

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

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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