Medical Policy: Biomarker Testing

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Created by: Dr. Howard Taekman
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Biomarker Testing

Policy

VCHCP covers biomarker testing and does not require prior authorization for biomarker testing (as mandated by SB535) for an enrollee with advanced or metastatic stage 3 or 4 cancer; and cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer, effective July 1, 2022.

VCHCP covers biomarker testing as mandated by SB496. This bill would require a health care service plans on or after July 1, 2024, to provide coverage for medically necessary biomarker testing, as prescribed, including whole genome sequencing, for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions.

In accordance with Health and Safety Code Section 1367.665(b), the Plan will cover and will not require prior authorization for biomarker testing for enrollees with a cancer diagnosis. Personal history of cancer is covered and will not require prior authorization; however, providers must provide applicable cancer or personal history of cancer diagnosis codes at point of claims. Any diagnosis codes (ICD 10 codes) included in the diagnosis code group below do not require prior authorization.

- Cancer diagnosis codes: C00 through C96.Z
- History of cancer diagnosis code: Z85 through Z85.9

In accordance with Health and Safety Code Section 1367.667, the plan will cover biomarker testing for enrollees who does not have cancer diagnosis and personal history of cancer if it meets medical necessity criteria after utilization management review. Medical necessity will be determined using applicable VCHCP medical policies or Milliman Care Guidelines criteria. Any restricted or denied use of biomarker testing for the purpose of diagnosis, treatment, and ongoing monitoring of any other medical condition may be disputed through the Plan's grievance and appeal processes.

Background

SB 496 clarifies the standards and coverage of biomarker testing, which Plans are required to cover without prior authorization under Health and Safety Code Section 1367.665, which is biomarker testing for advanced metastatic stage 3 or 4 cancer, and biomarker testing for cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.

The clarification of SB 496 requires the Plans, on or after July 1, 2024, to cover medically necessary biomarker testing subject to prior authorization for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions, under Health and Safety Code Section 1367.667.
The bill requires the Plans, on or after July 1, 2024, to cover biomarker tests that meet any of the following:

- A labeled indication for a test that has been approved and 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.

The bill requires the Plan to abide by the process described in Health and Safety Code Section 1363.5 to determine whether biomarker testing is medically necessary for the purposes of SB 496. Health and Safety Code Section 1363.5 involves the Plan's disclosure to members and providers its utilization management process to authorize, modify or deny health care services under the benefit provided by the Plan. This includes the criteria/medical policies used to make determinations. It also includes Plan's disclosure to members and providers the process to request its UM policy and procedure and criteria/medical policies used to make determinations. Health and Safety Code Section 1367.01 involves notifications of decisions to deny, delay or modify services requested by the providers, to enrollees verbally or in writing.

The bill requires the Plan to ensure that biomarker testing is provided in a manner that limits disruption in care, including the need for multiple biopsies or biospecimen samples. The bill also requires the Plan to ensure that restricted or denied use of biomarker testing for the purposes of diagnosis, treatment, or ongoing monitoring of any medical condition is subject to grievance and appeal processes.

Procedure

1. SB 535 Biomarker for advanced cancer includes CPT code range of 81400-81408.
2. SB 496 Biomarker includes but is not limited to these CPT codes:

81206, 81207, 81208 - BCR/ABL1
81270 - JAK2 (p.V617F)
81479 - CALR
81219 - CALR (exon 9)
81479 - CSF3R
81175, 81176 - ASXL1
81479 – TET2
81236, 81237 - EXH2
81351, 81352, 81353 – TP53
81273 – KIT (including p.D816V)
81517 - Liver disease (liver fibrosis), analysis of 3 biomarkers (HA, PIIINP, TIMP-1)
0062U – IgG and IgM analysis of 80 biomarkers of systemic lupus erythematosus in serum
0310U– Analysis of 3 biomarkers (NT-proBNP, C-reactive protein and T-uptake) for Kawaski disease in plasma specimen

3. Please refer to the Plan's Utilization Management Policy & Procedure: Treatment Authorization Request Authorization Process and Timeline Standards to address compliance with Health and Safety Code Section 1363.5. The Plan's Member and Provider Newsletters direct providers and members to the Plan's website on how to access Plan's criteria/guidelines and policies. This policy is posted on the Plan's website: https://www.vchealthcareplan.org/providers/medicalPolicies.aspx.
4. Please refer to the Plan's Utilization Management Policy for Appeals to address compliance with Health and Safety Code Section 1367.667d. The Plan's Member and Provider Newsletters direct providers and members to the Plan's website on how to access Plan's criteria/guidelines and policies. This is posted on the Plan's website: https://www.vchealthcareplan.org/providers/medicalPolicies.aspx.

A. Attachments: None

B. History

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Revision Date	Content Revised	Contributors	Review/Revision Notes

	(Yes/No)		
5/15/2024	Yes	Faustine Dela Cruz	Updated to meet DMHC additional language requirement.
6/18/2024	Yes	Faustine Dela Cruz	Updated to add clarification per DMHC requirement on Section 1367.665(b).
8/7/2024	Yes	Faustine Dela Cruz; Howard Taekman	Updated to add clarify per Section 1367.665(b) and Section 1367.667.
2/20/2025	No	Howard Taekman, MD and Robert Sterling, MD	Annual review