14 United States food and drug administration or indicated tests for a drug  
15 that is approved by the United States food and drug administration.

16 2. Centers for medicare and medicaid services national coverage  
17 determinations or medicare administrative contractor local coverage  
18 determinations.

19 3. Nationally recognized clinical practice guidelines and consensus  
20 statements.

21 C. A disability insurer must ensure that coverage is provided in a  
22 manner that limits disruptions in care, including the need for multiple  
23 biopsies or biospecimen samples.

24 D. The insured and prescribing practitioner must have access to a  
25 clear, readily accessible and convenient process to request an exception to

1 a coverage policy of a disability insurer. The process shall be readily  
2 accessible on the disability insurer's website. This subsection does not  
3 require a separate process if the disability insurer's existing process  
4 complies with this subsection.

5 E. A POLICY THAT IS ISSUED OR RENEWED BY A DISABILITY INSURER DOES  
6 NOT INCLUDE A POLICY THAT PROVIDES LIMITED BENEFIT COVERAGE AS DEFINED IN  
7 SECTION 20-1137.

8 ~~F.~~ F. For the purposes of this section:

9 1. "Biomarker":

10 (a) Means a characteristic that is objectively measured and  
11 evaluated as an indicator of normal biological processes, pathogenic  
12 processes or pharmacologic responses to a specific therapeutic  
13 intervention.

14 (b) Includes gene mutations or protein expression.

15 2. "Biomarker testing":

16 (a) Means the analysis of a patient's tissue, blood or other  
17 biospecimen for the presence of a biomarker.

18 (b) Includes single-analyte tests, multiplex panel tests and whole  
19 genome sequencing.

20 3. "Clinical utility" means the test result provides information  
21 that is used in the formulation of a treatment or monitoring strategy that  
22 informs a patient's outcome and impacts the clinical decision. The most  
23 appropriate test may include both information that is actionable and some  
24 information that cannot be immediately used in the formulation of a  
25 clinical decision.

26 4. "Consensus statements" means statements that ARE ALL OF THE  
27 FOLLOWING:

28 (a) ~~Are~~ Developed by an independent, multidisciplinary panel of  
29 experts using a transparent methodology and reporting structure that  
30 includes a conflict of interest policy.

31 (b) ~~Are~~ Based on the best available evidence for the purpose of  
32 optimizing clinical care outcomes.

1 (c) ~~Are~~ Aimed at specific clinical circumstances.

2 5. "Nationally recognized clinical practice guidelines" means  
3 evidence-based clinical practice guidelines that both:

4 (a) Are developed by independent organizations or medical  
5 professional societies using a transparent methodology and reporting  
6 structure and a conflict of interest policy.

7 (b) Establish standards of care that are informed by a systematic  
8 review of evidence and an assessment of the benefits and costs of  
9 alternative care options that includes recommendations intended to optimize  
10 patient care.

11 Sec. 2. Section 20-1406.10, Arizona Revised Statutes, is amended to  
12 read:

13 20-1406.10. Biomarker testing; coverage; definitions

14 A. A group or blanket disability insurer that issues, amends,  
15 delivers or renews a policy on or after January 1, 2023 shall provide  
16 coverage for biomarker testing.

17 B. A policy shall cover biomarker testing for the purposes of  
18 diagnosis, treatment, appropriate management or ongoing monitoring of an  
19 insured's disease or condition to guide treatment decisions when the test  
20 provides clinical utility as demonstrated by medical and scientific  
21 evidence, including any of the following:

22 1. Labeled indications for tests that are approved or cleared by the  
23 United States food and drug administration or indicated tests for a drug  
24 that is approved by the United States food and drug administration.

25 2. Centers for medicare and medicaid services national coverage  
26 determinations or medicare administrative contractor local coverage  
27 determinations.

28 3. Nationally recognized clinical practice guidelines and consensus  
29 statements.

30 C. A group or blanket disability insurer must ensure coverage is  
31 provided in a manner that limits disruptions in care, including the need  
32 for multiple biopsies or biospecimen samples.

1           D. The insured and prescribing practitioner must have access to a  
2 clear, readily accessible and convenient process to request an exception to  
3 a coverage policy of a group or blanket disability insurer. The process  
4 shall be readily accessible on ~~a~~ THE group or blanket disability insurer's  
5 website. This subsection does not require a separate process if the group  
6 or blanket disability insurer's existing process complies with this  
7 subsection.

8           E. A POLICY THAT IS ISSUED OR RENEWED BY A GROUP OR BLANKET  
9 DISABILITY INSURER DOES NOT INCLUDE A POLICY THAT PROVIDES A LIMITED  
10 BENEFIT COVERAGE AS DEFINED IN SECTION 20-1137.

11           ~~F.~~ F. For the purposes of this section:

12           1. "Biomarker":

13           (a) Means a characteristic that is objectively measured and  
14 evaluated as an indicator of normal biological processes, pathogenic  
15 processes or pharmacologic responses to a specific therapeutic  
16 intervention.

17           (b) Includes gene mutations or protein expression.

18           2. "Biomarker testing":

19           (a) Means the analysis of a patient's tissue, blood or other  
20 biospecimen for the presence of a biomarker.

21           (b) Includes single-analyte tests, multiplex panel tests and whole  
22 genome sequencing.

23           3. "Clinical utility" means the test result provides information  
24 that is used in the formulation of a treatment or monitoring strategy that  
25 informs a patient's outcome and impacts the clinical decision. The most  
26 appropriate test may include both information that is actionable and some  
27 information that cannot be immediately used in the formulation of a  
28 clinical decision.

29           4. "Consensus statements" means statements that ARE ALL OF THE  
30 FOLLOWING:

1 (a) ~~Are~~ Developed by an independent, multidisciplinary panel of  
2 experts using a transparent methodology and reporting structure that  
3 includes a conflict of interest policy.

4 (b) ~~Are~~ Based on the best available evidence for the purpose of  
5 optimizing clinical care outcomes.

6 (c) ~~Are~~ Aimed at specific clinical circumstances.

7 5. "Nationally recognized clinical practice guidelines" means  
8 evidence-based clinical practice guidelines that both:

9 (a) Are developed by independent organizations or medical  
10 professional societies using a transparent methodology and reporting  
11 structure and a conflict of interest policy.

12 (b) Establish standards of care that are informed by a systematic  
13 review of evidence and an assessment of the benefits and costs of  
14 alternative care options that includes recommendations intended to optimize  
15 patient care."

16 Amend title to conform

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