

**Subject: Molecular Diagnostic Management**

**Background:** Harvard Pilgrim Health Care (HPHC) has delegated utilization management of molecular genetic testing to AIM Specialty Health (AIM).

The Molecular Diagnostic Management program will require precertification/prior approval for all molecular genetic tests per the coverage criteria in the AIM Clinical Guidelines.

The AIM Clinical Guidelines are based on peer-reviewed literature and recommendations from evidence-based research centers as including, but not limited to: The American College of Medical Genetics (ACMG), The American College of Obstetrics and Gynecologists (ACOG), the American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN).

**Policy and Coverage Criteria:**

Harvard Pilgrim Health Care (HPHC) requires prior authorization and pre-approval through the Molecular Diagnostic Management program for molecular genetic tests in the following categories:

- Genetic Testing for Hereditary Cardiac Disease
- Genetic Testing for Hereditary Cancer Susceptibility
- Genetic Testing for Single-Gene and Multifactorial conditions
- Pharmacogenetic and Thrombophilia Genetic Testing
- Reproductive Carrier Screening and Prenatal Diagnosis
- Somatic Tumor Testing
- Whole Exome and Genome Sequencing

Corresponding clinical guidelines are available at: <http://www.aimspecialtyhealth.com>.

**Genetic Counseling Requirement:**

Genetic counseling is required prior to genetic testing for all tests addressed in the following guidelines:

- Genetic Testing for Hereditary Cardiac Disease
- Genetic Testing for Hereditary Cancer Susceptibility
- Whole Exome Sequencing

Genetic testing is covered when ALL the following are met:

- The member meets coverage criteria outlined in the corresponding guideline
- A recommendation for genetic testing has been confirmed by one of the following professionals who has evaluated the individual, has completed a three-generation pedigree and intends to engage in post-test follow-up counseling:
  - An independent Board-Certified or Board-Eligible Medical Geneticist

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*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

- In ME, RI, VT: An American Board of Medical Genetics or American Board of Genetic Counseling-certified Genetic Counselor not employed by a commercial genetic testing laboratory\*
- In CT, MA, NH: Licensure by the state to be a Genetic Counselor and not employed by a commercial genetic testing laboratory\*
- A genetic nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APGN) by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who is not employed by a commercial genetic testing laboratory\*

**\*Genetic counselors and genetic nurses are not excluded if they are employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself.**

### **Exclusions:**

Harvard Pilgrim Health Care (HPHC) considers molecular genetic/genomic testing that does not meet coverage criteria listed in these clinical guidelines as experimental/investigational or not medically necessary, and it is therefore not covered.

### **Coding:**

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

CPT codes for Molecular Diagnostic Management

### **Billing Guidelines:**

Coverage is subject to applicable terms and conditions under the member's Evidence of Coverage. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Schedule of Benefits) for member-specific benefit information.

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

### **References:**

1. AIM Clinical Guidelines

### **Summary of Changes**

<b>Date</b>	<b>Change</b>
<b>1/19</b>	Addition of new CPT codes
<b>7/18</b>	Addition of PLA CPT codes
<b>4/18</b>	Coding updates. Removal of Cologuard code.

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#### **Molecular Diagnostic Management**

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<b>2/18</b>	Coding Updates
<b>12/17</b>	New Policy

**Approved by Clinical Medical Policy Committee: 1/16/2019**

**Approved by Clinical Policy Operations Committee: N/A**

**Policy Effective date: 1/16/2019**

**Reviewed/ Revised: 12/17, 2/18, 4/18, 7/18, 1/19**

**Initiated: 12/17**

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