

**Second Regular Session
Seventy-fourth General Assembly
STATE OF COLORADO**

ENGROSSED

*This Version Includes All Amendments Adopted
on Second Reading in the House of Introduction*

LLS NO. 24-0481.01 Brita Darling x2241

SENATE BILL 24-124

SENATE SPONSORSHIP

Michaelson Jenet and Rich,

HOUSE SPONSORSHIP

Hartsook and Duran,

Senate Committees

Health & Human Services
Appropriations

House Committees

A BILL FOR AN ACT

101 **CONCERNING REQUIRING HEALTH-CARE COVERAGE FOR BIOMARKER**
102 **TESTING.**

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://leg.colorado.gov>.)

The bill requires all individual and group health benefit plans to provide coverage for biomarker testing to guide treatment decisions if the testing is supported by medical and scientific evidence. The bill defines "biomarker testing" as an analysis of a patient's tissue, blood, or other biospecimen for the presence of an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters or bold & italic numbers indicate new material to be added to existing law.
Dashes through the words or numbers indicate deletions from existing law.

SENATE
Amended 2nd Reading
April 25, 2024

therapeutic intervention. The required testing under the bill does not include biomarker testing for screening purposes or direct-to-consumer genetic tests.

The bill requires the commissioner of insurance to implement biomarker testing coverage for all individual and group health benefit plans issued or renewed on or after January 1, 2026.

Biomarker testing is subject to the health benefit plan's annual deductibles, copayment, or coinsurance but is not subject to any annual or lifetime maximum benefit limit.

Subject to federal authorization and federal financial participation, beginning July 1, 2025, the bill includes coverage for biomarker testing as part of the state medical assistance program to guide treatment decisions if the testing is supported by medical and scientific evidence.

The bill requires the medical assistance program to have a clear, easily accessible appeals process if biomarker testing is denied.

1 *Be it enacted by the General Assembly of the State of Colorado:*

2 **SECTION 1.** In Colorado Revised Statutes, 10-16-104, **add** (27)
3 as follows:

4 **10-16-104. Mandatory coverage provisions - definitions -**
5 **rules. (27) Biomarker testing. (a) ALL LARGE GROUP HEALTH BENEFIT**
6 **PLANS AND, TO THE EXTENT THAT SUCH COVERAGE IS NOT IN ADDITION TO**
7 **THE BENEFITS PROVIDED PURSUANT TO THE BENCHMARK PLAN, ALL**
8 **INDIVIDUAL AND SMALL GROUP HEALTH BENEFIT PLANS SHALL PROVIDE**
9 **COVERAGE FOR BIOMARKER TESTING PURSUANT TO THIS SUBSECTION (27).**

10 (b) COVERAGE MUST INCLUDE BIOMARKER TESTING FOR
11 DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT, AND ONGOING
12 MONITORING OF A COVERED PERSON'S DISEASE OR CONDITION TO GUIDE
13 TREATMENT DECISIONS WHEN THE TEST IS SUPPORTED BY MEDICAL AND
14 SCIENTIFIC EVIDENCE, INCLUDING:

15 (I) LABELED INDICATIONS FOR AN FDA-APPROVED OR
16 FDA-CLEARED TEST;

17 (II) INDICATED TESTS FOR AN FDA-APPROVED DRUG;

1 (III) WARNINGS AND PRECAUTIONS ON FDA-APPROVED DRUG
2 LABELS;

3 (IV) CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL
4 COVERAGE DETERMINATIONS OR MEDICARE ADMINISTRATIVE
5 CONTRACTOR LOCAL COVERAGE DETERMINATIONS; OR

6 (V) NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES,
7 CONSENSUS STATEMENTS, AND PEER-REVIEWED STUDIES.

8 (c) THE COVERAGE REQUIRED BY THIS SUBSECTION (27) IS SUBJECT
9 TO ANNUAL DEDUCTIBLES, COPAYMENTS, OR COINSURANCE
10 REQUIREMENTS UNDER THE HEALTH BENEFIT PLAN BUT IS NOT SUBJECT TO
11 ANY ANNUAL OR LIFETIME MAXIMUM BENEFIT LIMIT.

12 (d) THE COVERAGE REQUIRED BY THIS SUBSECTION (27) MUST BE
13 PROVIDED IN A MANNER THAT LIMITS UNREASONABLE DISRUPTIONS IN
14 CARE, INCLUDING LIMITING THE NEED FOR MULTIPLE BIOPSIES OR
15 BIOSPECIMEN SAMPLES.

16 (e) NOTHING IN THIS SUBSECTION (27) SHALL BE CONSTRUED TO
17 REQUIRE COVERAGE FOR BIOMARKER TESTING FOR SCREENING PURPOSES.

18 (f) A CARRIER MAY REQUIRE PRIOR AUTHORIZATION FOR
19 BIOMARKER TESTING IN THE SAME MANNER THAT PRIOR AUTHORIZATION
20 IS REQUIRED FOR ANY OTHER COVERED BENEFIT AND CONSISTENT WITH
21 SECTION 10-16-112.5.

22 (g)(I) WITHIN ONE HUNDRED TWENTY DAYS AFTER THE EFFECTIVE
23 DATE OF THIS SECTION, THE DIVISION SHALL SUBMIT TO THE FEDERAL
24 DEPARTMENT OF HEALTH AND HUMAN SERVICES:

25 (A) A DETERMINATION AS TO WHETHER THE BENEFIT SPECIFIED IN
26 THIS SUBSECTION (27) IS IN ADDITION TO ESSENTIAL HEALTH BENEFITS AND
27 WOULD BE SUBJECT TO DEFAYAL BY THE STATE PURSUANT TO 42 U.S.C.

1 SEC. 18031 (d)(3)(B); AND

2 (B) A REQUEST THAT THE FEDERAL DEPARTMENT OF HEALTH AND
3 HUMAN SERVICES CONFIRM THE DIVISION'S DETERMINATION WITHIN SIXTY
4 DAYS AFTER RECEIPT OF THE DIVISION'S REQUEST AND SUBMISSION OF ITS
5 DETERMINATION.

6 (II) THIS SUBSECTION (27) APPLIES TO, AND THE DIVISION SHALL
7 IMPLEMENT THE PROVISIONS OF THIS SUBSECTION (27) FOR, LARGE
8 EMPLOYER HEALTH BENEFIT PLANS ISSUED OR RENEWED IN THIS STATE ON
9 OR AFTER JANUARY 1, 2025.

10 (III) THIS SUBSECTION (27) APPLIES TO, AND THE DIVISION SHALL
11 IMPLEMENT THE REQUIREMENTS OF THIS SUBSECTION (27) FOR,
12 INDIVIDUAL AND SMALL GROUP HEALTH BENEFIT PLANS ISSUED OR
13 RENEWED IN THIS STATE TWELVE MONTHS AFTER THE EARLIER OF THE
14 FOLLOWING:

15 (A) THE DIVISION RECEIVES CONFIRMATION FROM THE FEDERAL
16 DEPARTMENT OF HEALTH AND HUMAN SERVICES THAT THE COVERAGE
17 SPECIFIED IN THIS SUBSECTION (27) DOES NOT CONSTITUTE AN ADDITIONAL
18 BENEFIT THAT REQUIRES DEFAYAL BY THE STATE PURSUANT TO 42 U.S.C.
19 SEC. 18031 (d)(3)(B);

20 (B) THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES
21 HAS OTHERWISE INFORMED THE DIVISION THAT THE COVERAGE DOES NOT
22 REQUIRE STATE DEFAYAL PURSUANT TO 42 U.S.C. SEC. 18031 (d)(3)(B);
23 OR

24 (C) MORE THAN THREE HUNDRED SIXTY-FIVE DAYS HAVE PASSED
25 SINCE THE DIVISION SUBMITTED ITS DETERMINATION AND REQUEST FOR
26 CONFIRMATION THAT THE COVERAGE SPECIFIED IN THIS SUBSECTION (27)
27 IS NOT AN ADDITIONAL BENEFIT THAT REQUIRES STATE DEFAYAL

1 PURSUANT TO 42 U.S.C. SEC. 18031 (d)(3)(B), AND THE FEDERAL
2 DEPARTMENT OF HEALTH AND HUMAN SERVICES HAS FAILED TO RESPOND
3 TO THE REQUEST WITHIN THAT PERIOD, IN WHICH CASE THE DIVISION
4 SHALL CONSIDER THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN
5 SERVICES' UNREASONABLE DELAY A PRECLUSION FROM REQUIRING
6 DEFRAYAL BY THE STATE.

7 (h) THE COMMISSIONER SHALL IMPLEMENT THIS SUBSECTION (27)
8 AND SHALL ADOPT RULES CONSISTENT WITH AND AS ARE NECESSARY TO
9 IMPLEMENT THIS SUBSECTION (27).

10 (i) AS USED IN THIS SUBSECTION (27):

11 (I) "BIOMARKER" MEANS A CHARACTERISTIC THAT IS OBJECTIVELY
12 MEASURED AND EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL
13 PROCESSES, PATHOGENIC PROCESSES, OR PHARMACOLOGIC RESPONSES TO
14 A SPECIFIC THERAPEUTIC INTERVENTION, INCLUDING KNOWN GENE-DRUG
15 INTERACTIONS FOR MEDICATIONS BEING CONSIDERED FOR USE OR
16 ALREADY BEING ADMINISTERED. "BIOMARKER" INCLUDES GENE
17 MUTATIONS, CHARACTERISTICS OF GENES, OR PROTEIN EXPRESSION.

18 (II) "BIOMARKER TESTING" MEANS THE ANALYSIS OF A PATIENT'S
19 TISSUE, BLOOD, OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A
20 BIOMARKER. "BIOMARKER TESTING" INCLUDES SINGLE-ANALYTE TESTS,
21 MULTIPLEX PANEL TESTS, PROTEIN EXPRESSION, AND WHOLE EXOME,
22 WHOLE GENOME, AND WHOLE TRANSCRIPTOME SEQUENCING. "BIOMARKER
23 TESTING" DOES NOT INCLUDE DIRECT-TO-CONSUMER GENETIC TESTS.

24 (III) "CONSENSUS STATEMENTS" MEANS STATEMENTS DEVELOPED
25 BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS UTILIZING
26 A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND WITH
27 A CONFLICT OF INTEREST POLICY. CONSENSUS STATEMENTS ARE

1 DEVELOPED FOR SPECIFIC CLINICAL CIRCUMSTANCES AND ARE BASED ON
2 THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF OPTIMIZING THE
3 OUTCOMES OF CLINICAL CARE.

4 (IV) "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES"
5 MEANS EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES DEVELOPED BY
6 INDEPENDENT ORGANIZATIONS OR MEDICAL PROFESSIONAL SOCIETIES
7 UTILIZING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE
8 AND WITH A CONFLICT OF INTEREST POLICY. CLINICAL PRACTICE
9 GUIDELINES:

10 (A) ESTABLISH STANDARDS OF CARE INFORMED BY A SYSTEMATIC
11 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND RISKS OF
12 ALTERNATIVE CARE OPTIONS; AND

13 (B) INCLUDE RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT
14 CARE.

15 **SECTION 2.** In Colorado Revised Statutes, 25.5-5-202, **add**
16 (1)(z) as follows:

17 **25.5-5-202. Basic services for the categorically needy - optional**
18 **services.** (1) Subject to the provisions of subsection (2) of this section,
19 the following are services for which federal financial participation is
20 available and that Colorado has selected to provide as optional services
21 under the medical assistance program:

22 (z) BIOMARKER TESTING, AS SPECIFIED IN SECTION 25.5-5-337.

23 **SECTION 3.** In Colorado Revised Statutes, **add** 25.5-5-337 as
24 follows:

25 **25.5-5-337. Biomarker testing - federal authorization - prior**
26 **authorization - definitions.** (1) AS USED IN THIS SECTION, UNLESS THE
27 CONTEXT OTHERWISE REQUIRES:

1 (a) "BIOMARKER" MEANS A CHARACTERISTIC THAT IS OBJECTIVELY
2 MEASURED AND EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL
3 PROCESSES, PATHOGENIC PROCESSES, OR PHARMACOLOGIC RESPONSES TO
4 A SPECIFIC THERAPEUTIC INTERVENTION, INCLUDING KNOWN GENE-DRUG
5 INTERACTIONS FOR MEDICATIONS BEING CONSIDERED FOR USE OR
6 ALREADY BEING ADMINISTERED. "BIOMARKER" INCLUDES GENE
7 MUTATIONS, CHARACTERISTICS OF GENES, OR PROTEIN EXPRESSION.

8 (b) "BIOMARKER TESTING" MEANS THE ANALYSIS OF A PATIENT'S
9 TISSUE, BLOOD, OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A
10 BIOMARKER. "BIOMARKER TESTING" INCLUDES SINGLE-ANALYTE TESTS,
11 MULTIPLEX PANEL TESTS, PROTEIN EXPRESSION, AND WHOLE EXOME,
12 WHOLE GENOME, AND WHOLE TRANSCRIPTOME SEQUENCING. "BIOMARKER
13 TESTING" DOES NOT INCLUDE DIRECT-TO-CONSUMER GENETIC TESTS.

14 ==
15 (2) (a) ON AND AFTER JULY 1, 2024, THE MEDICAL ASSISTANCE
16 PROGRAM MUST COVER BIOMARKER TESTING PURSUANT TO THE
17 ESTABLISHED PROCESSES FOR DETERMINING COVERAGE OF SERVICES
18 BASED ON CLINICAL UTILITY. ==

19 (b) A MANAGED CARE ENTITY, AS DEFINED IN SECTION 25.5-5-403,
20 THAT THE MEDICAL ASSISTANCE PROGRAM CONTRACTS WITH TO DELIVER
21 SERVICES SHALL PROVIDE BIOMARKER TESTING IN THE SAME SCOPE,
22 DURATION, AND FREQUENCY AS BIOMARKER TESTING IS PROVIDED TO
23 OTHER MEMBERS ENROLLED IN THE MEDICAL ASSISTANCE PROGRAM.

24 (c) NOTHING IN THIS SECTION SHALL BE CONSTRUED TO REQUIRE
25 COVERAGE OF BIOMARKER TESTING FOR SCREENING PURPOSES.

26 (3) THE MEDICAL ASSISTANCE PROGRAM MUST NOT IMPOSE A
27 LIFETIME LIMIT ON BIOMARKER TESTING FOR A MEMBER.

1 (4) THE MEDICAL ASSISTANCE PROGRAM MUST INCLUDE A CLEAR,
2 READILY ACCESSIBLE, AND CONVENIENT PROCESS FOR A MEMBER OR
3 PROVIDER TO REQUEST AN APPEAL IF BIOMARKER TESTING IS DENIED. THE
4 PROCESS MUST BE READILY ACCESSIBLE ONLINE TO ALL MEMBERS AND
5 PROVIDERS.

6 **SECTION 4. Safety clause.** The general assembly finds,
7 determines, and declares that this act is necessary for the immediate
8 preservation of the public peace, health, or safety or for appropriations for
9 the support and maintenance of the departments of the state and state
10 institutions.