

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1754 Session of 2023

INTRODUCED BY MULLINS, CUTLER, STURLA, STENDER, DONAHUE, BURGOS, MADDEN, FREEMAN, BOROWSKI, SANCHEZ, CERRATO, HOGAN, GILLEN, E. NELSON, FRITZ, MARSHALL, SCHEMEL, SHUSTERMAN, FRANKEL, FRIEL, KRAJEWSKI, ORTITAY, HADDOCK, ABNEY, A. BROWN, RYNCAVAGE, DALEY, PICKETT, KUZMA, DAVANZO, STAATS, WEBSTER, MEHAFFIE, HARKINS, MALAGARI, SCOTT, MUNROE, KOSIEROWSKI, BRENNAN, O'MARA, HOWARD, LEADBETER, MARCELL, PIELLI, TAKAC, HANBIDGE AND BERNSTINE, OCTOBER 16, 2023

AS REPORTED FROM COMMITTEE ON INSURANCE, HOUSE OF REPRESENTATIVES, AS AMENDED, JUNE 3, 2024

AN ACT

1 Amending the act of May 17, 1921 (P.L.682, No.284), entitled "An
2 act relating to insurance; amending, revising, and
3 consolidating the law providing for the incorporation of
4 insurance companies, and the regulation, supervision, and
5 protection of home and foreign insurance companies, Lloyds
6 associations, reciprocal and inter-insurance exchanges, and
7 fire insurance rating bureaus, and the regulation and
8 supervision of insurance carried by such companies,
9 associations, and exchanges, including insurance carried by
10 the State Workmen's Insurance Fund; providing penalties; and
11 repealing existing laws," in casualty insurance, providing
12 for coverage for biomarker testing.

13 The General Assembly of the Commonwealth of Pennsylvania
14 hereby enacts as follows:

15 Section 1. The act of May 17, 1921 (P.L.682, No.284), known
16 as The Insurance Company Law of 1921, is amended by adding a
17 section to read:

18 ~~Section 635.9. Coverage for Biomarker Testing. (a) An~~ <--
19 ~~insurer or medical assistance or Children's Health Insurance~~

~~1 Program managed care plan that amends, delivers or renews a  
2 health insurance policy or an agreement with the Department of  
3 Human Services on or after January 1, 2024, shall include  
4 biomarker testing as a covered benefit.~~

~~5 (b) Biomarker testing shall be covered for the purposes of  
6 diagnosis, treatment, appropriate management or ongoing  
7 monitoring of an insured or enrollee's disease or condition when  
8 the test is supported by medical and scientific evidence,  
9 including, but not limited to, any of the following:~~

~~10 (1) labeled indications for an FDA approved or cleared test;~~

~~11 (2) indicated tests for an FDA approved drug;~~

~~12 (3) warnings and precautions on FDA approved drug labels;~~

~~13 (4) Centers for Medicare and Medicaid Services National  
14 Coverage Determinations or Medicare Administrative Contractor  
15 Local Coverage Determinations; or~~

~~16 (5) nationally recognized clinical practice guidelines and  
17 consensus statements.~~

~~18 (b.1) The information obtained through biomarker testing is  
19 to be used only for the purposes specified in subsection (b) and  
20 is protected by the Health Insurance Portability and  
21 Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936).  
22 The information shall not be used for any other purpose by an  
23 insurer.~~

~~24 (c) Biomarker testing covered under subsections (a) and (b)  
25 shall be provided in a manner that limits disruptions in care,  
26 including the need for multiple biopsies or biospecimen samples.~~

~~27 (d) If prior authorization is required for biomarker  
28 testing, an insurer or medical assistance or Children's Health  
29 Insurance Program managed care plan shall approve or deny a  
30 prior authorization request and notify the enrollee, the~~

1 ~~enrollee's health care provider and any entity requesting~~  
2 ~~authorization of the service within 72 hours for nonurgent~~  
3 ~~requests or within 24 hours for urgent requests.~~

4 ~~(e) The patient and prescribing practitioner shall have~~  
5 ~~access to clear, readily accessible and convenient processes to~~  
6 ~~request an exception to a coverage policy or an adverse~~  
7 ~~utilization review determination of a health insurer, nonprofit~~  
8 ~~health service plan and health maintenance organization. The~~  
9 ~~process shall be made readily accessible on the health~~  
10 ~~insurer's, nonprofit health service plan's or health maintenance~~  
11 ~~organization's publicly accessible Internet website.~~

12 ~~(f) An insurer shall submit a report to the Insurance~~  
13 ~~Department and a medical assistance or Children's Health~~  
14 ~~Insurance Program managed care plan shall submit to the~~  
15 ~~Department of Human Services by January 31 of the following~~  
16 ~~year, the following data from the preceding calendar year in a~~  
17 ~~form and manner prescribed by the respective department, which~~  
18 ~~the respective department shall publish to the President pro~~  
19 ~~tempore of the Senate, the Speaker of the House of~~  
20 ~~Representatives, the members of the Banking and Insurance~~  
21 ~~Committee of the Senate and the members of the Insurance~~  
22 ~~Committee of the House of Representatives:~~

23 ~~(1) The number of exception requests received by exception.~~

24 ~~(2) The type of health care providers or the medical~~  
25 ~~specialties of the health care providers submitting exception~~  
26 ~~requests.~~

27 ~~(3) The number of exception requests by exception that were~~  
28 ~~denied and the reasons for the denials.~~

29 ~~(4) The number of exception requests by exception that were~~  
30 ~~approved.~~

1 ~~(5) The number of exception requests by exception that were~~  
2 ~~initially denied and then appealed.~~

3 ~~(6) The number of exception requests by exception that were~~  
4 ~~initially denied and then subsequently reversed by internal~~  
5 ~~appeals or external reviews.~~

6 ~~(7) The medical conditions for which patients are granted~~  
7 ~~exceptions due to the likelihood that not receiving biomarker~~  
8 ~~testing will likely result in treatment decisions that could~~  
9 ~~cause an adverse reaction or physical harm to the insured.~~

10 ~~(g) As used in this section, the following words and phrases~~  
11 ~~shall have the meanings given to them in this subsection unless~~  
12 ~~the context clearly indicates otherwise:~~

13 ~~"Biomarker." A characteristic that is objectively measured~~  
14 ~~and evaluated as an indicator of normal biological processes,~~  
15 ~~pathogenic processes or pharmacologic responses to a specific~~  
16 ~~therapeutic intervention, including known gene drug interactions~~  
17 ~~for medications being considered for use or already being~~  
18 ~~administered. The term includes gene mutations, characteristics~~  
19 ~~of genes or protein expression.~~

20 ~~"Biomarker testing." The analysis of a patient's tissue,~~  
21 ~~blood or other biospecimen for the presence of a biomarker. The~~  
22 ~~term includes single analyte tests, multi plex panel tests,~~  
23 ~~protein expression and whole exome, whole genome and whole~~  
24 ~~transcriptome sequencing.~~

25 ~~"Consensus statements." Statements developed by an~~  
26 ~~independent, multidisciplinary panel of experts utilizing a~~  
27 ~~transparent methodology and reporting structure and with a~~  
28 ~~conflict of interest policy. These statements should be aimed at~~  
29 ~~specific clinical circumstances and base the statements on the~~  
30 ~~best available evidence for the purpose of optimizing the~~

1 ~~outcomes of clinical care.~~

2 ~~"Covered benefit." A health care service as specified in the~~  
3 ~~terms of a health insurance policy or an agreement with the~~  
4 ~~Department of Human Services.~~

5 ~~"Health insurance policy." A policy, subscriber contract,~~  
6 ~~certificate or plan issued by an insurer that provides medical~~  
7 ~~or health care coverage. The term does not include any of the~~  
8 ~~following:~~

9 ~~(1) An accident only policy.~~

10 ~~(2) A credit only policy.~~

11 ~~(3) A long term care or disability income policy.~~

12 ~~(4) A specified disease policy.~~

13 ~~(5) A Medicare supplement policy.~~

14 ~~(6) A TRICARE policy, including a Civilian Health and~~  
15 ~~Medical Program of the Uniformed Services (CHAMPUS) supplement~~  
16 ~~policy.~~

17 ~~(7) A fixed indemnity policy.~~

18 ~~(8) A hospital indemnity policy.~~

19 ~~(9) A worker's compensation policy.~~

20 ~~(10) An automobile medical payment policy under 75 Pa.C.S.~~  
21 ~~(relating to vehicles).~~

22 ~~(11) A homeowner's insurance policy.~~

23 ~~(12) Any other similar policies providing for limited~~  
24 ~~benefits.~~

25 ~~(13) A dental only policy.~~

26 ~~(14) A vision only policy.~~

27 ~~"Insurer." An entity licensed by the Insurance Department~~  
28 ~~that offers, issues or renews a health insurance policy and~~  
29 ~~governed under any of the following:~~

30 ~~(1) Section 630 and Article XXIV of this act.~~

1 ~~(2) The act of December 29, 1972 (P.L.1701, No.364), known~~  
2 ~~as the Health Maintenance Organization Act.~~

3 ~~(3) 40 Pa.C.S. Ch. 61 (relating to hospital plan~~  
4 ~~corporations).~~

5 ~~(4) 40 Pa.C.S. Ch. 63 (relating to professional health~~  
6 ~~services plan corporations).~~

7 ~~"Medical assistance" or "Children's Health Insurance Program~~  
8 ~~managed care plan." A health care plan that uses a gatekeeper~~  
9 ~~to manage the utilization of health care services, including~~  
10 ~~biomarker testing, by medical assistance or children's health~~  
11 ~~insurance program enrollees and integrates the financing and~~  
12 ~~delivery of health care services, including biomarker testing.~~

13 ~~"Nationally recognized clinical practice guidelines."~~  
14 ~~Evidence based clinical practice guidelines developed by~~  
15 ~~independent organizations or medical professional societies~~  
16 ~~utilizing a transparent methodology and reporting structure and~~  
17 ~~with a conflict of interest policy. Clinical practice guidelines~~  
18 ~~establish standards of care informed by a systemic review of~~  
19 ~~evidence and an assessment of the benefits and risks of~~  
20 ~~alternative care options and include recommendations intended to~~  
21 ~~optimize patient care.~~

22 Section 2. This act shall apply as follows:

23 (1) For health insurance policies for which either rates  
24 or forms are required to be filed with the Federal Government  
25 or the Insurance Department, the addition of section 635.9 of  
26 the act shall apply to any policy for which a form or rate is  
27 first filed on or after the effective date of this section.

28 (2) For health insurance policies for which neither  
29 rates nor forms are required to be filed with the Federal  
30 Government or the Insurance Department, the addition of

1 ~~section 635.9 of the act shall apply to any policy issued or~~  
2 ~~renewed on or after 120 days after the effective date of this~~  
3 ~~section.~~

4 ~~Section 3. This act shall take effect in 60 days.~~

5 SECTION 635.9. COVERAGE FOR BIOMARKER TESTING.-- (A) AN <--  
6 INSURER THAT OFFERS, ISSUES OR RENEWS A HEALTH INSURANCE POLICY  
7 IN THIS COMMONWEALTH SHALL INCLUDE BIOMARKER TESTING AS A  
8 COVERED BENEFIT. THE FOLLOWING SHALL APPLY:

9 (1) AN INSURER'S COVERAGE FOR BIOMARKER TESTING SHALL BE  
10 REQUIRED FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE  
11 MANAGEMENT OR ONGOING MONITORING OF A COVERED PERSON'S DISEASE  
12 OR CONDITION TO GUIDE TREATMENT DECISIONS FOR THE COVERED  
13 PERSON. BIOMARKER TESTING COVERED UNDER THIS SUBSECTION SHALL BE  
14 SUBJECT TO:

15 (I) ARTICLE XXI OF THIS ACT.

16 (II) APPLICABLE FEDERAL LAWS AND REGULATIONS.

17 (III) APPLICABLE LAWS AND REGULATIONS OF THIS COMMONWEALTH.

18 (IV) THE TERMS AND CONDITIONS OF A HEALTH INSURANCE POLICY,  
19 INCLUDING DETERMINATIONS OF MEDICAL NECESSITY AND CLINICAL  
20 REVIEW CRITERIA USED FOR UTILIZATION REVIEW OF HEALTH CARE  
21 SERVICES ALONG WITH COPAYMENT, DEDUCTIBLE AND COINSURANCE  
22 PROVISIONS.

23 (2) COVERAGE FOR BIOMARKER TESTING SHALL BE ADMINISTERED IN  
24 A SIMILAR MANNER TO OTHER HEALTH CARE SERVICES PROVIDED FOR  
25 UNDER THE TERMS AND CONDITIONS OF A HEALTH INSURANCE POLICY.

26 (3) NOTHING IN THIS SUBSECTION SHALL BE CONSTRUED AS  
27 REQUIRING AN INSURER TO COVER BIOMARKER TESTING FOR THE PURPOSE  
28 OF SCREENING BEYOND THE BRCA-RELATED SCREENINGS REQUIRED UNDER  
29 SECTION 633.1.

30 (B) SUBJECT TO FEDERAL APPROVAL, AS NECESSARY, A MEDICAL

1 ASSISTANCE OR CHILDREN'S HEALTH INSURANCE PROGRAM MANAGED CARE  
2 PLAN SHALL PROVIDE COVERAGE OF BIOMARKER TESTING. THE FOLLOWING  
3 SHALL APPLY:

4 (1) A MEDICAL ASSISTANCE OR CHILDREN'S HEALTH INSURANCE  
5 PROGRAM MANAGED CARE PLAN'S COVERAGE FOR BIOMARKER TESTING UNDER  
6 THIS SUBSECTION SHALL BE SUBJECT TO:

7 (I) ARTICLE XXI OF THIS ACT.

8 (II) APPLICABLE FEDERAL LAWS AND REGULATIONS.

9 (III) APPLICABLE LAWS AND REGULATIONS OF THIS COMMONWEALTH.

10 (IV) THE TERMS AND CONDITIONS OF AN AGREEMENT WITH THE  
11 DEPARTMENT OF HUMAN SERVICES, INCLUDING DETERMINATIONS OF  
12 MEDICAL NECESSITY AND CLINICAL REVIEW CRITERIA USED FOR  
13 UTILIZATION REVIEW OF HEALTH CARE SERVICES ALONG WITH COPAYMENT,  
14 DEDUCTIBLE AND COINSURANCE PROVISIONS.

15 (2) COVERAGE FOR BIOMARKER TESTING SHALL BE ADMINISTERED IN  
16 A SIMILAR MANNER TO OTHER HEALTH CARE SERVICES PROVIDED UNDER  
17 THE TERMS AND CONDITIONS OF AN AGREEMENT WITH THE DEPARTMENT OF  
18 HUMAN SERVICES.

19 (3) NOTHING IN THIS SUBSECTION SHALL BE CONSTRUED AS  
20 REQUIRING A MEDICAL ASSISTANCE OR CHILDREN'S HEALTH INSURANCE  
21 PROGRAM MANAGED CARE PLAN TO COVER BIOMARKER TESTING FOR THE  
22 PURPOSE OF SCREENING.

23 (C) THE TERMS IN THIS SECTION SHALL BE GIVEN THE SAME  
24 DEFINITIONS AS THE TERMS DEFINED PURSUANT TO SECTION 2102 UNLESS  
25 OTHERWISE NOTED. AS USED IN THIS SECTION, THE FOLLOWING WORDS  
26 AND PHRASES SHALL HAVE THE MEANINGS GIVEN TO THEM IN THIS  
27 SUBSECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE:

28 "AGREEMENT WITH THE DEPARTMENT OF HUMAN SERVICES." AN  
29 AGREEMENT BETWEEN A MEDICAL ASSISTANCE OR CHILDREN'S HEALTH  
30 INSURANCE PROGRAM MANAGED CARE PLAN AND THE DEPARTMENT OF HUMAN

1 SERVICES.

2 "BIOMARKER." A DEFINED CHARACTERISTIC THAT IS MEASURED AS AN  
3 INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC PROCESSES  
4 OR RESPONSES TO AN EXPOSURE OR INTERVENTION, INCLUDING  
5 THERAPEUTIC INTERVENTIONS. MOLECULAR, HISTOLOGIC, RADIOLOGIC OR  
6 PHYSIOLOGIC CHARACTERISTICS ARE TYPES OF BIOMARKERS. A BIOMARKER  
7 IS NOT AN ASSESSMENT OF HOW A COVERED PERSON OR ENROLLEE FEELS,  
8 FUNCTIONS OR SURVIVES.

9 "BIOMARKER TESTING." THE ANALYSIS OF A COVERED PERSON OR  
10 ENROLLEE'S TISSUE, BLOOD OR OTHER BIOSPECIMEN FOR THE PRESENCE  
11 OF A BIOMARKER. BIOMARKER TESTING INCLUDES, BUT IS NOT LIMITED  
12 TO, SINGLE-ANALYTE TESTS AND MULTI-PLEX PANELS PERFORMED AT A  
13 PARTICIPATING IN-NETWORK LABORATORY THAT IS CLIA CERTIFIED BY  
14 THE FEDERAL FOOD AND DRUG ADMINISTRATION.

15 "MEDICAL ASSISTANCE" OR "CHILDREN'S HEALTH INSURANCE PROGRAM  
16 MANAGED CARE PLAN." A HEALTH CARE PLAN THAT USES A GATEKEEPER  
17 TO MANAGE THE UTILIZATION OF HEALTH CARE SERVICES, INCLUDING  
18 BIOMARKER TESTING, BY MEDICAL ASSISTANCE OR CHILDREN'S HEALTH  
19 INSURANCE PROGRAM ENROLLEES AND INTEGRATES THE FINANCING AND  
20 DELIVERY OF HEALTH CARE SERVICES, INCLUDING BIOMARKER TESTING.

21 "SCREENING." A MEDICAL PROCEDURE OR TEST FOR A COVERED  
22 PERSON OR ENROLLEE WHO HAS YET TO DISPLAY SYMPTOMS OF A  
23 PARTICULAR DISEASE OR CONDITION FOR THE PURPOSE OF DETERMINING  
24 THEIR LIKELIHOOD OF HAVING THE DISEASE OR CONDITION.

25 SECTION 2. THIS ACT SHALL APPLY AS FOLLOWS:

26 (1) FOR HEALTH INSURANCE POLICIES FOR WHICH EITHER RATES  
27 OR FORMS ARE REQUIRED TO BE FILED WITH THE FEDERAL GOVERNMENT  
28 OR THE INSURANCE DEPARTMENT, THE ADDITION OF SECTION 635.9(A)  
29 OF THE ACT SHALL APPLY TO ANY POLICY FOR WHICH A FORM OR RATE  
30 IS FIRST FILED ON OR AFTER THE EFFECTIVE DATE OF THIS

1 SECTION.

2 (2) FOR HEALTH INSURANCE POLICIES FOR WHICH NEITHER  
3 RATES NOR FORMS ARE REQUIRED TO BE FILED WITH THE FEDERAL  
4 GOVERNMENT OR THE INSURANCE DEPARTMENT, THE ADDITION OF  
5 SECTION 635.9(A) OF THE ACT SHALL APPLY TO ANY POLICY ISSUED  
6 OR RENEWED ON OR AFTER 120 DAYS AFTER THE EFFECTIVE DATE OF  
7 THIS SECTION.

8 (3) FOR MEDICAL ASSISTANCE AND CHILDREN'S HEALTH  
9 INSURANCE PROGRAM MANAGED CARE PLANS, THE ADDITION OF SECTION  
10 635.9(B) SHALL APPLY BEGINNING JANUARY 1, 2026.  
11 SECTION 3. THIS ACT SHALL TAKE EFFECT IN 180 DAYS.