

Contra Costa Health Plan

Utilization Management.

Title: Biomarker Testing

Policy #: UM15.072

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Revised: 09/2025

Reviewer: Jill Perez, RN, UM Director

Reviewed and approved by Quality Council: 4/2024, 10/2025

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Applies to:

- | | | | |
|---|------------------------------|---|---|
| <input type="checkbox"/> Medi-Cal | | <input type="checkbox"/> Medicare | x Commercial |
| <input type="checkbox"/> State Sponsored | <input type="checkbox"/> All | <input type="checkbox"/> N/A | |
| Regulatory/Accreditation: | | | |
| x DMHC: | | <input type="checkbox"/> CMS: | <input type="checkbox"/> DHCS: |
| <input type="checkbox"/> Other Reg. References: | | <input type="checkbox"/> NCQA: | <input type="checkbox"/> N/A |
| Units: | | | |
| <input type="checkbox"/> Administration | | <input type="checkbox"/> Advice Nurses | X All Staff |
| <input type="checkbox"/> Business Services | | <input type="checkbox"/> Case Management | <input type="checkbox"/> Health Ed/Cultural Ling. |
| <input type="checkbox"/> Marketing | | <input type="checkbox"/> Member Services | <input type="checkbox"/> Planning, Survey, Reg Affairs |
| <input type="checkbox"/> Provider Affairs | | <input type="checkbox"/> Quality Management | <input checked="" type="checkbox"/> Auth/Utilization Management |

BACKGROUND

Biomarker testing is utilized by oncology providers to identify genes, proteins, or biomarkers that can provide additional information about an individual's cancer and guide treatment decisions. Biomarker testing can be performed for cancers involving the blood and cancers that take the form of solid tumors. Biomarker testing may also be referred to as tumor testing, tumor genetic testing, genomic testing or profiling, molecular testing or molecular profiling, somatic testing, or tumor subtyping.

Through Biomarker testing, providers can determine if an individual's cancer may be susceptible to certain cancer treatments, such as targeted therapies and immunotherapies. Biomarker testing may also help identify individuals who are able to benefit from clinical trials. Biomarker testing is a part of precision medicine, or personalized medicine, which is an approach to medical care in which disease prevention, diagnosis, and treatment, are tailored to genes, proteins, and other substances that a particular individual possesses.

The standards and coverage of Biomarker testing have been clarified in California Senate Bill 496 (SB 496) on Biomarker Testing. This Bill was codified in Health and Safety Code Section 1369.667. On or after July 1, 2024, plans are required to cover medically necessary Biomarker Testing, subject to utilization review management. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a member's disease or condition to guide treatment decisions.

PROCEDURE

Requests for Biomarker testing will be processed and reviewed according to our existing CCHP Authorization/Utilization Policies and Procedures, which are in alignment with California Health and Safety Code Section 1363.5.

Starting July 1, 2024, CCHP will cover biomarker tests that meet any of the following:

- A labeled indication for a test that has been approved or cleared by the FDA or is an indicated test for an FDA-approved drug
- A national coverage determination made by the Centers for Medicare and Medicaid Services

- A local coverage determination made by a Medicare Administrative Contractor for California
- 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
- Standards set by the National Academy of Medicine

CCHP will ensure that biomarker testing is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

In situations where the use of biomarker testing for the purposes of diagnosis, treatment or ongoing monitoring of any medical condition may have been denied or restricted, CCHP will ensure that these restrictions or denials are subject to our standard grievance and appeal processes.

CCHP will 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.

In accordance with APL 22-1010, CCHP will not require 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, CCHP will require prior authorization for such testing.