



Biomarkers for Companion Diagnostic Testing & Targeted Drug Therapy

Effective August 1, 2023, the Maryland Department of Health (MDH) will begin covering biomarkers for companion diagnostic testing for Maryland Medicaid members. MedStar Family Choice will follow MDH Biomarkers for Companion Diagnostic Testing and Targeted Drug Therapy Criteria for Coverage Determination. **MedStar Family Choice will require prior authorization for biomarker testing.**

Companion diagnostic tests are intended to direct specific cancer treatments. These biomarker tests must be approved by the Food Drug Association (FDA), meet specific National Comprehensive Cancer Network (NCCN) cancer guidelines, meet Clinical Laboratory Improvement Amendments Standards, and the companion drug/therapy has been approved by the FDA for that specific cancer treatment.

When utilized as a companion diagnostic test, all Biomarker tests must be recommended under the current NCCN guidelines for their intended and specific use. **Maryland Medicaid will consider coverage of a Biomarker Test (for its specific NCCN algorithm of care recommendation) for use as a companion diagnostic test when the NCCN level evidence is Category 2A and above.**

NCCN Levels of Evidence and Consensus Categories:

- **Category 1:** Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- **Category 2A:** Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- **Category 2B:** Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- **Category 3:** based upon any level of evidence there is major NCCN disagreement that the intervention is appropriate.

Companion Biomarkers can be performed once per lifetime with a few exceptions:

- The patient presents with more than one primary cancer diagnosis.
- The patient develops a new primary cancer diagnosis.
- Repeat biomarker testing, for Measurable Residual Disease testing, may be considered when supported by the medical literature and clinical evidence.

Biomarkers for Companion Diagnostic Testing and Targeted Drug Therapy are not covered:

- Biomarker is not FDA approved or the level of evidence by NCCN is category 2B or below.
- Biomarker testing is done on asymptomatic patients for screening patient or their relatives.

For more information, please refer to the Maryland Department of Health Biomarkers for Companion Diagnostic Testing and Targeted Drug Therapy (Criteria for Coverage Determination) Transmittal which is expected to be published in July 2023.