

California Law Prohibits Prior Authorization for Biomarker Testing

Effective July 1, 2022

Background

Senate Bill 535 was signed into law on October 6, 2021, to prohibit prior authorization of biomarker testing for advanced cancer patients. Biomarker testing informs treatment decisions and helps ensure patients receive the right precision therapies to treat their cancer.

As noted in the California Health Benefits Review Program (CHBRP) analysis of SB 535, studies indicate that biomarker testing improves patient outcomes: compared to patients receiving standard chemotherapy, cancer patients who receive biomarker testing and targeted therapy have a significant increase in median overall survival (51.7 weeks vs. 25.8 weeks) and lower average treatment costs.¹

In a 2021 American Medical Association survey of 1,000 physicians, 93% of providers indicated that prior authorization resulted in delays to patient care and 91% said prior authorization had a negative impact on clinical outcomes.² Prior to SB535, 31% of Californians enrolled in state-regulated insurance had benefits coverage that required prior authorization for biomarker testing.³

SB 535: What you need to know:

When is prior authorization prohibited?

Individual or group health care service plans and policies issued, amended, delivered, or renewed in the state of California on or after January 1, 2022, cannot require prior authorization for:

- (1) Biomarker testing for an enrollee with advanced or metastatic stage 3 or 4 cancer.
- (2) Biomarker testing for cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.

How is a biomarker test defined?

The legislation defines a biomarker test as a diagnostic test of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations to identify an individual with a subtype of cancer, in order to guide patient treatment.

When does this law apply?

The law applies to

- California Department of Insurance (CDI)-regulated plans (including large group, small group, and individual commercial plans)
- Department of Managed Health Care (DMHC)-regulated plans (including large group, small group, and individual commercial plans, CalPERS HMOs, and Medi-Cal managed care plans)

The law does not apply to:

- Medi-Cal FFS (Fee-for-service) plans
- Medi-Cal COHS (County Organized Health System) plans
- Federally regulated plans (i.e. Medicare beneficiaries, self-insured plans)
- Uninsured patients
- A biomarker test that is not a covered benefit under the plan or policy

¹ California Health Benefits Review Program. Analysis of California Senate Bill 535 Biomarker Testing. April 20, 2021. <http://analyses.chbrp.com/document/view.php?id=1567>

² American Medical Association (AMA). 2021 AMA prior authorization (PA) physician survey. 2022. <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

³ California Health Benefits Review Program. Analysis of California Senate Bill 535 Biomarker Testing. April 20, 2021. <http://analyses.chbrp.com/document/view.php?id=1567>