§ 1367.667. Health care service plan; Biomarker testing

(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.

HISTORY:
Added Stats 2023 ch 401 § 1 (SB 496), effective January 1, 2024.

§ 1367.668. Insurance contract colorectal cancer screening requirement

(a) Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, or renewed on or after January 1, 2022, shall provide coverage without any cost sharing for a colorectal cancer screening test assigned either a grade of A or a grade of B by the United States Preventive Services Task Force. The required colonoscopy for a positive result on a test or procedure, other than a colonoscopy, that is a colorectal cancer screening examination or laboratory test identified assigned either a grade of A or a grade of B by the United States Preventive Services Task Force shall also be provided without any cost sharing.

(b) This section does not preclude a health care service plan that has coverage for out-of-network benefits from imposing cost-sharing requirements for the items or services described in this section that are delivered by an out-of-network provider.

HISTORY:
Added Stats 2021 ch 436 § 1 (AB 342), effective January 1, 2022.