

Document ID#: 2107123
 Subject: Genetic Testing: General Policy for Tests not
 Specifically Listed in Separate Policies
 Effective Date: February 1, 2010

Clinical Documentation and Prior Authorization Required	√	Type of Review - Case Management	
Not Covered		Type of Review – Precertification Department	√
		Administrative Process (Internal Use Only)	LPN

Note: Background, product, and disclaimer information is located at the end of this document.

Overview

Genetic testing can provide information about a person’s genes and chromosomes. There are many types of genetic testing. Newborn screening just after birth identifies genetic disorders that can be treated early in life. Most state governments mandate coverage of several of these tests. Tufts Health Plan covers many of these tests without prior authorization.

Diagnostic testing identifies or rules out a specific genetic or chromosomal condition. In many cases, genetic testing confirms a diagnosis when a particular condition is suspected based on physical signs and symptoms. Diagnostic testing can be performed before birth or at any time during a person’s life, but is not available for all genes or all genetic conditions. The results of a diagnostic test can influence a person’s choices about health care and the management of the disorder.

Carrier testing is used to identify people who carry 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. If both parents are tested, the test can provide information about a couple’s risk of having a child with a genetic condition.

Prenatal testing detects changes in a fetus’s genes or chromosomes before birth. This type of testing is offered during pregnancy if there is an increased risk that the baby will have a genetic or chromosomal disorder.

Preimplantation testing, also called preimplantation genetic diagnosis (PGD), is a specialized technique to detect genetic changes in embryos that were created using assisted reproductive techniques, such as in-vitro fertilization.

Predictive and presymptomatic types of testing detects gene mutations associated with disorders that appear after birth, often later in life. These tests can be helpful to people who have a family member with a genetic disorder, but who have no features of the disorder themselves at the time of testing. Predictive testing can identify mutations that increase a person’s risk of developing disorders with a genetic basis, such as certain types of cancer. Presymptomatic testing can determine whether a person will develop a genetic disorder, before any signs or symptoms appear. The results of predictive and presymptomatic testing can provide information about a person’s risk of developing a specific disorder and help with making decisions about medical care.

Forensic testing uses DNA sequences to identify an individual for legal purposes. Unlike the tests described above, forensic testing is not used to detect gene mutations associated with disease. This type of testing can identify crime or catastrophe victims, rule out or implicate a crime suspect, or establish biological relationships between people (for example, paternity) (Genetics Home Reference, 2007).

Additional definitions:

- High Risk Group: individual with personal or family history of an autosomal dominant, autosomal recessive, X-linked recessive or X-linked dominant condition or an individual with a family history of a chromosomal abnormality including a chromosomal translocation or inversion.
- First Degree Relative: an individual's parents, siblings, and children.
- Second Degree Relatives: an individual's grandparents, aunts, uncles, half-siblings, nieces, nephews, and grandchildren.

Coverage Guidelines

Tufts Health Plan may authorize coverage for specific genetic testing, for a member, when the member meets ALL of the following criteria:

- The member falls within a high-risk group for a particular disease(s) based on personal history, family history, documentation of a genetic mutation, and/or ethnic background.
- Documentation is provided, including a pedigree and letter of medical necessity, from a licensed genetic counselor or MD with expertise in genetic counseling that supports the recommendation for testing based on a review of risk factors, clinical scenario, and family history.
- The results of the genetic test will significantly alter the medical management of the member and/or the member's current pregnancy.
- The testing method is considered a proven method for the identification of a specific genetically linked inheritable disease (i.e., the genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of a specific disease, and the observations must be independently replicated and subject to peer review).

Limitations

- Testing for the purposes of confirming a suspected diagnosis of a disorder that can be diagnosed based on clinical evaluations alone will not be covered.
- Testing for conditions which cannot be altered by treatment or prevented by specific interventions will not be covered.
- Testing solely for the purpose of informing the care or management of Member's family member(s) will not be covered.
- Testing must be performed at a contracting laboratory when available.

Codes

The following HCPCS/CPT code(s) require prior authorization:

Code	Description
S3840	DNA analysis for germline mutations of the RET proto-oncogene for susceptibility to multiple endocrine neoplasia type 2
S3842	Genetic testing for Von Hippel-Lindau disease
S3865	Comprehensive gene sequence analysis for hypertrophic cardiomyopathy

Code	Description
S3866	Genetic analysis for a specific gene mutation for hypertrophic cardiomyopathy (HCM) in an individual with a known HCM mutation in the family (Effective 4/1/09)
S3870	Comparative genomic hybridization (CGH) microarray testing for developmental delay, autism spectrum disorder and/or mental retardation (e.g., SingnatureChip [®])

References

1. U.S. National Library of Medicine. What are the types of genetic tests? Genetics Home Reference. Retrieved on January 25, 2007 from: <http://ghr.nlm.nih.gov/handbook/testing/uses>

Approval History

Reviewed by the Clinical Coverage Criteria Committee on February 1, 2007.

Subsequent Endorsement Date(s) and Changes Made:

- January 30, 2008: Comparative genomic hybridization through microarray analysis and Preimplantation Genetic Determination limitations were removed from this guideline.
- February 11, 2009 for an April 1, 2009 effective date: New codes added
- August 5, 2009 for a January 1, 2010 effective date: S3870 added to MNG
- February 1, 2010: Reviewed by Medical Policy Advisory Group Committee(MPAGC), no changes.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for Tufts Health Plan benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. Tufts Health Plan makes coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to all fully insured Tufts Health Plan products unless otherwise noted in this guideline or the Member's benefit document. This guideline does not apply to Tufts Health Plan Medicare Preferred or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. Providers in the New Hampshire service area are subject to CIGNA HealthCare's provider arrangement for the purpose of CareLinkSM.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of

benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.