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

Introduced By: Representatives Ackerman, McNamara, Serpa, Chippendale, Bennett, Baginski, Filippi, Diaz, and Amore

Date Introduced: February 18, 2022

Referred To: House Finance

It is enacted by the General Assembly as follows:

SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness Insurance Policies is hereby amended adding thereto the following section:

27-18-89. Coverage for biomarker testing.

(a) As used in this section:

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

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

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

(4) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies.
utilizing a transparent methodology and reporting structure and with a conflict of interest policy.

Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

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

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

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

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

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

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

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


(a) As used in this section:

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

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

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

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

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

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

(2) Centers for Medicare and Medicaid Services (“CMS”) National Coverage Determinations or Medicare Administrative Contractor (“MAC”) Local Coverage Determinations; or

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

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

(d) The patient and prescribing practitioner shall have access to clear, readily accessible, and convenient processes to request an exception to a coverage policy of a health insurer, nonprofit health service plan, and health maintenance organization. The process shall be made readily accessible on the health insurers', nonprofit health service plans', or health maintenance organizations’ website.
SECTION 3. Chapter 27-20 of the General Laws entitled “Nonprofit Medical Service Corporations” is hereby amended by adding thereto the following section:

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

(a) As used in this section:

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

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

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

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

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

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

(2) Centers for Medicare and Medicaid Services (“CMS”) National Coverage Determinations or Medicare Administrative Contractor (“MAC”) Local Coverage Determinations;
(3) Nationally recognized clinical practice guidelines and consensus statements.

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

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

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

27-41-94. Coverage for biomarker testing.

(a) As used in this section:

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

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

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

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

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

1. Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-approved drug;

2. Centers for Medicare and Medicaid Services (“CMS”) National Coverage Determinations or Medicare Administrative Contractor (“MAC”) Local Coverage Determinations;

or


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

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

SECTION 5. Chapter 40-8.4 of the General Laws entitled “Health Care for Families” is hereby amended by adding thereto the following section:

40-8.4-21. Coverage for biomarker testing.

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

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

1. Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-approved drug;

2. Centers for Medicare and Medicaid Services (“CMS”) National Coverage Determinations or Medicare Administrative Contractor (“MAC”) Local Coverage Determinations;

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

(c) Risk-bearing entities contracted to the Rhode Island medical assistance program ("Medicaid program") to deliver services to beneficiaries shall provide biomarker testing at the same scope, duration and frequency as the Medicaid program otherwise provides to enrollees.

(d) The enrollee and participating provider shall have access to clear, readily accessible, and convenient processes to request an exception to a coverage policy of the Rhode Island medical assistance program ("Medicaid program") or by risk-bearing entities contracted to the Rhode Island medical assistance program ("Medicaid program"). The process shall be made readily accessible to all participating providers and enrollees online.

SECTION 6. This act shall take effect upon passage.
This act would require health insurers, nonprofit hospital service corporations, nonprofit medical service corporations and health maintenance organizations to issue policies that provide coverage for biomarker testing, on or after January 1, 2023, and would require the Rhode Island medical assistance program to provide similar coverage as well. This act would take effect upon passage.