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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2022

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

17 (4) "Nationally recognized clinical practice guidelines" means evidence-based clinical
18 practice guidelines developed by independent organizations or medical professional societies

1 utilizing a transparent methodology and reporting structure and with a conflict of interest policy.
2 Clinical practice guidelines establish standards of care informed by a systematic review of evidence
3 and an assessment of the benefits and costs of alternative care options and include
4 recommendations intended to optimize patient care.

5 (b) Every individual or group health insurance contract, or every individual or group
6 hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery,
7 or renewed in this state on or after January 1, 2023, shall provide coverage for the services of
8 biomarker testing in accordance with each health insurer's respective principles and mechanisms
9 of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the
10 purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's
11 disease or condition when the test is supported by medical and scientific evidence, including, but
12 not limited to:

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

15 (2) Centers for Medicare and Medicaid Services ("CMS") National Coverage
16 Determinations or Medicare Administrative Contractor ("MAC") Local Coverage Determinations;
17 or

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

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

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

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

28 **27-19-81. Coverage for biomarker testing.**

29 (a) As used in this section:

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

34 (2) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for

1 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
2 multi-plex panel tests, and whole genome sequencing.

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

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

14 (b) Every individual or group health insurance contract, or every individual or group
15 hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery,
16 or renewed in this state on or after January 1, 2023, shall provide coverage for the services of
17 biomarker testing in accordance with each health insurer's respective principles and mechanisms
18 of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the
19 purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's
20 disease or condition when the test is supported by medical and scientific evidence, including, but
21 not limited to:

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

24 (2) Centers for Medicare and Medicaid Services ("CMS") National Coverage
25 Determinations or Medicare Administrative Contractor ("MAC") Local Coverage Determinations;
26 or

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

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

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

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

3 **27-20-77. 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" is the analysis of a patient's tissue, blood, or other biospecimen for
10 the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests,
11 multi-plex panel tests, and whole genome sequencing.

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

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

23 (b) Every individual or group health insurance contract, or every individual or group
24 hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery,
25 or renewed in this state on or after January 1, 2023, shall provide coverage for the services of
26 biomarker testing in accordance with each health insurer's respective principles and mechanisms
27 of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the
28 purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's
29 disease or condition when the test is supported by medical and scientific evidence, including, but
30 not limited to:

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

33 (2) Centers for Medicare and Medicaid Services ("CMS") National Coverage
34 Determinations or Medicare Administrative Contractor ("MAC") Local Coverage Determinations;

1 or

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

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

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

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

12 **27-41-94. Coverage for biomarker testing.**

13 (a) As used in this section:

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

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

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

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

32 (b) Every individual or group health insurance contract, or every individual or group
33 hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery,
34 or renewed in this state on or after January 1, 2023, shall provide coverage for the services of

1 biomarker testing in accordance with each health insurer's respective principles and mechanisms
2 of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the
3 purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's
4 disease or condition when the test is supported by medical and scientific evidence, including, but
5 not limited to:

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

8 (2) Centers for Medicare and Medicaid Services ("CMS") National Coverage
9 Determinations or Medicare Administrative Contractor ("MAC") Local Coverage Determinations;
10 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 5. Chapter 40-8.4 of the General Laws entitled "Health Care for Families" is
20 hereby amended by adding thereto the following section:

21 **40-8.4-21. Coverage for biomarker testing.**

22 (a) No later than January 1, 2023, the executive office of health and human services
23 (EOHHS) shall apply for the appropriate federal approval to provide Medicaid beneficiaries
24 coverage for biomarker testing, as defined and described pursuant to the provisions of §§ 27-18-
25 89, 27-19-81, 27-20-77 and 27-41-94, for inclusion in the Rhode Island medical assistance program
26 (Medicaid program).

27 (b) Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate
28 management, or ongoing monitoring of an enrollee's disease or condition when the test is supported
29 by medical and scientific evidence, including, but not limited to:

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

32 (2) Centers for Medicare and Medicaid Services ("CMS") National Coverage
33 Determinations or Medicare Administrative Contractor ("MAC") Local Coverage Determinations;
34 or

1 (3) Nationally recognized clinical practice guidelines and consensus statements.
2 (c) Risk-bearing entities contracted to the Rhode Island medical assistance program
3 ("Medicaid program") to deliver services to beneficiaries shall provide biomarker testing at the
4 same scope, duration and frequency as the Medicaid program otherwise provides to enrollees.
5 (d) The enrollee and participating provider shall have access to clear, readily accessible,
6 and convenient processes to request an exception to a coverage policy of the Rhode Island medical
7 assistance program ("Medicaid program") or by risk-bearing entities contracted to the Rhode Island
8 medical assistance program ("Medicaid program"). The process shall be made readily accessible to
9 all participating providers and enrollees online.

10 SECTION 6. 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, 2023, and would require the Rhode Island
4 medical assistance program to provide similar coverage as well.

5 This act would take effect upon passage.

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