

PROPOSED
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. 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 ~~E.~~ 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
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25 informs a patient's outcome and impacts the clinical decision. The most
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9 (a) Are developed by independent organizations or medical
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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

STEVE KAISER

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01/31/2023

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C: SK