



Genetic Testing

Clinical Coverage Criteria

Overview

Genetic testing refers to the laboratory analysis of DNA. Compared to other types of laboratory testing, genetic testing is unique in that it can provide a diagnosis and/or a prediction of the likelihood of developing a particular disease before symptoms even appear; it can also reveal if a person is carrying a specific gene that could be passed on to his or her children. While genetic testing holds great potential, it also has many limitations:

- Genetic tests may predict the chances of developing a particular disease. Such results may leave a person wondering what to do with the results, particularly if there are treatments available that may change the course of the disease.
- While genetic tests may reveal if a mutation exists, it does not guarantee that the disease will develop, nor can it predict how severely the disease will manifest in the person carrying the mutation, e.g., some individuals with cystic fibrosis have mild symptoms, while others develop debilitating lung disease and pancreatitis.
- Many genetic tests cannot detect all mutations that can cause disease, and thus, while a positive result can be informative, a negative result is "not always conclusive" or "may be inconclusive."
- Many diseases are the result of an interaction between genes and environment, and the way these interactions cause disease is not clearly understood.
- There are many legal and social issues that must be considered.

Because of these limitations, it is essential that individuals are thoroughly informed before undergoing any type of genetic testing. Results of genetic testing can have implications not only for an individual, but for an individual's family as well. Genetic counseling is advised to communicate the limitations of genetic testing and to also counsel patients about the results.

Massachusetts law Chapter 111, Section 70G, requires prior written consent before genetic testing. The consent form must be signed by the person who is the subject of the test or, if that person lacks capacity to consent, signed by the person authorized to consent for such person. Prior written consent must include:

1. A statement of the purpose of the test;
2. A statement that prior to signing the consent form, the consenting person discussed with the medical practitioner ordering the test the reliability of positive or negative test results and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease;
3. A statement that the consenting person was informed about the availability and importance of genetic counseling and provided with written information identifying a genetic counselor or medical geneticist from whom the consenting person might obtain such counseling;
4. A general description of each specific disease or condition tested for (inclusive of a description of the specific genes being tested); and

5. The person or persons to whom the test results may be disclosed.

Definitions

First-degree relative: A blood relative with whom an individual shares approximately 50% of his or her genes, including parents, full siblings and children.

Second-degree relative: A blood relative with whom an individual shares approximately 25% of his/her genes, including grandparents, grandchildren, aunts, uncles, nephews, nieces and half-siblings.

Policy

Fallon Health requires Prior Authorization for Genetic Testing. Fallon Health utilizes Interqual Criteria for specific testing when available. If no specific testing criteria is available the below criteria will be utilized.

Please be advised all requests must come directly from the **Ordering Provider** (i.e. a Clinician, a Clinician's staff, or the Genetic Counselor rather than the rendering lab provider). These requests must include all recent clinical information such as the most recent physical examination, lab work, and any other relevant clinical information to support this request. Failure to provide this information will result in a denial of the request.

All of the Guidelines for Genetic Testing and the disease specific criteria below must be met to satisfy coverage requirements for genetic testing:

1. The test is to be used for the diagnosis or determination of risk for a suspected disease for a plan member who is either:
 - Symptomatic (e.g., exhibiting signs and symptoms of a disease), or;
 - Presymptomatic, but at an increased risk of disease, as determined by current scientific literature which may be due to family history, ethnicity, or gender.
2. The results of the test will be clinically useful to the medical management of the patient (e.g., initiate a new course of therapy, alter an existing therapy, or determine level of surveillance).
3. There is a sufficient amount of evidence in the scientific literature to support the validity and predictive accuracy of the test.
4. The patient/family has consulted with a genetic practitioner to discuss their questions and concerns about the test and how the results will be used.
5. Prior written consent has been obtained.
6. All testing must be at a contracted facility when available.
7. Current clinical records inclusive of the most recent exam and lab work.

If the test is only for Cystic Fibrosis or Spinal Muscular Atrophy (not part of panel test) for member's who are attempting to become pregnant or in the early stages of pregnancy the test will be covered once per lifetime.

Due to the rapidly evolving field of genetic tests, this policy is not inclusive of all known genetic tests. The above Guidelines for Genetic Testing apply to all genetic testing whether or not disease specific criteria are listed below. Coverage for other genetic tests

are managed on an individual basis. Refer to the Infertility Clinical Coverage Criteria for coverage of pre-implantation genetic testing.

In regards to panel testing, if any tests included in the panel do not meet criteria the entire panel will be denied.

McKesson Z-Code™ identifiers are unique 5 digit alpha-numeric codes assigned to specific molecular tests based on the uniqueness of the specific test. Effective January 1, 2017 for Independent Laboratory claims and April 1, 2017 for Hospital based lab claims the Provider is required to submit the applicable Z-Code™ with a molecular testing claim

Exclusions

- Genetic Testing performed that does not meet the above or Interqual's criteria.
- Repeat genetic testing is not covered.
- Fallon Health does not cover direct-to-consumer genetic testing, including, but not limited to, "home-testing kits" or genetic tests ordered by patients over the telephone or Internet. The American College of Medical Genetics recommends that genetic testing should only be provided 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.

Policy History

Origination date: 05/2002
Approval(s): Technology Assessment Committee: 05/23/2006, 11/06/2013, 01/28/2015 (updated template, added language regarding panel testing) 01/27/2016 (added requirement that all requests come directly from the ordering provider) 01/25/2017 (added language regarding Z-Code submission on claims), 01/24/2018 (clarified panel testing will be denied if one test does not meet criteria) , 01/23/2019 (annual review, no updates), 02/27/2019 (added information regarding cystic fibrosis testing in relation to pregnancy) 03/27/2019 (added language in relation to spinal muscular atrophy testing related to pregnancy)

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.

For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.