Maryland
DEPARTMENT OF HEALTH

Biomarkers & Biomarker Testing- Clinical Criteria

In accordance with SB 805 (Chapters 322 and 323 of the Acts of 2023), *Required Coverage for Biomarker Testing*, Maryland Medicaid, inclusive of all Managed Care Organizations (MCOs), is mandated to provide coverage for biomarkers as defined by the statute. This legislation clearly outlines the definition of a biomarker, biomarker testing, and the requisite criteria for coverage.

I. Definitions

Biomarker:
A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. "Biomarker" includes gene mutations, characteristics of genes or protein expression.

Biomarker testing: Analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex panel tests, protein expression and whole exome, whole genome, and whole transcriptome sequencing.
The results of biomarker testing provide information that may be used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision; and include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision.

Nationally recognized clinical practice guidelines: Evidence-based clinical practice guidelines that are developed by independent organizations or medical professional societies using a transparent methodology and reporting structure with a conflict-of-interest policy.

II. Criteria for Coverage Consideration

Biomarker Tests, will be considered for Maryland Medicaid Fee-For-Service (FFS) coverage when all of the criteria below are met:

- The biomarker test has been approved for use by the Food and Drug Administration (FDA); **AND**
- The biomarker testing facility meets Clinical Laboratory Improvement Amendments (CLIA) Standards; **AND**
- Biomarker testing is used for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a member's disease or condition when the test is supported by medical and scientific evidence; **AND**

- There is a National Coverage Determination (NCD) **OR** a Local Coverage Determination (LCD) which is applicable to Maryland; * **OR**
  an FDA package insert for a medication recommends the biomarker for therapeutic monitoring of the medication;
    - to ensure an enrollee is a good candidate for the drug treatment, or required or recommended through a warning or precaution.
    - to identify whether an enrollee will have an adverse reaction to the drug treatment or dosage. **AND**
- The biomarker test is supported by nationally recognized clinical practice guidelines that are:
    - Developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and that have a conflict of interest policy; and
    - Established standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care; **AND**
    - The biomarker test is not investigational.

***A biomarker can be considered for approval if it does not yet have an NCD or LCD but meets the rest of the coverage criteria.**

III. FDA Approval Requirements

To be considered for Maryland Medicaid Coverage:
All biomarker tests must be approved under current FDA guidelines for their intended and specific use.

IV. Prior Authorization and Utilization Requirements:

Biomarkers which meet this Clinical Coverage Criteria should be considered a covered benefit. Some Biomakers may require a Prior Authorization (PA).

- PA may direct coverage to specific "preferred" biomarker tests that are also consistent with "nationally recognized clinical practice guidelines" to determine appropriate use.
- PA may restrict biomarker testing when used for research and not direct patient care.
- PA may require a specialist as the preferred provider type.
- PA 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.

VI. Non-Covered Indications:

Biomarkers will not be considered for coverage;

1. When a biomarker is either not FDA approved or does not meet the Clinical Criteria as defined in Section II of this document.

Approved by MDH Clinical Criteria Committee: 1.1.2026
Last Reviewed Date: 1.1.2026