

State of California—Health and Human Services Agency
Department of Health Care Services



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DIRECTOR



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DATE: June 22, 2022

ALL PLAN LETTER 22-010

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: CANCER BIOMARKER TESTING

PURPOSE:

The purpose of this All Plan Letter (APL) is to provide information to Medi-Cal managed care health plans (MCPs) about coverage requirements for cancer biomarker testing as required by Senate Bill (SB) 535 (Limón, Chapter 605, Statutes of 2021).¹

BACKGROUND:

SB 535 amended section 1367.665 of the Health and Safety Code (HSC), which mandates new coverage requirements for biomarker testing for applicable members diagnosed with cancer, effective July 1, 2022.² The bill prohibits an MCP from requiring prior authorization for biomarker testing for members with advanced or metastatic stage 3 or 4 cancer. SB 535 also prohibits MCPs from requiring prior authorization for biomarker testing for cancer progression or recurrence in members with advanced or metastatic stage 3 or 4 cancer. These prohibitions are intended to remove barriers for members with late-stage cancer, allowing them to access cancer biomarker testing to help inform their treatment in order to better expedite care. SB 535 provides that coverage policies do not limit, prohibit, or modify a member's rights to cancer biomarker testing as part of an approved clinical trial under HSC section 1370.6.

For the purposes of this APL, "Biomarker test" is defined as a diagnostic test, single or multigene, of an individual's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide treatment. Biomarkers, also called tumor markers, are substances found in higher-than-normal levels in the cancer itself, or in blood, urine, or tissues of some individuals with cancer. Biomarkers can determine the likelihood some types of cancer will spread. They can also help doctors choose the best treatment. For some cancers, certain tumor markers may be more helpful for staging than treatment planning.³

¹ Bills are searchable at: <https://leginfo.legislature.ca.gov/faces/home.xhtml>

² State law is searchable at: <https://leginfo.legislature.ca.gov/faces/billSearchClient.xhtml>

³ Information on stages of cancer can be found here: <https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/stages-cancer>.

Staging is a way to describe a cancer. The cancer's stage specifies where a cancer is located and its size, how far it has grown into nearby tissues, and if it has spread to nearby lymph nodes or other parts of the body. Before starting any cancer treatment, doctors may use physical exams, imaging scans, and other tests to determine a cancer's stage. Staging may not be completed until all the tests are finished. Stages of cancer vary based on the type of cancer. Providers use the Tumor, Node, Metastasis (TNM) staging system for most types of cancer. The TNM system uses letters and numbers to describe the size and extent of the main or primary tumor (T), the number of nearby lymph nodes (N) that have cancer, and whether or not the cancer has metastasized (M) or spread from the primary tumor to other parts of the body. Each letter and number identifies something about the cancer. The specific definitions for each category are different for each type of cancer that is staged using this system. In general and for purposes of this APL, "advanced cancer" refers to a cancer with significant local spread (stage 3) or cancer with distant metastases (stage 4) that has spread beyond the initial location to other organs or parts of the body.

POLICY:

MCPs are required to cover medically necessary biomarker testing for members with:

- Advanced or metastatic stage 3 or 4 cancer.
- Cancer progression or recurrence in the member with advanced or metastatic stage 3 or 4 cancer.

MCPs are prohibited from imposing prior authorization requirements on biomarker testing that is associated with a federal Food and Drug Administration (FDA)-approved therapy for advanced or metastatic stage 3 or 4 cancer. If the biomarker test is not associated with an FDA-approved cancer therapy for advanced or metastatic stage 3 or 4 cancer, MCPs may still require prior authorization for such testing.

The requirements contained in this APL will necessitate a change in MCPs' policies and procedures (P&Ps). MCPs must submit their updated P&Ps, including those pertaining to utilization management and authorization protocols for clinical trials and coverage for biomarker testing, to their Managed Care Operations Division (MCPD) contract manager within 90 days of the release of this APL.

MCPs are responsible for ensuring that their Subcontractors and Network Providers comply with all applicable state and federal laws and regulations, contract requirements, and other Department of Health Care Services' guidance, including APLs and Policy

Letters.⁴ These requirements must be communicated by each MCP to all Subcontractors and Network Providers.

If you have any questions regarding this APL, please contact your MCOD Contract Manager.

Sincerely,

Original Signed by Dana Durham

Dana Durham, Chief
Managed Care Quality and Monitoring Division

⁴ For more information on Subcontractors and Network Providers, including the definition and applicable requirements, see APL 19-001, and any subsequent APLs on this topic.