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Biomarker Policy Changes

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Overview

- Biomarker tests can provide useful information that can affect treatment options for an individual.
- A biomarker test can be considered a companion diagnostic test when it can determine if a specific medication/therapy will be more effective in treatment, thereby guiding clinical management.
- **Effective August 1, 2023, both Fee-for-Service (FFS) Medicaid and HealthChoice will cover biomarker tests used as a companion diagnostic test designed to direct specific cancer treatments.**

Criteria

Biomarker tests must:

- Be approved for use by the Food and Drug Administration (FDA);
- Meet specific National Comprehensive Cancer Network (NCCN) cancer guidelines;
- Meet Clinical Laboratory Improvement Amendments (CLIA) standards; and,
- The companion drug/therapy identified has been FDA approved for that specific cancer treatment and is covered by the Maryland Medicaid FFS Program.

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Prior Authorization (PA)

MCOs have the discretion to establish PA requirements subject to the following criteria:

- May direct coverage to specific “preferred” biomarker testing that are consistent with NCCN recommendations to determine companion therapy.
- Poorly differentiated tumors, unclassified primary tumors, may be eligible for broader biomarker screening.
- May restrict biomarker testing in patients who do not have either an established diagnosis of cancer or substantiated suspicion of cancer as determined by a clinical evaluation and abnormal results (cancer or suspicious for cancer) from histologic and/or cytologic examination.
- May restrict biomarker testing used for research and not direct patient care.
- May require an oncologist as the preferred provider type.
- May direct coverage to specific “preferred” lab vendors. If there is a proprietary test that is covered under this policy, however, that lab vendor shall be used.

Non-Covered Indications

Biomarkers for companion diagnostic testing and targeted drug therapy will **not** be considered for coverage when:

1. A biomarker is either NOT FDA approved or the NCCN Level of Evidence is Category 2B and below.
2. Biomarker testing is performed on asymptomatic patients for the purposes of screening patients or their relatives.

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Next Steps

- Provider transmittal published
  - https://health.maryland.gov/mmcp/provider/Documents/Transmittals_FY2024/PT%2013-24%20Expanded%20Coverage%20of%20Cancer%20Biomarkers%20for%20Companion%20Diagnostic%20Testing%20and%20Targeted%20Drug%20Therapies%20sk%20signed%207.24.2023.pdf
- Final Clinical Criteria Policy published
  - https://health.maryland.gov/mmcp/Documents/BioMarkers%20for%20Companion%20Diagnostic%20Testing%20%26%20Target%20Drug%20Therapy%20-%20Clinical%20Criteria.pdf

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Looking Ahead

SB 805/HB 1217, *Maryland Medical Assistance Program and Health Insurance - Required Coverage for Biomarker Testing* (Chs. 322 & 323 of the Acts of 2023)

- Effective July 1, 2025, expands Medicaid coverage of biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition, e.g.,
  - Autoimmune diseases, cardiovascular disease, kidney disease, certain infectious diseases, and metabolic diseases.

Medicaid will report by December 1, 2024:

- Fiscal impact of biomarker testing, data on the use of testing, anticipated fiscal and access impacts of expanding coverage in FY 2026, and recommendations on any legislative changes.