

2022 -- S 2201 SUBSTITUTE A

LC004362/SUB A/3

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2022

A N A C T

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES --  
BIOMARKER TESTING COVERAGE

Introduced By: Senators Goodwin, McCaffrey, Coyne, Miller, Pearson, Gallo, and  
Ruggerio

Date Introduced: February 08, 2022

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness Insurance

2 Policies is hereby amended adding thereto the following section:

3 **27-18-89. Coverage for biomarker testing.**

4 (a) As used in this section:

5 (1) "Biomarker" means a characteristic that is objectively measured and evaluated as an  
6 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a  
7 specific therapeutic intervention. Biomarkers include, but are not limited to, gene mutations or  
8 protein expression.

9 (2) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen  
10 for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte  
11 tests, multi-plex panel tests, and whole genome sequencing.

12 (3) "Clinical utility" means the test result provides information that is used in the  
13 formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the  
14 clinical decision. The most appropriate test may include both information that is actionable and  
15 some information that cannot be immediately used in the formulation of a clinical decision.

16 (4) "Consensus statements" means statements developed by an independent,  
17 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and  
18 with a conflict of interest policy. These statements are aimed at specific clinical circumstances and

1 base the statements on the best available evidence for the purpose of optimizing the outcomes of  
2 clinical care.

3 (5) "Nationally recognized clinical practice guidelines" means evidence-based clinical  
4 practice guidelines developed by independent organizations or medical professional societies  
5 utilizing a transparent methodology and reporting structure and with a conflict of interest policy.  
6 Clinical practice guidelines establish standards of care informed by a systematic review of evidence  
7 and an assessment of the benefits and costs of alternative care options and include  
8 recommendations intended to optimize patient care.

9 (b) Every individual or group health insurance contract, or every individual or group  
10 hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery,  
11 or renewed in this state on or after January 1, 2024, shall provide coverage for the services of  
12 biomarker testing in accordance with each health insurer's respective principles and mechanisms  
13 of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the  
14 purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's  
15 disease or condition to guide treatment decisions, when the test provides clinical utility as  
16 demonstrated by medical and scientific evidence, including, but not limited to:

17 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-  
18 approved drug;

19 (2) Centers for Medicare Services ("CMS") National Coverage Determinations or  
20 Medicare Administrative Contractor ("MAC") Local Coverage Determinations; or

21 (3) Nationally recognized clinical practice guidelines and consensus statements.

22 (c) Coverage as defined in subsection (b) of this section shall be provided in a manner that  
23 limits disruptions in care including the need for multiple biopsies or biospecimen samples.

24 (d) The patient and prescribing practitioner shall have access to clear, readily accessible,  
25 and convenient processes to request an exception to a coverage policy of a health insurer, nonprofit  
26 health service plan, and health maintenance organization. The process shall be made readily  
27 accessible on the health insurers', nonprofit health service plans', or health maintenance  
28 organizations' website.

29 SECTION 2. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service  
30 Corporations" is hereby amended by adding thereto the following section:

31 **27-19-81. Coverage for biomarker testing.**

32 (a) As used in this section:

33 (1) "Biomarker" means a characteristic that is objectively measured and evaluated as an  
34 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a

1 specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or  
2 protein expression.

3 (2) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for  
4 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,  
5 multi-plex panel tests, and whole genome sequencing.

6 (3) "Clinical utility" means the test result provides information that is used in the  
7 formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the  
8 clinical decision. The most appropriate test may include both information that is actionable and  
9 some information that cannot be immediately used in the formulation of a clinical decision.

10 (4) "Consensus statements" as used here are statements developed by an independent,  
11 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and  
12 with a conflict of interest policy. These statements are aimed at specific clinical circumstances and  
13 base the statements on the best available evidence for the purpose of optimizing the outcomes of  
14 clinical care.

15 (5) "Nationally recognized clinical practice guidelines" as used here are evidence-based  
16 clinical practice guidelines developed by independent organizations or medical professional  
17 societies utilizing a transparent methodology and reporting structure and with a conflict of interest  
18 policy. Clinical practice guidelines establish standards of care informed by a systematic review of  
19 evidence and an assessment of the benefits and costs of alternative care options and include  
20 recommendations intended to optimize patient care.

21 (b) Every individual or group health insurance contract, or every individual or group  
22 hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery,  
23 or renewed in this state on or after January 1, 2024, shall provide coverage for the services of  
24 biomarker testing in accordance with each health insurer's respective principles and mechanisms  
25 of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the  
26 purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's  
27 disease or condition to guide treatment decisions, when the test provides clinical utility as  
28 demonstrated by medical and scientific evidence, including, but not limited to:

29 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-  
30 approved drug;

31 (2) Centers for Medicare Services ("CMS") National Coverage Determinations or  
32 Medicare Administrative Contractor ("MAC") Local Coverage Determinations; or

33 (3) Nationally recognized clinical practice guidelines and consensus statements.

34 (c) Coverage as defined in subsection (b) is provided in a manner that limits disruptions in

1 care including the need for multiple biopsies or biospecimen samples.

2 (d) The patient and prescribing practitioner shall have access to clear, readily accessible,  
3 and convenient processes to request an exception to a coverage policy of a health insurer, nonprofit  
4 health service plan, and health maintenance organization. The process shall be made readily  
5 accessible on the health insurers', nonprofit health service plans', or health maintenance  
6 organizations' website.

7 SECTION 3. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service  
8 Corporations" is hereby amended by adding thereto the following section:

9 **27-20-77. Coverage for biomarker testing.**

10 (a) As used in this section:

11 (1) "Biomarker" means a characteristic that is objectively measured and evaluated as an  
12 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a  
13 specific therapeutic intervention. Biomarkers include, but are not limited to, gene mutations or  
14 protein expression.

15 (2) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for  
16 the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests,  
17 multi-plex panel tests, and whole genome sequencing.

18 (3) "Clinical utility" means the test result provides information that is used in the  
19 formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the  
20 clinical decision. The most appropriate test may include both information that is actionable and  
21 some information that cannot be immediately used in the formulation of a clinical decision.

22 (4) "Consensus statements" as used here are statements developed by an independent,  
23 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and  
24 with a conflict of interest policy. These statements are aimed at specific clinical circumstances and  
25 base the statements on the best available evidence for the purpose of optimizing the outcomes of  
26 clinical care.

27 (5) "Nationally recognized clinical practice guidelines" as used here are evidence-based  
28 clinical practice guidelines developed by independent organizations or medical professional  
29 societies utilizing a transparent methodology and reporting structure and with a conflict of interest  
30 policy. Clinical practice guidelines establish standards of care informed by a systematic review of  
31 evidence and an assessment of the benefits and costs of alternative care options and include  
32 recommendations intended to optimize patient care.

33 (b) Every individual or group health insurance contract, or every individual or group  
34 hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery,

1 or renewed in this state on or after January 1, 2024, shall provide coverage for the services of  
2 biomarker testing in accordance with each health insurer's respective principles and mechanisms  
3 of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the  
4 purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's  
5 disease or condition to guide treatment decisions, when the test provides clinical utility as  
6 demonstrated by medical and scientific evidence, including, but not limited to:

7 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-  
8 approved drug;

9 (2) Centers for Medicare Services ("CMS") National Coverage Determinations or  
10 Medicare Administrative Contractor ("MAC") Local Coverage Determinations; or

11 (3) Nationally recognized clinical practice guidelines and consensus statements.

12 (c) Coverage as defined in subsection (b) is provided in a manner that limits disruptions in  
13 care including the need for multiple biopsies or biospecimen samples.

14 (d) The patient and prescribing practitioner shall have access to clear, readily accessible,  
15 and convenient processes to request an exception to a coverage policy of a health insurer, nonprofit  
16 health service plan, and health maintenance organization. The process shall be made readily  
17 accessible on the health insurers', nonprofit health service plans', or health maintenance  
18 organizations' website.

19 SECTION 4. Chapter 27-41 of the General Laws entitled "Health Maintenance  
20 Organizations" is hereby amended by adding thereto the following section:

21 **27-41-94. Coverage for biomarker testing.**

22 (a) As used in this section:

23 (1) "Biomarker" means a characteristic that is objectively measured and evaluated as an  
24 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a  
25 specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or  
26 protein expression.

27 (2) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for  
28 the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests,  
29 multi-plex panel tests, and whole genome sequencing.

30 (3) "Clinical utility" means the test result provides information that is used in the  
31 formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the  
32 clinical decision. The most appropriate test may include both information that is actionable and  
33 some information that cannot be immediately used in the formulation of a clinical decision.

34 (4) "Consensus statements" as used here are statements developed by an independent,

1 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and  
2 with a conflict of interest policy. These statements are aimed at specific clinical circumstances and  
3 base the statements on the best available evidence for the purpose of optimizing the outcomes of  
4 clinical care.

5 (5) "Nationally recognized clinical practice guidelines" as used here are evidence-based  
6 clinical practice guidelines developed by independent organizations or medical professional  
7 societies utilizing a transparent methodology and reporting structure and with a conflict of interest  
8 policy. Clinical practice guidelines establish standards of care informed by a systematic review of  
9 evidence and an assessment of the benefits and costs of alternative care options and include  
10 recommendations intended to optimize patient care.

11 (b) Every individual or group health insurance contract, or every individual or group  
12 hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery,  
13 or renewed in this state on or after January 1, 2024, shall provide coverage for the services of  
14 biomarker testing in accordance with each health insurer's respective principles and mechanisms  
15 of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the  
16 purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's  
17 disease or condition to guide treatment decisions, when the test provides clinical utility as  
18 demonstrated by medical and scientific evidence, including, but not limited to:

19 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-  
20 approved drug;

21 (2) Centers for Medicare Services ("CMS") National Coverage Determinations or  
22 Medicare Administrative Contractor ("MAC") Local Coverage Determinations; or

23 (3) Nationally recognized clinical practice guidelines and consensus statements.

24 (c) Coverage as defined in subsection (b) is provided in a manner that limits disruptions in  
25 care including the need for multiple biopsies or biospecimen samples.

26 (d) The patient and prescribing practitioner shall have access to clear, readily accessible,  
27 and convenient processes to request an exception to a coverage policy of a health insurer, nonprofit  
28 health service plan, and health maintenance organization. The process shall be made readily  
29 accessible on the health insurers', nonprofit health service plans', or health maintenance  
30 organizations' website.

31 SECTION 5. This act shall take effect upon passage.

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EXPLANATION  
BY THE LEGISLATIVE COUNCIL  
OF

A N A C T

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES --  
BIOMARKER TESTING COVERAGE

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1           This act would require health insurers, nonprofit hospital service corporations, nonprofit  
2 medical service corporations and health maintenance organizations to issue policies that provide  
3 coverage for biomarker testing, on or after January 1, 2024.

4           This act would take effect upon passage.

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