



California Association of
Health Plans

CAHP IMPLEMENTATION GUIDELINE

SB 535 (Limon) Chapter 605, Statutes of 2021

As a service to our members, the California Association of Health Plans produces guidelines designed to assist in the interpretation and implementation of new laws, and to promote full compliance with those laws. This document, however, is not intended to be authoritative. Any questions about official interpretations of the law should be directed to the appropriate state regulatory agency such as the Department of Managed Health Care or the Department of Health Care Services, as well as your legal counsel.

BIOMARKER TESTING

BACKGROUND

Senate Bill 535 was authored by Senator Monique Limon (D-Santa Barbara) and supported by various advocacy groups, providers and pharmaceutical companies. The stated intent by the author of the bill was to improve access to targeted therapy for advanced cancer patients. The author and supporters argued that prior authorization for testing delays reduces survival rates and quality of life.

CAHP opposed the introduced version of SB 535 because it initially included coverage for biomarker testing that is not only experimental but beyond the existing standard of care. As a result, it would increase healthcare costs while potentially subjecting patients to lower levels of care. CAHP was ultimately able to remove its opposition to the bill after it was amended to allow prior authorization for non-FDA-approved therapies and the effective date was delayed until July 1, 2022.

SB 535 was very popular in the Legislature passing with strong bi-partisan support throughout the process.

REQUIREMENTS

This bill prohibits health plans from requiring prior authorization for biomarker testing for an enrollee with advanced or metastatic stage 3 or 4 cancer. Applies to contracts issued, amended, delivered or renewed on or after July 1, 2022.

Specifically, this bill:

- 1) Defines “biomarker tests,” as specified, to identify an individual with a subtype of cancer, in order to guide patient treatment.
- 2) Permits prior authorization that is not for an FDA-approved therapy for advanced or metastatic stage 3 or 4 cancer.

3) Excludes specialized health plan contracts but includes health care service plan contracts and Medi-Cal managed care plan contracts with the Department of Health Care Services (DHCS).

COMPLIANCE DATES

Applies to contracts issued, amended, delivered or renewed on or after July 1, 2022.

IMPLEMENTATION ISSUES

Applicability:

This bill applies to commercial health care service plans, except for specialized plans, and provisions relating to biomarker testing apply to Medi-Cal managed care plans.

Implementation Issues:

Plans should review all service contracts issued on or after July 1, 2022 to ensure that they do not require prior authorization for biomarker testing services provided to specified enrollees as specified. Plans may also need to review their existing Policies and Procedures (P&P), especially those related to utilization management (UM) practices, as well as member handbooks/Evidence of Coverage (EOC) to ensure compliance with this section.

If you have any questions regarding this document, please contact Nick Louizos at nlouizos@calhealthplans.org