

health insurance coverage; biomarker testing

State of Arizona
House of Representatives
Fifty-fifth Legislature
Second Regular Session
2022

CHAPTER 219
HOUSE BILL 2144

AN ACT

AMENDING TITLE 20, CHAPTER 4, ARTICLE 3, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-841.13; AMENDING TITLE 20, CHAPTER 4, ARTICLE 9, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-1057.19; AMENDING TITLE 20, CHAPTER 6, ARTICLE 4, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-1376.10; AMENDING TITLE 20, CHAPTER 6, ARTICLE 5, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-1406.10; AMENDING TITLE 36, CHAPTER 29, ARTICLE 1, ARIZONA REVISED STATUTES, BY ADDING SECTION 36-2907.03; RELATING TO HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it enacted by the Legislature of the State of Arizona:

2 Section 1. Title 20, chapter 4, article 3, Arizona Revised
3 Statutes, is amended by adding section 20-841.13, to read:

4 20-841.13. Biomarker testing; coverage; definitions

5 A. A HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE CORPORATION
6 THAT ISSUES, AMENDS, DELIVERS OR RENEWS A SUBSCRIPTION CONTRACT ON OR
7 AFTER JANUARY 1, 2023 SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING.

8 B. A SUBSCRIPTION CONTRACT SHALL COVER BIOMARKER TESTING FOR THE
9 PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING
10 MONITORING OF A SUBSCRIBER'S DISEASE OR CONDITION TO GUIDE TREATMENT
11 DECISIONS WHEN THE TEST PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY
12 MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

13 1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY
14 THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A
15 DRUG 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 HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE CORPORATION
22 MUST ENSURE THAT COVERAGE IS PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS
23 IN CARE, INCLUDING THE NEED FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

24 D. THE SUBSCRIBER AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO
25 A CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION
26 TO A COVERAGE POLICY OF A HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE
27 CORPORATION. THE PROCESS SHALL BE READILY ACCESSIBLE ON THE HOSPITAL
28 SERVICE CORPORATION'S OR MEDICAL SERVICE CORPORATION'S WEBSITE. THIS
29 SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF THE HOSPITAL SERVICE
30 CORPORATION'S OR MEDICAL SERVICE CORPORATION'S EXISTING PROCESS COMPLIES
31 WITH THIS SUBSECTION.

32 E. FOR THE PURPOSES OF THIS SECTION:

33 1. "BIOMARKER":

34 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
35 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
36 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
37 INTERVENTION.

38 (b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

39 2. "BIOMARKER TESTING":

40 (a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER
41 BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

42 (b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE
43 GENOME SEQUENCING.

1 3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION
2 THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT
3 INFORMS A PATIENT'S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST
4 APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME
5 INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A
6 CLINICAL DECISION.

7 4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

8 (a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF
9 EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT
10 INCLUDES A CONFLICT OF INTEREST POLICY.

11 (b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF
12 OPTIMIZING CLINICAL CARE OUTCOMES.

13 (c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

14 5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
15 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

16 (a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL
17 PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING
18 STRUCTURE AND A CONFLICT OF INTEREST POLICY.

19 (b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC
20 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF
21 ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO
22 OPTIMIZE PATIENT CARE.

23 Sec. 2. Title 20, chapter 4, article 9, Arizona Revised Statutes,
24 is amended by adding section 20-1057.19, to read:

25 20-1057.19. Biomarker testing; coverage; definitions

26 A. A HEALTH CARE SERVICES ORGANIZATION THAT ISSUES, AMENDS,
27 DELIVERS OR RENEWS AN EVIDENCE OF COVERAGE ON OR AFTER JANUARY 1, 2023
28 SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING.

29 B. AN EVIDENCE OF COVERAGE SHALL COVER BIOMARKER TESTING FOR THE
30 PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING
31 MONITORING OF AN ENROLLEE'S DISEASE OR CONDITION TO GUIDE TREATMENT
32 DECISIONS WHEN THE TEST PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY
33 MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

34 1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY
35 THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A
36 DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

37 2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE
38 DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE
39 DETERMINATIONS.

40 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
41 STATEMENTS.

42 C. A HEALTH CARE SERVICES ORGANIZATION MUST ENSURE THAT COVERAGE IS
43 PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS IN CARE, INCLUDING THE NEED
44 FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

1 D. THE ENROLLEE AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A
2 CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION
3 TO A COVERAGE POLICY OF A HEALTH CARE SERVICES ORGANIZATION. THE PROCESS
4 SHALL BE READILY ACCESSIBLE ON THE HEALTH CARE SERVICES ORGANIZATION'S
5 WEBSITE. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF THE
6 HEALTH CARE SERVICES ORGANIZATION'S EXISTING PROCESS COMPLIES WITH THIS
7 SUBSECTION.

8 E. 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) INCLUDE 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 BOTH:

27 (a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF
28 EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT
29 INCLUDES A CONFLICT OF INTEREST POLICY.

30 (b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF
31 OPTIMIZING CLINICAL CARE OUTCOMES.

32 (c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

33 5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
34 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

35 (a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL
36 PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING
37 STRUCTURE AND A CONFLICT OF INTEREST POLICY.

38 (b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC
39 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF
40 ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO
41 OPTIMIZE PATIENT CARE.

1 Sec. 3. Title 20, chapter 6, article 4, Arizona Revised Statutes,
2 is amended by adding section 20-1376.10, to read:

3 20-1376.10. Biomarker testing; coverage; definitions

4 A. A DISABILITY INSURER THAT ISSUES, AMENDS, DELIVERS OR RENEWS A
5 POLICY ON OR AFTER JANUARY 1, 2023 SHALL PROVIDE COVERAGE FOR BIOMARKER
6 TESTING.

7 B. A POLICY SHALL COVER BIOMARKER TESTING FOR THE PURPOSES OF
8 DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF AN
9 INSURED'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST
10 PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY MEDICAL AND SCIENTIFIC
11 EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

12 1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY
13 THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A
14 DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

15 2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE
16 DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE
17 DETERMINATIONS.

18 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
19 STATEMENTS.

20 C. A DISABILITY INSURER MUST ENSURE THAT COVERAGE IS PROVIDED IN A
21 MANNER THAT LIMITS DISRUPTIONS IN CARE, INCLUDING THE NEED FOR MULTIPLE
22 BIOPSIES OR BIOSPECIMEN SAMPLES.

23 D. THE INSURED AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A
24 CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION
25 TO A COVERAGE POLICY OF A DISABILITY INSURER. THE PROCESS SHALL BE
26 READILY ACCESSIBLE ON THE DISABILITY INSURER'S WEBSITE. THIS SUBSECTION
27 DOES NOT REQUIRE A SEPARATE PROCESS IF THE DISABILITY INSURER'S EXISTING
28 PROCESS COMPLIES WITH THIS SUBSECTION.

29 E. FOR THE PURPOSES OF THIS SECTION:

30 1. "BIOMARKER":

31 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
32 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
33 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
34 INTERVENTION.

35 (b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

36 2. "BIOMARKER TESTING":

37 (a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER
38 BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

39 (b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE
40 GENOME SEQUENCING.

41 3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION
42 THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT
43 INFORMS A PATIENT'S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST
44 APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME

1 INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A
2 CLINICAL DECISION.

3 4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

4 (a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF
5 EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT
6 INCLUDES A CONFLICT OF INTEREST POLICY.

7 (b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF
8 OPTIMIZING CLINICAL CARE OUTCOMES.

9 (c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

10 5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
11 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

12 (a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL
13 PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING
14 STRUCTURE AND A CONFLICT OF INTEREST POLICY.

15 (b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC
16 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF
17 ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO
18 OPTIMIZE PATIENT CARE.

19 Sec. 4. Title 20, chapter 6, article 5, Arizona Revised Statutes,
20 is amended by adding section 20-1406.10, to read:

21 20-1406.10. Biomarker testing; coverage; definitions

22 A. A GROUP OR BLANKET DISABILITY INSURER THAT ISSUES, AMENDS,
23 DELIVERS OR RENEWS A POLICY ON OR AFTER JANUARY 1, 2023 SHALL PROVIDE
24 COVERAGE FOR BIOMARKER TESTING.

25 B. A POLICY SHALL COVER BIOMARKER TESTING FOR THE PURPOSES OF
26 DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF AN
27 INSURED'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST
28 PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY MEDICAL AND SCIENTIFIC
29 EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

30 1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY
31 THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A
32 DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

33 2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE
34 DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE
35 DETERMINATIONS.

36 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
37 STATEMENTS.

38 C. A GROUP OR BLANKET DISABILITY INSURER MUST ENSURE COVERAGE IS
39 PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS IN CARE, INCLUDING THE NEED
40 FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

41 D. THE INSURED AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A
42 CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION
43 TO A COVERAGE POLICY OF A GROUP OR BLANKET DISABILITY INSURER. THE
44 PROCESS SHALL BE READILY ACCESSIBLE ON A GROUP OR BLANKET DISABILITY
45 INSURER'S WEBSITE. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF

1 THE GROUP OR BLANKET DISABILITY INSURER'S EXISTING PROCESS COMPLIES WITH
2 THIS SUBSECTION.

3 E. FOR THE PURPOSES OF THIS SECTION:

4 1. "BIOMARKER":

5 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
6 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
7 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
8 INTERVENTION.

9 (b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

10 2. "BIOMARKER TESTING":

11 (a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER
12 BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

13 (b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE
14 GENOME SEQUENCING.

15 3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION
16 THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT
17 INFORMS A PATIENT'S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST
18 APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME
19 INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A
20 CLINICAL DECISION.

21 4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

22 (a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF
23 EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT
24 INCLUDES A CONFLICT OF INTEREST POLICY.

25 (b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF
26 OPTIMIZING CLINICAL CARE OUTCOMES.

27 (c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

28 5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
29 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

30 (a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL
31 PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING
32 STRUCTURE AND A CONFLICT OF INTEREST POLICY.

33 (b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC
34 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF
35 ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO
36 OPTIMIZE PATIENT CARE.

37 Sec. 5. Title 36, chapter 29, article 1, Arizona Revised Statutes,
38 is amended by adding section 36-2907.03, to read:

39 36-2907.03. Biomarker testing; coverage; definitions

40 A. THE ADMINISTRATION AND ITS CONTRACTORS SHALL PROVIDE BIOMARKER
41 TESTING FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT
42 OR ONGOING MONITORING OF A MEMBER'S DISEASE OR CONDITION TO GUIDE
43 TREATMENT DECISIONS WHEN THE TEST PROVIDES CLINICAL UTILITY AS
44 DEMONSTRATED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE
45 FOLLOWING:

1 1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY
2 THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A
3 DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.
4 2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE
5 DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE
6 DETERMINATIONS.
7 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
8 STATEMENTS.
9 B. THE ADMINISTRATION AND ITS CONTRACTORS SHALL PROVIDE BIOMARKER
10 TESTING WITH THE SAME SCOPE, DURATION AND FREQUENCY AS THE SYSTEM
11 OTHERWISE PROVIDES TO MEMBERS PURSUANT TO THIS ARTICLE.
12 C. THE MEMBER AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A
13 CLEAR, READILY ACCESSIBLE AND CONVENIENT ONLINE PROCESS TO REQUEST AN
14 EXCEPTION TO A COVERAGE POLICY OF THE SYSTEM. THIS SUBSECTION DOES NOT
15 REQUIRE A SEPARATE PROCESS IF THE ADMINISTRATION'S AND ITS CONTRACTOR'S
16 EXISTING PROCESS COMPLIES WITH THIS SUBSECTION. ANY REQUEST FOR A
17 COVERAGE EXCEPTION SHALL BE SUBMITTED ELECTRONICALLY BY THE PRESCRIBING
18 PRACTITIONER.
19 D. FOR THE PURPOSES OF THIS SECTION:
20 1. "BIOMARKER":
21 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
22 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
23 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
24 INTERVENTION.
25 (b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.
26 2. "BIOMARKER TESTING":
27 (a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER
28 BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.
29 (b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE
30 GENOME SEQUENCING.
31 3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION
32 THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT
33 INFORMS A PATIENT'S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST
34 APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME
35 INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A
36 CLINICAL DECISION.
37 4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:
38 (a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF
39 EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT
40 INCLUDES A CONFLICT OF INTEREST POLICY.
41 (b) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.
42 (c) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF
43 OPTIMIZING CLINICAL CARE OUTCOMES.
44 5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
45 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

1 (a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL
2 PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING
3 STRUCTURE AND A CONFLICT OF INTEREST POLICY.

4 (b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC
5 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF
6 ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO
7 OPTIMIZE PATIENT CARE.

APPROVED BY THE GOVERNOR MAY 6, 2022.

FILED IN THE OFFICE OF THE SECRETARY OF STATE MAY 6, 2022.