

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

**PREAMENDED**

*This Unofficial Version Includes Committee  
Amendments Not Yet Adopted on Second Reading*

LLS NO. 24-0481.01 Brita Darling x2241

**SENATE BILL 24-124**

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**SENATE SPONSORSHIP**

**Michaelson Jenet and Rich,**

**HOUSE SPONSORSHIP**

**Hartsook,**

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**Senate Committees**

Health & Human Services  
Appropriations

**House Committees**

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**A BILL FOR AN ACT**

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

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**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.

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.

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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 PROVIDES CLINICAL UTILITY AS  
14 DEMONSTRATED BY MEDICAL AND 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) THE DIVISION SHALL SUBMIT TO THE FEDERAL DEPARTMENT  
23 OF HEALTH AND HUMAN SERVICES:

24 (A) A DETERMINATION AS TO WHETHER THE BENEFIT SPECIFIED IN  
25 THIS SUBSECTION (27) IS IN ADDITION TO ESSENTIAL HEALTH BENEFITS AND  
26 WOULD BE SUBJECT TO DEFAYAL BY THE STATE PURSUANT TO 42 U.S.C.  
27 SEC. 18031 (d)(3)(B); AND

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

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

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

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

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

23          (C) MORE THAN THREE HUNDRED SIXTY-FIVE DAYS HAVE PASSED  
24          SINCE THE DIVISION SUBMITTED ITS DETERMINATION AND REQUEST FOR  
25          CONFIRMATION THAT THE COVERAGE SPECIFIED IN THIS SUBSECTION (27)  
26          IS NOT AN ADDITIONAL BENEFIT THAT REQUIRES STATE DEFAYAL  
27          PURSUANT TO 42 U.S.C. SEC. 18031 (d)(3)(B), AND THE FEDERAL

1 DEPARTMENT OF HEALTH AND HUMAN SERVICES HAS FAILED TO RESPOND  
2 TO THE REQUEST WITHIN THAT PERIOD, IN WHICH CASE THE DIVISION  
3 SHALL CONSIDER THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN  
4 SERVICES' UNREASONABLE DELAY A PRECLUSION FROM REQUIRING  
5 DEFRAYAL BY THE STATE.

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

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

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

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

23 (III) "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES  
24 INFORMATION THAT IS USED IN THE FORMULATION OF A TREATMENT OR  
25 MONITORING STRATEGY THAT INFORMS A PATIENT'S OUTCOME AND  
26 IMPACTS THE CLINICAL DECISION. THE MOST APPROPRIATE TEST MAY  
27 INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME

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

3 (IV) "CONSENSUS STATEMENTS" MEANS STATEMENTS DEVELOPED  
4 BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS UTILIZING  
5 A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND WITH  
6 A CONFLICT OF INTEREST POLICY. CONSENSUS STATEMENTS ARE  
7 DEVELOPED FOR SPECIFIC CLINICAL CIRCUMSTANCES AND ARE BASED ON  
8 THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF OPTIMIZING THE  
9 OUTCOMES OF CLINICAL CARE.

10 (V) "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES"  
11 MEANS EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES DEVELOPED BY  
12 INDEPENDENT ORGANIZATIONS OR MEDICAL PROFESSIONAL SOCIETIES  
13 UTILIZING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE  
14 AND WITH A CONFLICT OF INTEREST POLICY. CLINICAL PRACTICE  
15 GUIDELINES:

16 (A) ESTABLISH STANDARDS OF CARE INFORMED BY A SYSTEMATIC  
17 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND RISKS OF  
18 ALTERNATIVE CARE OPTIONS; AND

19 (B) INCLUDE RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT  
20 CARE.

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

23 **25.5-5-202. Basic services for the categorically needy - optional**  
24 **services.** (1) Subject to the provisions of subsection (2) of this section,  
25 the following are services for which federal financial participation is  
26 available and that Colorado has selected to provide as optional services  
27 under the medical assistance program:

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

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

4 **25.5-5-337. Biomarker testing - federal authorization - prior**  
5 **authorization - definitions.** (1) AS USED IN THIS SECTION, UNLESS THE  
6 CONTEXT OTHERWISE REQUIRES:

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

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

20 ==  
21 (2) (a) ON AND AFTER JULY 1, 2024, THE MEDICAL ASSISTANCE  
22 PROGRAM MUST COVER BIOMARKER TESTING PURSUANT TO THE  
23 ESTABLISHED PROCESSES FOR DETERMINING COVERAGE OF SERVICES  
24 BASED ON CLINICAL UTILITY. ==

25 (b) A MANAGED CARE ENTITY, AS DEFINED IN SECTION 25.5-5-403,  
26 THAT THE MEDICAL ASSISTANCE PROGRAM CONTRACTS WITH TO DELIVER  
27 SERVICES SHALL PROVIDE BIOMARKER TESTING IN THE SAME SCOPE,

1 DURATION, AND FREQUENCY AS BIOMARKER TESTING IS PROVIDED TO  
2 OTHER MEMBERS ENROLLED IN THE MEDICAL ASSISTANCE PROGRAM.

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

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

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

12 **SECTION 4. Safety clause.** The general assembly finds,  
13 determines, and declares that this act is necessary for the immediate  
14 preservation of the public peace, health, or safety or for appropriations for  
15 the support and maintenance of the departments of the state and state  
16 institutions.