HOUSE CONSUMER AND PUBLIC AFFAIRS COMMITTEE SUBSTITUTE FOR HOUSE BILL 73

56TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2023

AN ACT

RELATING TO HEALTH INSURANCE COVERAGE; ENACTING SECTIONS OF THE HEALTH CARE PURCHASING ACT, THE PUBLIC ASSISTANCE ACT, THE NEW MEXICO INSURANCE CODE, THE HEALTH MAINTENANCE ORGANIZATION LAW AND THE NONPROFIT HEALTH CARE PLAN LAW TO REQUIRE COVERAGE OF BIOMARKER TESTING.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. A new section of the Health Care Purchasing Act is enacted to read:

"[NEW MATERIAL] BIOMARKER TESTING INSURER COVERAGE.--

A. Group health coverage, including self-insurance, offered, issued, amended, delivered or renewed under the Health Care Purchasing Act shall provide coverage for insureds to receive biomarker testing.

B. Coverage provided pursuant to this section shall

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be for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an insured's disease or condition when the test is supported by medical and scientific evidence, including:

(1) labeled indications for a United States food and drug administration-approved or -cleared test;

(2) indicated tests for a United States food and drug administration-approved drug;

(3) warnings and precautions on United States food and drug administration labels;

(4) federal centers for medicare and medicaid services national coverage determinations or medicare administrative contractor local coverage determinations; or

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

C. An insurer providing coverage for biomarker testing pursuant to this section shall ensure that:

(1) coverage is provided in a manner that limits disruptions in care, including coverage for multiple biopsies or biospecimen samples; and

(2) a patient and a practitioner who prescribes biomarker testing have clear, accessible and convenient processes to request an appeal of a benefit denial by the insurer and that those processes are accessible on the insurer's website.

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D. Coverage for biomarker testing may be subject to deductibles and coinsurance consistent with those imposed on other benefits under the same group health care coverage, including any form of self-insurance.

E. The provisions of this section do not apply to accident-only or limited or specified disease policies, plans or certificates of health insurance.

F. 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, including known gene-drug interactions for medications being considered for use or already being administered. "Biomarker" includes gene mutations, characteristics of genes or protein expression;

(2) "biomarker testing" means analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex panel tests, protein expression and whole exome, whole genome and whole transcriptome sequencing;

(3) "consensus statements" means statements that are:

(a) developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict-of-

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interest policy; and

(b) aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care; and

(4) "nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that are:

(a) developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) used to establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care."

SECTION 2. A new section of the Public Assistance Act is enacted to read:

"[NEW MATERIAL] BIOMARKER TESTING COVERAGE.--

A. In accordance with federal law, the secretary shall adopt and promulgate rules that provide medical assistance coverage for enrollees to receive biomarker testing.

B. A medical assistance plan providing coverage pursuant to this section shall be for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an enrollee's disease or condition when the test

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is supported by medical and scientific evidence, including:

(1) labeled indications for a United States food and drug administration-approved or -cleared test;

(2) indicated tests for a United States food and drug administration-approved drug;

(3) warnings and precautions on United States food and drug administration labels;

(4) federal centers for medicare and medicaid services national coverage determinations or medicare administrative contractor local coverage determinations; or

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

C. Medicaid contractors delivering services to enrollees shall provide biomarker testing at the same scope, duration and frequency as the medical assistance plan otherwise provides to enrollees.

D. A medical assistance plan providing coverage for biomarker testing pursuant to this section shall ensure that:

(1) coverage is provided in a manner that limits disruptions in care, including coverage for multiple biopsies or biospecimen samples; and

(2) a patient and a practitioner who prescribes biomarker testing have clear, readily accessible and convenient processes to request an appeal of a benefit denial by the insurer and that those processes are accessible on the

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medical assistance division of the department's website.

E. 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, including known gene-drug interactions for medications being considered for use or already being administered. "Biomarker" includes gene mutations, characteristics of genes or protein expression;

(2) "biomarker testing" means analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex panel tests, protein expression and whole exome, whole genome and whole transcriptome sequencing;

(3) "consensus statements" means statements that are:

(a) developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care; and

(4) "nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines

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that are:

(a) developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) used to establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care."

SECTION 3. A new section of Chapter 59A, Article 22 NMSA 1978 is enacted to read:

"[NEW MATERIAL] BIOMARKER TESTING COVERAGE.--

A. An individual or group health insurance policy, health care plan or certificate of health insurance that is delivered, issued for delivery or renewed in this state shall provide coverage for insureds to receive biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an insured's disease or condition when the test is supported by medical and scientific evidence.

B. Coverage provided pursuant to this section shall be for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an insured's disease or condition when the test is supported by medical and scientific evidence, including:

(1) labeled indications for a United States

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food and drug administration-approved or -cleared test;

(2) indicated tests for a United States food and drug administration-approved drug;

(3) warnings and precautions on United States food and drug administration labels;

(4) federal centers for medicare and medicaid services national coverage determinations or medicare administrative contractor local coverage determinations; or

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

C. An individual or group health policy, health care plan or certificate of health insurance providing coverage for biomarker testing pursuant to this section shall ensure that:

(1) coverage is provided in a manner that limits disruptions in care, including coverage for multiple biopsies or biospecimen samples; and

(2) a patient and a practitioner who prescribe biomarker testing have clear, accessible and convenient processes to request an appeal of a benefit denial by the insurer and that those processes are accessible on the insurer's website.

D. Coverage for biomarker testing may be subject to deductibles and coinsurance consistent with those imposed on other benefits under the same policy, plan or certificate.

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E. The provisions of this section do not apply to short-term travel, accident-only or limited or specified disease policies, plans or certificates of health insurance.

F. 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, including known gene-drug interactions for medications being considered for use or already being administered. "Biomarker" includes gene mutations, characteristics of genes or protein expression;

(2) "biomarker testing" means analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex panel tests, protein expression and whole exome, whole genome and whole transcriptome sequencing;

(3) "consensus statements" means statements that are:

(a) developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy; and

(b) aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care; and

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(4) "nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that are:

(a) developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) used to establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care."

SECTION 4. A new section of Chapter 59A, Article 23 NMSA 1978 is enacted to read:

"[NEW MATERIAL] BIOMARKER TESTING COVERAGE.--

A. A blanket or group health insurance policy, health care plan or certificate of health insurance that is delivered, issued for delivery or renewed in this state shall provide coverage for insureds to receive biomarker testing.

B. Coverage provided pursuant to this section shall be for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an insured's disease or condition when the test is supported by medical and scientific evidence, including:

(1) labeled indications for a United States food and drug administration-approved or -cleared test;

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(2) indicated tests for a United States food and drug administration-approved drug;

(3) warnings and precautions on United States food and drug administration labels;

(4) federal centers for medicare and medicaid services national coverage determinations or medicare administrative contractor local coverage determinations; or

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

C. A blanket or group health policy, health care plan or certificate of health insurance providing coverage for biomarker testing pursuant to this section shall ensure that:

(1) coverage is provided in a manner that limits disruptions in care, including coverage for multiple biopsies or biospecimen samples; and

(2) a patient and a practitioner who prescribes biomarker testing have clear, accessible and convenient processes to request an appeal of a benefit denial by the insurer and that those processes are accessible on the insurer's website.

D. Coverage for biomarker testing may be subject to deductibles and coinsurance consistent with those imposed on other benefits under the same policy, plan or certificate.

E. The provisions of this section do not apply to accident-only or limited or specified disease policies, plans

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or certificates of health insurance.

F. 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, including known gene-drug interactions for medications being considered for use or already being administered. "Biomarker" includes gene mutations, characteristics of genes or protein expression;

(2) "biomarker testing" means analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex panel tests, protein expression and whole exome, whole genome and whole transcriptome sequencing;

(3) "consensus statements" means statements that are:

(a) developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care; and

(4) "nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines

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that are:

(a) developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) used to establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care."

SECTION 5. A new section of the Health Maintenance Organization Law is enacted to read:

"[NEW MATERIAL] BIOMARKER TESTING COVERAGE.--

A. An individual or group health maintenance organization contract that is delivered, issued for delivery or renewed in this state shall provide coverage for eligible enrollees to receive biomarker testing.

B. Coverage provided pursuant to this section shall be 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:

(1) labeled indications for a United States food and drug administration-approved or -cleared test;

(2) indicated tests for a United States food and drug administration-approved drug;

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(3) warnings and precautions on United States food and drug administration labels;

(4) federal centers for medicare and medicaid services national coverage determinations or medicare administrative contractor local coverage determinations; or

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

C. A health maintenance organization contract providing coverage for biomarker testing pursuant to this section shall ensure that:

(1) coverage is provided in a manner that limits disruptions in care, including coverage for multiple biopsies or biospecimen samples; and

(2) a patient and a practitioner who prescribes biomarker testing have clear, accessible and convenient processes to request an appeal of a benefit denial by the carrier and that those processes are accessible on the carrier's website.

D. Coverage for biomarker testing may be subject to deductibles and coinsurance consistent with those imposed on other benefits under the same contract.

E. The provisions of this section do not apply to accident-only or limited or specified disease policies, plans or certificates of health insurance.

F. As used in this section:

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(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, including known gene-drug interactions for medications being considered for use or already being administered. "Biomarker" includes gene mutations, characteristics of genes or protein expression;

(2) "biomarker testing" means analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex panel tests, protein expression and whole exome, whole genome and whole transcriptome sequencing;

(3) "consensus statements" means statements that are:

(a) developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care; and

(4) "nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that are:

(a) developed by independent

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organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) used to establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care."

SECTION 6. A new section of the Nonprofit Health Care Plan Law is enacted to read:

"[NEW MATERIAL] BIOMARKER TESTING COVERAGE.--

A. An individual or group health care plan that is delivered, issued for delivery or renewed in this state shall provide coverage for subscribers to receive biomarker testing.

B. Coverage provided pursuant to this section shall be for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a subscriber's disease or condition when the test is supported by medical and scientific evidence, including:

(1) labeled indications for a United States food and drug administration-approved or -cleared test;

(2) indicated tests for a United States food and drug administration-approved drug;

(3) warnings and precautions on United States food and drug administration labels;

(4) federal centers for medicare and medicaid

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services national coverage determinations or medicare administrative contractor local coverage determinations; or

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

C. Health care plans providing coverage for biomarker testing pursuant to this section shall ensure that:

(1) coverage is provided in a manner that limits disruptions in care, including coverage for multiple biopsies or biospecimen samples; and

(2) a patient and a practitioner who prescribes biomarker testing have clear, accessible and convenient processes to request an appeal of a benefit denial by the health care plan and that those processes are accessible on the health care plan's website.

D. Coverage for biomarker testing may be subject to deductibles and coinsurance consistent with those imposed on other benefits under the same policy, plan or certificate.

E. The provisions of this section do not apply to short-term travel, accident-only or limited or specified disease policies, plans or certificates of health insurance.

F. 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, including

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known gene-drug interactions for medications being considered for use or already being administered. "Biomarker" includes gene mutations, characteristics of genes or protein expression;

(2) "biomarker testing" means analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex panel tests, protein expression and whole exome, whole genome and whole transcriptome sequencing;

(3) "consensus statements" means statements that are:

(a) developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care; and

(4) "nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that are:

(a) developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy; and

(b) used to establish standards of care

informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care."

SECTION 7. APPLICABILITY.--The provisions of this act apply to health insurance policies, health care plans, certificates of health insurance or health maintenance organization contracts that are delivered, issued for delivery or renewed in this state on or after January 1, 2024.

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