



CLINICAL MEDICAL POLICY

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Disclaimer

Gateway HealthSM's (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT:

Gateway HealthSM covers medically necessary genetic testing under the laboratory services of the medical surgical benefit of the Company's Medicaid products to establish a molecular diagnosis of an inheritable disease. This policy is not inclusive of all known genetic tests.

Genetic testing coverage is provided when the information is needed to adequately assess risk in the Gateway member; *and* the information is expected to make an impact on the member's treatment plan or the responsible family member/legal guardian intends to use the information in making decisions about his/her care or treatment plan.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrants individual consideration, based upon review of applicable medical records.

DEFINITIONS:

Prior Authorization Review Panel – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Biochemical Genetic Test – Diverse spectrum of laboratory analysis of biomolecules (metabolites, enzyme activities and functional assays) in serum or tissue to detect inborn errors of metabolism, genotype or mutations for clinical purposes (e.g. predict risk of disease, identify carriers and establish prenatal or clinical diagnoses or prognosis).

Genetic testing – Genetic testing requires the analysis of human chromosomes, DNA (deoxyribonucleic acid), RNA (ribonucleic acid), genes or gene products in order to detect or predict risk of inherited or non-inherited genetic variants related to disease, identify carriers, establish prenatal and clinical diagnosis or prognosis.

Carrier Testing: Carrier testing is used to determine whether they possess one copy of a gene mutation that, when present in two copies, causes a genetic disorder. This type of testing is offered to individuals who have a family history of a genetic disorder and to people in certain ethnic groups with an increased risk of specific genetic conditions.

Genetic Counseling: The process in which a specially trained professional evaluates family history, medical records, and genetic test results, in the risk assessment of an individual for genetic disease, understanding the limitations and risks of genetic testing.

Genetic Screening: Genetic screening issued to identify individuals who do not currently exhibit signs or symptoms but may have an increased risk of developing or transmitting a specific genetic disorder.

Genetic Screening Panels: These screening panels are genetic tests that are performed for multiple conditions such as the Ashkenazi Jewish Panel.

Diagnostic/Confirmatory Testing in Symptomatic Individuals: Genetic testing that is performed to rule out, identify, or confirm a suspected genetic disorder in an affected individual.

Direct Risk: This is when there is documentation in the family history of a disorder that involves an autosomal dominant inheritance which has been demonstrated in either the mother or the father or evidence of a disorder inherited in an autosomal recessive or X-linked recessive manner with supporting documentation suggestive of family history of a suspected disorder.

Family:

- First degree relatives are defined as the parents, brothers, sisters, or children of an individual member.
- Second degree relatives are those people with whom one quarter of the member's genes is shared (e.g., grandparent, grand child, uncle, aunt, nephew, niece or half-sibling).
- Third degree relatives are those people with whom one eighth of a member's genes is shared (e.g., cousin, great grandparent, great aunt, or great uncle).

Predictive Testing: Predictive testing is used to determine whether individuals who have a family history of a disease but no current symptoms have the gene alteration associated with the disease. Predictive genetic testing includes pre-symptomatic testing and predispositional testing.

PROCEDURES

1. When Gateway HealthSM does not have a specific medical guideline for genetic testing, the following medical necessity criteria must be met:

- a. A complete history, physical examination, family history and pedigree analysis, laboratory, imaging and other diagnostic testing, and a specific medical differential diagnosis has been established; AND
- b. The results of the genetic testing will have a direct impact on the plan member's care/treatment plan, including the determination of the intensity of surveillance or initiate new course of treatment of that disease or altering an existing therapy; AND
- c. The member is at direct risk of inheriting the genetic mutation (pre-symptomatic) as determined on review of family history and risk factors-(carrier identification); AND
- d. The genetic disorder is associated with the potential for significant disability or has a lethal natural history;
OR
- e. The member displays clinical features as documented in the physical exam and conventional testing are inconclusive and a definitive diagnosis is uncertain (diagnostic); AND
- f. The member has not had like or similar genetic testing previously. This does not apply to requests for comprehensive genetic testing when targeted testing has been previously performed; AND
- g. The providing laboratory is approved by the FDA and/or other professional or governmental agencies; AND
- h. The specific mutation or set of mutations has been established in the scientific literature as a reliable test associated with the disease; AND
- i. Peer reviewed literature is available that provides evidence for the indications and performance of the testing this policy is to be used in situations in which there is an absence of a medical policy.

Note: When available, please reference the separate Gateway HealthSM medical policies for specific genetic tests.

2. Genetic Counseling

Pre- and post-test genetic counseling is required to be performed by an independent (not employed by a genetic testing lab) genetic provider prior to genetic counseling for mutations. This service is necessary in order to inform persons being tested about the benefits and limitations of a specific genetic test for the specific patient. Genetic testing for mutation requires documentation of medical necessity from one of the following providers who has evaluated the member and intends to see the person after testing has been performed for counseling:

- Board Eligible or Board Certified Genetic Counselor
- Advanced Genetics Nurse
- Genetic Clinical Nurse
- Advanced Practice Nurse in Genetics
- Board Eligible or Board Certified Clinical Geneticist
- A physician with experience in cancer genetics
- A physician specializing in the care for the indication(s) for genetic testing

3. When services are not covered

- a. For conditions other than those listed above scientific evidence has not been established.
- b. Generally, genetic testing for a particular disease should be performed once per lifetime; however, there are rare circumstances in which testing may be performed more than once in a lifetime (e.g., previous testing methodology is inaccurate or a new discovery has added significant relevant mutations for a disease).
- c. Direct-to-consumer testing including but not limited to 'in-home' test kits or genetic tests order by plan member over the phone or internet.
- d. Genetic testing of children to predict adult onset diseases is considered not medically necessary unless test results will guide current decisions concerning prevention which would be lost by waiting until the member has reached adulthood.

e. Genetic testing or gene mapping in the screening of the general population.

4. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health Plan® at any time pursuant to the terms of your provider agreement.

5. Governing Bodies Approval

FDA

- a. The FDA has only regulated a relatively small number of genetic tests sold to laboratories as kits. In 2010, the FDA announced plans to expand regulation to all genetic tests, this expansion has yet to take place (as of April 19, 2016).
- b. The majority of genetic testing are laboratory developed tests that do not require premarket approval by the FDA. These types of tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1998. The regulations of the CLIA Amendments do not include validation of specific test but rather there is procedural compliance.
- c. Additional information available at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm>.

6. Place of Service

The place of service for these laboratory services is outpatient.

Literature Summary

General Genetic Testing

As medical technology continues to advance, it is not surprising that there is a parallel advancement and utilization of genetic testing. Due to the rapidly evolving field of genetic testing, every genetic test must be thoroughly evaluated in order to determine whether or not the identified genetic mutation represents a genetic disorder.

There are four categories of genetic testing: predictive, diagnostic, prognostic and therapeutic. The testing is conducted using several methods that include: molecular genetic tests that analyze single genes or short lengths of DNA to identify variations or mutations tied to specific genetic disorder; chromosomal genetic tests where the whole chromosome of long lengths of DNA are examined to identify large genetic changes; and biochemical genetic tests which measure the activity level or amount of specific proteins, metabolites or enzymes that can be indicative of changes to the DNA which may result in a genetic disorder (NLM 2016). Biochemical genetic tests analyzes gene products (proteins) and microscopic analysis of stained chromosomes. For some diseases, such as Tay-Sachs, use of biochemical genetic testing can detect more cases than standard DNA testing alone.

The American College of Medical Genetics recommends that genetic testing should only be requested by a qualified health care professional who is responsible for both ordering and interpreting the genetic tests as well as pretest and post-test counseling of individuals and families regarding the medical significance of the test results and the need for follow-up, if any.

The 2015 NCCN guidelines for genetic counseling have counseling services divided into pre-test and post-test categories. The pre-test counseling requirements include:

- Collection of a comprehensive family history (close blood relatives include first, second and third degree relatives on each side of the family);
- Evaluation of a patient's cancer risk;

- Generation of a differential diagnosis and education of the patient on inheritance patterns, penetrance, variable expressivity and the possibility of genetic heterogeneity.

Post-test counseling includes:

- Providing results along with their significance and impact and recommended medical management options;
- Informing and testing at-risk family members;
- Providing available resources such as disease specific support groups and research studies.

The National Society of Genetic Counselors (NSGC) has recommended that genetic testing be performed utilizing the informed decision-making process (Berliner et al., 2013). Issues included in this process should include the following:

- Obtaining all pertinent personal medical and family history data
- Psychosocial assessment
- Discussion of cancer and mutation risk and how personalized risk estimates are derived
- Facilitation of the informed consent process through discussion of the risks, benefits, limitations, and likelihood of identifying a mutation with genetic susceptibility testing
- Result disclosure, when appropriate
- Discussion of medical management options
- Review of issues related to genetic discrimination

Direct-to-Consumer Genetic Testing

Usually genetic testing is available through health care providers. These providers order appropriate genetic tests from a qualified laboratory and interprets the results. Recently direct-to-consumer genetic testing has become available as seen on television, printed advertisements and the internet. However, direct-to-consumer (DTC) genetic testing raises scientific, ethical and regulatory questions. The European Academies of Science Advisory Council (EASAC) and the Federation of European Academies of Medicine (FEAM) have recommended developing general principles for the governance of DTC services which includes: establishing scientific validity, extending quality control, supervising disclosure of information, understanding and addressing consequences for health systems and clarifying research use. In addition, there are key issues for consumer protection in DTC services include: information provision, analytical validity, scientific and clinical validity, access to advice and control of claims (Fears et al. 2013).

Consumers may be misled by results of DTC testing if the results are unproven or the testing is invalid. Consumer treatment decisions may be based on inaccurate, incomplete or misunderstood information without the guidance of a trained healthcare provider. More research is needed to fully understand the benefits and limitations of DTC.

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