Subject: Genetic Testing	**Original Effective Date:** 5/22/08
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PREFACE

This Medical Guidance 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 following website: http://www.cms.hhs.gov/center/coverage.asp.

FDA INDICATIONS

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. [59]

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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 medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

There are no National Coverage Determinations available for Genetic testing. Local coverage determinations are available for guidance on general genetic testing and individual and specific genetic tests. [56]

Please search the Medicare Local Coverage Determination (LCD) search website for coverage criteria that may be available in your specific region at: http://www.cms.gov/mcd/search.asp?clickon=search

POLICY STATEMENT

Effective 7/1/14 MHI is using the CareCore DNA Direct Criteria for evaluation of all genetic testing requests. MCG-051 must be applied to all requests and all genetic test requests are to be referred to the Medical Director if the member meets the criteria outlined below.

Genetic testing 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[33;] ***and***

- ❑ Pre-and post- test genetic counseling is performed by a board-certified MD medical geneticist or certified genetic counselor [12 14 15 53 60]; ***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;[11,12,13,35] ***or***
  - following history, physical examination, pedigree analysis and completion of conventional diagnostic testing, a definitive diagnosis remains uncertain and a hereditary diagnosis is suspected;[11,12,13] ***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 test results 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).; [11,12,13,29]

  OR

  - Sci**e**ntific literature providing evidence of the following:[46] **[ALL]**

    - ◊ > 3 published studies from widely recognized peer reviewed scientific journals that clearly establish the phenotype/genotype relationship of the condition; [46] **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) [46]

AND

- 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.[46] Conditions with no available treatment or prevention options such as Alzheimer disease must be evaluated by a Medical Director for authorization.

Note: Refer to the 'Genetic Testing Characteristics' section under the 'General Information' section of this document for additional information regarding evaluation of testing results

AND

- ❑ The clinical testing laboratory must be accredited by CLIA, the State and/or other applicable accrediting agencies [59]

CONTINUATION OF THERAPY

- ❑ Testing is allowed once during the member's lifetime per disease for diagnostic purposes [1,23]
- ❑ A second genetic test may be authorized in either of the following circumstances: **[ONE]**
  - The genetic test identifies other mutations not previously tested and is considered to be different from the original test;

    OR

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

COVERAGE EXCLUSIONS

Genetic testing 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). [11,12,13,29] 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 in children under the age of 18 [21 51 62]

- ❑ Predictive or Carrier Testing without documentation supporting that a causative genetic change has been identified in an affected family member [46 62]
- ❑ Minors under the age of 18 for adult onset conditions that have no preventative or therapeutic options [9 20 21]
- ❑ 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[11,12,13]
- ❑ More than one lifetime test for each disease or condition[1,23]
- ❑ Whole Exome or Genome Sequencing to identify genetic variants in patients not diagnosed by conventional diagnostic and genetic testing methods due to insufficient evidence available to assess the use of whole exome or genome sequencing for clinical purposes [48 49 50 61 64 65]

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

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Genetic testing is defined by the National Human Genome Research Institute as "The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn, and carrier screening, as well as testing in high risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes. Tests conducted purely for research are excluded from the definition, as are tests for somatic (as opposed to heritable) mutations, and testing for forensic purposes".

Whole Exome and Genome Sequencing

According to the Hayes GTE Overview Whole Exome Sequencing for rare genetic conditions and cancer diagnosis and treatment; sequencing of the human exome has been proposed to identify genetic variants in patients not diagnosed by conventional diagnostic and genetic testing methods. Whole exome sequencing is predicted to have advantages over whole genome sequencing, including fewer uninterpretable results, faster turnaround times, and lower cost. Limitations of whole exome sequencing include incomplete capture of all coding regions, incomplete sequencing coverage of some regions, the inability to detect certain variants (such as large rearrangements, copy number variants [CNVs], mitochondrial genome variants, and trinucleotide repeats etc.), and the identification of variants of unknown clinical significance. At this time there is currently insufficient evidence to assess the use of this technology in clinical patient care. [48 49 50]

Genetic Testing Access to Test Information [35 45]

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

CODING INFORMATION

CPT	Description
	No specific codes for this document

HCPCS	Description
	No specific codes for this document

ICD-9 & ICD-10CM	Description
	No specific Diagnoses for this document

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