SB-496 Biomarker testing. (2023-2024)

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Senate Bill No. 496

CHAPTER 401

An act to add Section 1367.667 to the Health and Safety Code, to add Section 10123.209 to the Insurance Code, and to add Section 14132.09 to the Welfare and Institutions Code, relating to health care coverage.

[Approved by Governor October 07, 2023. Filed with Secretary of State October 07, 2023.]

LEGISLATIVE COUNSEL'S DIGEST

SB 496, Limón. Biomarker testing.

(1) Existing law, the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act) provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after July 1, 2000, to provide coverage for all generally medically accepted cancer screening tests, and prohibits that contract or policy issued, amended, delivered, or renewed on or after July 1, 2022, from requiring prior authorization for biomarker testing for certain enrollees or insureds. Existing law applies the provisions relating to biomarker testing to Medi-Cal managed care plans, as prescribed.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after July 1, 2024, to provide coverage for medically necessary biomarker testing, as prescribed, including whole genome sequencing, for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's or insured's disease or condition to guide treatment decisions, as prescribed. The bill would specify that it does not require a health care service plan or health insurer to cover biomarker testing for screening purposes unless otherwise required by law. The bill would subject restricted or denied use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of a medical condition to state and federal grievance and appeal processes. Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

(2) Existing law provides for the Medi-Cal program, administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services pursuant to a schedule of benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing law includes Rapid Whole Genome Sequencing as a covered benefit for any Medi-Cal beneficiary who is one year of age or younger and is receiving inpatient hospital services in an intensive care unit.

Subject to the extent that federal financial participation is available and not otherwise jeopardized, and any necessary federal approvals have been obtained, this bill, by July 1, 2024, would expand the Medi-Cal schedule of benefits to include biomarker testing, as prescribed, for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a Medi-Cal beneficiary's disease or condition to guide treatment decisions, as prescribed. The bill would authorize the department to implement these provisions by various means without taking regulatory action.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.
Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.667 is added to the Health and Safety Code, immediately following Section 1367.665, to read:

1367.667. (a) A health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after July 1, 2024, shall cover medically necessary biomarker testing, subject to utilization review management, pursuant to this section. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions. Coverage shall include biomarker tests that meet any of the following:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.

(2) A national coverage determination made by the federal Centers for Medicare and Medicaid Services.

(3) A local coverage determination made by a Medicare Administrative Contractor for California.

(4) Evidence-based clinical practice guidelines, supported by peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(5) Standards set by the National Academy of Medicine.

(b) A health care service plan shall use the process described in Section 1363.5 to determine whether biomarker testing is medically necessary for purposes of this section.

(c) A health care service plan that is subject to this section shall ensure that biomarker testing is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. This section does not require coverage of biomarker testing for screening purposes unless otherwise required by this chapter.

(d) Restricted or denied use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is subject to grievance and appeal processes under state and federal law.

(e) (1) This section shall not apply to any Medi-Cal managed care plan contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code. For these plans, the biomarker testing coverage pursuant to Section 14132.09 of the Welfare and Institutions Code shall apply.

(2) This subdivision shall not be construed to remove any obligation that is otherwise applicable to Medi-Cal managed care plans licensed under this chapter.

(f) For purposes of this section, the following definitions apply:

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

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

(g) This section is subject to the provisions of Section 1367.665 as amended by Chapter 605 of the Statutes of 2021 for an enrollee with advanced or metastatic stage III or IV cancer.

SEC. 2. Section 10123.209 is added to the Insurance Code, to read:

10123.209. (a) A health insurance policy that is issued, amended, delivered, or renewed on or after July 1, 2024, shall include coverage for medically necessary biomarker testing, subject to utilization review management, pursuant to this section. Biomarker

testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions. Coverage shall include biomarker tests that meet any of the following:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.

(2) A national coverage determination made by the federal Centers for Medicare and Medicaid Services.

(3) A local coverage determination made by a Medicare Administrative Contractor for California.

(4) Evidence-based clinical practice guidelines, supported by peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(5) Standards set by the National Academy of Medicine.

(b) A health insurer shall use the process described in subdivision (f) of Section 10123.135 to determine whether biomarker testing is medically necessary for purposes of this section.

(c) A health insurance policy that is subject to this section shall ensure that biomarker testing is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. This section shall not be construed to require coverage of biomarker testing for screening purposes unless otherwise required by this part.

(d) Restricted or denied use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is subject to grievance and appeal processes under state and federal law, including Section 2719 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-19) and any regulations subsequently adopted thereunder, and the Independent Medical Review System under Article 3.5 (commencing with Section 10169).

(e) For purposes of this section, the following definitions apply:

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

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

(f) This section is subject to the provisions of Section 10123.20 as amended by Chapter 605 of the Statutes of 2021 for an insured with advanced or metastatic stage III or IV cancer.

SEC. 3. Section 14132.09 is added to the Welfare and Institutions Code, to read:

14132.09. (a) By July 1, 2024, biomarker testing, as specified in this section, is a covered benefit, subject to utilization controls and medical necessity requirements, as described in Section 14059.5. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a Medi-Cal beneficiary's disease or condition to guide treatment decisions. Coverage shall include biomarker tests that meet any of the following:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.

(2) A national coverage determination made by the federal Centers for Medicare and Medicaid Services, to the extent allowed under the Medicaid program.

(3) A local coverage determination made by a Medicare Administrative Contractor for California.

(4) Evidence-based clinical practice guidelines, supported by peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(5) Standards set by the National Academy of Medicine.

(b) (1) This section does not preclude any obligation on a Medi-Cal managed care plan subject to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code, including any obligations under Section 1363.5 of the Health and Safety Code.

(2) This section does not require coverage of biomarker testing for screening purposes unless otherwise required by this chapter.

(3) The department shall direct, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, that biomarker testing is to be provided in a manner that limits disruptions in care.

(c) Restricted or denied use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is subject to grievance and appeal processes under state and federal law.

(d) This section shall be implemented only to the extent that federal financial participation is available and not otherwise jeopardized, and any necessary federal approvals have been obtained.

(e) (1) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, and make specific this section by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking any further regulatory action.

(2) An all-county letter, plan letter, plan or provider bulletin, or similar instructions promulgated pursuant to paragraph (1) shall be based at a minimum on evidence-based clinical practice guidelines.

(f) For purposes of this section, the following definitions apply:

(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. A biomarker includes, but is not limited to, gene mutations or protein expression.

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

(g) This section is subject to the provisions of Section 1367.665 of the Health and Safety Code as amended by Chapter 605 of the Statutes of 2021 for a Medi-Cal beneficiary with advanced or metastatic stage III or IV cancer covered by a Medi-Cal managed care plan.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.