

# MedStar Health, Inc.

## POLICY AND PROCEDURE MANUAL

Policy Number: PA.097.MH  
Last Review Date: 02/04/2016  
Effective Date: 03/01/2016  
Renewal Date: 02/01/2017

### PA.097.MH – Molecular/Genetic Testing

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers molecular/genetic tests medically necessary for the following indications:

1. The member demonstrates signs/symptoms of a genetically-linked disease, or the member/member's fetus has a direct and documented risk factor for development of a genetically-linked disease, or the member has a malignancy or physical condition for which an established treatment is associated with a specific mutation.
2. A molecular/genetic test, specific mutation, or set of mutations have been established in peer-reviewed scientific literature to be reliably associated with the specific diseases being evaluated for (condition or response to treatment identified).
3. The results of the molecular/genetic test will specifically determine medication, treatment, and/or clinical management decisions. Results are furnished for the diagnosis, direct care, and treatment of a medical condition and not mainly for the convenience of the member, provider, or laboratory.
4. The ordered test must directly impact clinical decision making and patient management.

Or

Any molecular/genetic test which is state mandated (see Variations section below).

Requests for molecular/genetic testing billed using unlisted codes or emerging technology will be evaluated on a case by case basis. Documentation must be provided by the requesting physician satisfying the criteria listed above.

#### Limitations

1. Molecular/genetic testing for a germ line or constitutional mutation is allowed only one time per member's lifetime.
2. Using molecular/genetic testing for risk selection or risk classification purposes in providing health coverage is prohibited and not covered.

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3. Molecular/genetic testing for asymptomatic general screening of a disease/condition is not covered unless specifically provided under a specific benefit plan.
4. Molecular/genetic testing for identification of late onset adult disorders will be covered only if an effective treatment exists that has documented better efficacy if initiated prior to onset of symptoms.
5. Direct-to-consumer (DTC) self-testing home kits and other DTC genetic tests are not covered.
6. Storing or using stored human biological specimens for molecular/genetic testing is considered experimental/not covered and should be under the purview of the responsible IRB (Institutional Review Board) or other comparable body.
7. Testing of anonymous human biological samples is considered not medically necessary/not covered.

### Variations

Any molecular/genetic test which is state mandated such as newborn screen (e.g. phenylketonuria (PKU), cystic fibrosis or congenital hypothyroidism) does not require prior authorization under this policy.

### Background

The emergence of personalized laboratory medicine has been characterized by a multitude of testing options which can more precisely pinpoint management needs of individual patients. As a result, the growing compendium of products described as biomarkers requires a careful evaluation by both clinicians and laboratorians as to what testing configurations are reasonable and necessary.

There are a plethora of burgeoning tools, including both gene-based (genomic) and protein-based (proteomic) assay formats, in tandem with more conventional (longstanding) flow cytometric, cytogenetic, etc. biomarkers. There are also highly-diverse approaches ranging from single mutation biomarkers to multiple biomarker platforms, the latter of which often depend upon sophisticated biomathematical interpretative algorithms.

### Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
81479	Unlisted molecular pathology procedure

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81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure
87999	Unlisted microbiology procedure
88299	Unlisted cytogenetic study

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### **Disclaimer:**

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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