



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:

- has been approved for use by the Food and Drug Administration (FDA) **OR** the test is a Laboratory Developed Test (LDT) developed and validated for clinical use by a CLIA-certified laboratory **AND**
- The biomarker testing facility meets Clinical Laboratory Improvement Amendments (CLIA) Standards; **AND**

- The biomarker testBiomarker 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. Laboratory Test Approval Requirements

To be considered for Maryland Medicaid Coverage all biomarker tests must be approved under:

1. Current FDA guidelines for their intended and specific use, or
2. As a Laboratory developed test, or LDT. LDT’s, are intended for clinical use and designed, manufactured, and used within a single clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meets the regulatory requirements under CLIA to perform high complexity testing.

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: 2.13.2026 Revision to include coverage of a Biomarker that is either approved by FDA or as an LDT. Rationale: May 6, 2024, the FDA issued a rule to classify Laboratory Developed Tests (LDT) as medical devices, aiming to phase out their enforcement discretion over four years. In March 2025, a federal court vacated this rule, stating that regulating LDTs as medical devices exceeded the FDA's statutory authority. Consequently, as of September 2025, the FDA reverted to its pre-existing regulatory definition, leaving LDT oversight primarily to CMS/CLIA.