Subject: Genetic Testing	Original Effective Date: 5/22/2008
Policy Number: MCP-051	**Revision Date(s):** 12/3/2009, 4/27/2011, 12/14/2011, 6/29/2012, 8/28/2013, 6/25/2014, 4/24/2017, 7/10/2018
Review Date: 12/16/2015, 6/15/2016, 4/18/2018	
MCPC Approval Date: 6/22/2017, 7/10/2018	

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Genetic testing is defined by the National Human Genome Research Institute as an array of techniques including analysis of human DNA, RNA, or protein. Genetic tests are used as a health care tool to detect gene variants associated with a specific disease or condition, as well as for non-clinical uses such as paternity testing and forensics. In the clinical setting, genetic tests can be performed to determine the genetic cause of a disease, confirm a suspected diagnosis, predict future illness, detect when an individual might pass a genetic mutation to his or her children, and predict response to therapy. They are also performed to screen newborns, fetuses, or embryos used in in vitro fertilization for genetic defects. [5]

Genetic Testing Access to Test Information [3]

The Genetic Testing Registry (GTR) website is a resource for medical genetic information that lists available genetic tests for thousands of conditions, with a directory of certified clinical laboratories specializing in genetic testing (chose “tests” from the homepage http://www.ncbi.nlm.nih.gov/gtr/). As of June 2013, the site lists over 2700 diseases for which a genetic basis has been established and for which clinical genetic testing is available.

Gene Tests is an alternative resource for genetic testing information. Gene Tests is a medical genetics information resource developed for physicians, genetic counselors, healthcare providers, and researchers. [27] Access to the website at this link: http://www.genetests.org/

FDA

There are three levels of oversight of genetic and genomic tests in the United States: FDA regulation of medical devices; Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulation of laboratories that develop laboratory-developed tests (LDTs) and, in some cases (i.e., New York State and Washington State), state regulation of clinical laboratories. LDTs are defined by the U.S. Food and Drug Administration (FDA) as tests that are developed by a single laboratory for use only in that laboratory. [5]

RECOMMENDATION [24-28 29-32]

Effective 7/1/14 MHI is using the eviCore healthcare criteria[31] for evaluation of all genetic testing requests. MCP-051 must be applied to all requests with the exception of any genetic testing MCP's that include but are not limited to MCP-157 Non-invasive Prenatal Testing. All genetic test requests are to be referred to the Medical Director if the member meets the criteria outlined below.

Genetic testing is considered medically necessary and may be authorized when ***all*** of the following criteria are met**: [ALL]**

- ❑ The genetic test must be ordered by board certified physician within the scope of their practice or a board certified MD medical geneticist; ***and***

- ❑ Pre-and post- test genetic counseling is performed by a board-certified MD medical geneticist, certified genetic counselor or appropriate MD specialist; ***and***

- ❑ Documented key risk factors that suggest a genetic disorder is present: [ONE];
  - clinical features indicative of a condition or disease; ***or***
  - high risk of inheriting the disease based upon personal history, family history, documentation of a genetic mutation and/or ethnic background; ***or***
  - following history, physical examination, pedigree analysis and completion of conventional diagnostic testing, a definitive diagnosis remains uncertain and a hereditary diagnosis is suspected; ***and***

- ❑ Carrier or Predictive testing requires documentation confirming that a causative genetic change has been identified in an affected family member; ***and***

  Note: Genetic testing of an asymptomatic person in a family with several relatives affected with disease is considered predictive genetic testing. Targeted predictive genetic testing of individual diseases is appropriate when the specific indications for each test are met.

- ❑ Documentation is provided that supports the clinical utility of test results that will be used to significantly alter the management or treatment of the disease (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy);

OR

- o Sci**e**ntific literature providing evidence of the following: **[ALL]**

  - ◊ > 3 published studies from widely recognized peer reviewed scientific journals that clearly establish the phenotype/genotype relationship of the condition; **OR**

  - ◊ ≥1 from widely recognized peer reviewed scientific journals published study on clinical validity with high accuracy that a test predicts the presence or absence of a clinical predisposition or condition (e.g., prediction of overall survival or recurrence-free survival)

AND

- o There is a clinically significant impact from a positive or negative test result on patient care/an effective treatment option, or other measurable clinical benefit is available following the test results to significantly improve health-related outcomes. Conditions with no available treatment or prevention options such as Alzheimer disease must be evaluated by a Medical Director for authorization.

AND

- ❑ The clinical testing laboratory must be accredited by CLIA, the State and/or other applicable accrediting agencies

CONTINUATION OF THERAPY [32]

- ❑ Testing is allowed once during the member's lifetime per disease for diagnostic purposes

- ❑ A second genetic test may be authorized in either of the following circumstances: **[ONE]**

  - o The genetic test identifies other mutations not previously tested and is considered to be different from the original test;

  OR

  - o If the genetic test measures gene expressions or identifies somatic mutations which can vary over time, only when clinically appropriate

COVERAGE EXCLUSIONS [22 23 31 32]

Genetic testing is considered not medically necessary and will **not** be authorized under the following circumstances:

- ❑ Criteria other than those outlined under the "Coverage Criteria" section above
- ❑ Testing for conditions or purposes where the test results would not directly influence the management or treatment of the disease or condition (e.g., disease without known treatment). Refer to the corporate/plan experimental and investigational policy as appropriate.
- ❑ Testing for informational purposes or management of a member's family member
- ❑ Predictive or Carrier Testing without documentation supporting that a causative genetic change has been identified in an affected family member
- ❑ Minors under the age of 18 for adult onset conditions that have no preventative or therapeutic options
- ❑ Population screening in individuals without a personal or family history, with the exception of state mandated or required newborn screening or prenatal screening for certain conditions
- ❑ More than one lifetime test for each disease or condition
- ❑ Whole Genome Sequencing (WGS)

Note: *Exceptions for more than one lifetime test are outlined in the above 'Continuation of Therapy' section.*

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Revision History: 7/10/18: This policy was reviewed and the clinical criteria has changed based on new evidence based literature and updated professional society guidelines. The following exclusions were removed: whole exome sequencing (WES) and carrier testing in children under the age of 18 years. The criteria was updated to allow an appropriate MD specialist to perform pre/post genetic counseling. The following sections were also updated: summary of medical evidence, professional society guidelines and references.