Maryland
DEPARTMENT OF HEALTH

Biomarkers for Companion Diagnostic Testing & Targeted Drug Therapy (Criteria for Coverage Determination)

Cancer Biomarkers are an ever evolving science involving genes, proteins, or other substances that can be tested to reveal important details about a patient's cancer. There are many roles that Biomarkers can be utilized for in a patient's cancer management, including when Biomarker Testing can provide useful information that can affect treatment options.

Medical genetics has helped us to understand not all cancer cells are alike. Even among cancers of the same organ system (such as breast or lung cancer), cancer cells can have different genetic makeup that can affect their behavior. These genetic changes might also affect how well the cancer responds to certain types of treatment, such as targeted drug therapy and immunotherapy. Some of these differences can be tested for as biomarkers.

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.

I. Criteria for Coverage Consideration

Biomarker Tests, when utilized as **a companion diagnostic test** designed to direct specific cancer treatments, will be considered for Maryland Medicaid 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).
- The Biomarker Test meets specific National Comprehensive Cancer Network (NCCN) cancer Guidelines.
- The Biomarker Testing Facility meets Clinical Laboratory Improvement Amendments (CLIA) Standards.
- The companion drug/therapy has been FDA Approved for that specific cancer treatment, and it is covered by the Maryland Medicaid FFS Program.

II. FDA Approval Requirements

To be considered for Maryland Medicaid Coverage:

*All Biomarker tests when utilized as **a companion diagnostic test** must be approved under current FDA guidelines for their intended and specific use.*

III. NCCN Approval Requirements

To be considered for Maryland Medicaid Coverage:
*All Biomarker tests, when utilized as **a companion diagnostic test,** must be recommended under current NCCN guidelines for their intended and specific use.*

The NCCN Biomarkers Compendium supports clinical decision making by aggregating and curating NCCN guidelines and treatment recommendations relevant to oncology. Recommendations for treatment are categorized based on the level of clinical evidence available as well as consensus among the multidisciplinary Guidelines Panel regarding the efficacy and safety of the intervention.

NCCN Levels of Evidence and Consensus Categories[1]:

- **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.

[1]For the 'uniform NCCN consensus' defined in Category 1 and Category 2A, a majority Panel vote of at least 85% is required.

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 of Evidence is Category 2A and above.

IV. Companion Drug Requirements:

Drug therapies (Companion Drug) identified by qualifying Companion diagnostic tests must be an FDA Approved drug and approved for coverage by Maryland Medicaid FFS Program.

V. Prior Authorization and Utilization Requirements:

- Testing to identify Companion Biomarkers can be performed once per lifetime.

- Exceptions:
    - Patients presenting with more than one Primary cancer diagnosis.
    - If a patient develops a new Primary cancer diagnosis.
    - Repeat biomarker testing, for Measurable Residual Disease (MRD) testing, may be considered when supported by the medical literature and clinical evidence.

- Biomarkers which meet this Clinical Coverage Criteria should be considered a covered benefit.
- Biomarker Testing may require a Prior Authorization (PA).
    - PA 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 Biomaker screening.
    - PA 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.
    - PA may restrict Biomarker testing used for research and not direct patient care.
    - PA may require an oncologist 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.

- **Non-Covered Indications**:

  Biomarkers for Companion Diagnostic Testing & Targeted Drug Therapy will not be considered for coverage;

  1. When a biomarker is either NOT FDA approved or Levels of Evidence, identified by NCCN, are Category 2B and below.
  2. When biomarker testing is performed on asymptomatic patients for the purposes of screening patients or their relatives. This use of screening biomarkers is not covered under this clinical criteria.

Last Reviewed Date: 7.1.2023