MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1432**	
Subject:	**Biomarkers for Companion Diagnostic Testing & Targeted Drug Therapy**	
Section:	**Medical Non-Pharmacy Protocols**	
Initial Effective Date:	**08/23, 07/24**	
Revision Effective Date(s):		
Review Effective Date(s):	**07/23**	
Responsible Parties:	**Medical Director**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Policy Biomarkers for Companion Diagnostic Testing & Targeted Drug Therapy (Criteria for Coverage Determination) and PT 13-24 MCO Transmittal No 178, July 21, 2023**	
Approved:	**AVP Clinical Operations**	**Chief Medical Officer**

Purpose: **To define the conditions under which MedStar Family Choice (MFC) will cover biomarkers for companion diagnostic testing and targeted drug treatment.**

Scope: **MedStar Family Choice, Maryland**

Policy: **It is the policy of MFC to require prior authorization for biomarker testing as outlined in the criteria below. This guideline is in accordance with Maryland Department of Health's (MDH) policy Biomarkers for Companion Diagnostic Testing and Targeted Drug Therapy (Criteria for Coverage Determination) and Biomarkers CPT List Targeted Treatments Policy Attachment**

Background:

MFC will follow the criteria outlined in the MDH Biomarkers for Companion Diagnostic Testing and Targeted Drug Therapy (Criteria for Coverage Determination) and Biomarkers CPT List Targeted Treatments Policy Attachment.

Cancer Biomarkers can be used in several ways, including providing information that can affect treatment options. A biomarker test can be considered a companion diagnostic test when it can determine if a specific medication will be a more effective treatment, thereby guiding medical management.

Criteria for Coverage Consideration:

I. Biomarker Tests, when used as a companion diagnostic test* to direct specific cancer treatments, may be considered for approval when all the below criteria are met:
   a. The Biomarker Test has been approved for use by the Food and Drug Administration (FDA)
      i. FDA Approval Requirements
         - To be considered for approval the Biomarker test must be approved under current FDA guidelines for their intended and specific use (i.e., they must be FDA approved for the type of cancer that the member being testing has)
   b. The Biomarker Test must meet specific National Comprehensive Cancer Network (NCCN) Guidelines.
      i. All Biomarker tests, when used as a companion diagnostic test, must be recommended under current NCCN guidelines for their intended and specific use.
      ii. The Biomarker test must have an NCCN level of evidence Category 1 or Category 2A.
   c. The Biomarker Testing Facility meets Clinical Laboratory Improvement Amendments (CLIA) Standards
   d. The companion drug/therapy has been FDA approved for that specific cancer treatment
   e. The companion drug/therapy is on the Maryland Medicaid Fee Schedule

II. Utilization Requirements
   a. Testing to identify companion biomarkers can be performed **once** per lifetime.
      i. Exceptions:
         - Members presenting with more than one primary cancer diagnosis
         - Members that develop 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. This literature and clinical evidence must be submitted with the request.

III. Other Considerations

a. Biomarker testing must be ordered by a hematology/oncology specialist
b. Biomarker testing may be directed to "preferred" lab vendors unless it is a covered proprietary test.
c. Biomarker testing used for research will not be covered
d. Biomarker testing in members that do not have either an established diagnosis of cancer or a substantiated suspicion of cancer as determined by a clinical evaluation AND abnormal results (cancer or suspicion for cancer) from histologic and/or cytologic examination may not be covered.
e. Biomarker testing can be redirected to specific MCO preferred tests that are consistent with NCCN recommendations to determine companion therapy

IV. Excluded From Coverage

Biomarkers for Companion Diagnostic Testing and Targeted Drug Therapy will not be considered for coverage:

a. When the biomarker is not FDA approved
b. When the NCCN levels of evidence are Category 2B or below (Categories 2B and 3)
c. When biomarker testing is performed on asymptomatic members for the purpose of screening members or their relatives. The use of screening biomarkers is not covered under this clinical criterion.

V. Procedure:

MFC will require prior authorization for biomarker testing:

a. MFC nurse will enter requests for biomarker testing into the clinical software system and attach the supporting clinical information.
b. The request with the supporting clinical will be forwarded to a medical director for review.
c. Medical Director will review for medical necessity and issue a decision.
d. The nurse will make notification to the requesting provider of decision in accordance with timelines outlined in UM Process Policy 110.

*Companion diagnostic test – a biomarker test is considered a companion diagnostic test when it can determine if a specific medication/therapy will be more effective in treatment, thereby guiding clinical management.

Summary of Changes:	**07/24:** • Removed specific names for "Responsible Parties" and "Approved"; just using titles • Added PT 13-24 to further identify MCO Transmittal used for regulatory reference **07/23:** • New policy.