Biomarker Testing Clinical Criteria

Policy Number: PA 31
Last Review Date:
Effective Date: 8/1/2026

Policy

Maryland Care, Inc., dba Maryland Physicians Care (MPC) utilizes this clinical policy when specific criteria are not available for the requested Biomarker testing. MPC considers Biomarker testing medically necessary when all the following criteria 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 the DFA package insert for a medication recommends the biomarker for therapeutic monitoring of the medication;
    - To ensure a member is a good candidate for the drug treatment or required or recommended through a warning or precaution.
    - To identify whether a member 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 all of the other coverage criteria.

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.

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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.

Limitations
All biomarker tests must be approved under current FDA guidelines for their intended and specific use.

Biomarkers will not be considered for coverage when a biomarker is either not FDA approved or does not meet the Clinical Criteria as defined in this document.

Background
NA

Codes/Devices/Services

Service	Description
	Refer to the Medicaid Fee Schedule for covered codes

References
Maryland SB 805 (Chapters 322 and 323 of the Acts of 2023)

Revision Log

New Policy created	08/01/2026