

Corporate Medical Policy

Genetic Testing for Non-Malignant Inherited Disorders

File Name: genetic testing for non-malignant inherited disorders
Origination: 8/2011
Last CAP Review: Not applicable
Next CAP Review: 2/2012
Last Review: 8/2011

Description of Procedure or Service

Genetic testing is the analysis of DNA, genes or gene products to detect mutations predictive of inheritable disorders. Inherited gene mutations are thought to contribute to thousands of clinical conditions, including sickle cell anemia, Huntington's disease and cystic fibrosis. Gene testing can be classified as prenatal, diagnostic, pre-dispositional, pre-symptomatic or pharmacogenetic.

Genetic tests are performed using a sample of blood, hair, skin, amniotic fluid or other tissue. The results of a genetic test can validate the existence of or rule out a suspected genetic condition. Test results also help determine a person's risk of developing or passing on a genetic disorder. Genetic test results not only apply to the individual across his/her entire lifespan, but have implications to other family members as well.

Several hundred genetic tests are currently in use, and more are being developed. Although genetic testing can provide helpful information for diagnosing, treating and preventing illness, there are limitations. For example, in a healthy patient, a positive result from a genetic test doesn't always mean the patient will develop a disease. On the other hand, in some situations, a negative result doesn't guarantee the patient won't have a certain disorder.

Please refer to the BCBSNC medical policies indicated below for information regarding specific genetic testing for **non-malignant** clinical conditions:

Biochemical Markers For Alzheimer's Disease
Genetic Testing For Familial Alzheimer's Disease
Laboratory Tests For Heart Transplant Rejection
Pharmacogenetic Testing For Warfarin Dose
Genetic Testing For Long QT Syndrome
KIF6 Genotyping For Predicting Cardiovascular Risk
Genetic Testing For Lipoprotein a As A Decision For Aspirin Treatment
Genotyping For 9p21 To Predict Risk Of Cardiovascular Disease
Gene Expression Testing To Predict Cardiovascular Disease
Novel Lipid Factors In Prediction Of Cardiovascular Disease
Genetic Testing for Helicobacter pylori Treatment
Array Comparative Genomic Hybridization (aCGH) For Genetic Evaluation Of Developmental Delay/Autism Spectrum Disorder
Cytochrome P450 Genotyping
Genetic Testing for Predisposition to Inherited Hypertrophic Cardiomyopathy

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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Policy

BCBSNC will provide coverage for Genetic Testing for Non-Malignant Inherited Disorders when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Most BCBSNC benefit plans exclude coverage for genetic testing, except for high risk patients when the therapeutic or diagnostic course would be determined by the outcome of the testing. This exclusion would include genetic testing for forensic purposes or parental identification.

When Genetic Testing for Non-Malignant Inherited Disorders is covered

Genetic testing for non-malignant inherited disorders may be considered medically necessary when the following criteria are met:

1. The genetic disorder is associated with significant disability or has a lethal natural history; **AND**
2. The risk of the significant disability or lethality from the genetic disorder cannot be determined through other diagnostic testing, **AND**
3. A specific mutation, or set of mutations, has been proven valid in the scientific literature to be reliably associated with the disease; **AND**
4. The results of the genetic test could impact the medical management of the individual being tested; **AND**
5. The genetic test will likely result in an anticipated improvement in net health outcomes for the individual being tested; (i.e. the disease is treatable or preventable) **AND**
6. Testing is accompanied by genetic counseling **AND**
7. Proper informed consent is obtained.

When Genetic Testing for Non-Malignant Inherited Disorders is not covered

Genetic testing for individuals not meeting the above criteria is considered not medically necessary.

Whole genome sequencing in which an individual's entire DNA is sequenced is considered investigational.

Use of home testing kits is considered investigational.

Policy Guidelines

Clinical laboratories may develop and validate tests in-house and then market them as a laboratory service. Laboratories offering such tests must meet the regulatory standards of the Clinical

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Laboratory Improvement Act (CLIA) and must be licensed by CLIA for high-complexity testing. Additionally, laboratories should follow the College of American Pathology Guidelines.

Whole genome sequencing is a laboratory procedure to determine an individual's entire DNA sequence. Research is in progress to determine if whole genome sequencing can be used to not only accurately predict the development of a specific disease in asymptomatic individuals, but be used to either minimize the impact of or completely avoid the development of the disease. The role of whole genome sequencing in the clinical setting has yet to be established.

Due to ethical and psychological implications, genetic counseling is vital. Counseling should involve the guidance of a trained professional in the evaluation of family history (pedigree analysis), medical records, and genetic test results. Genetic counselors can explain the genetic risks or diagnoses and the treatment options that are available to the client.

Home test kits are genetic tests marketed directly to consumers, without the need for a physician order. Unfortunately, consumers who receive the results from these kits are left to interpret the results on their own without the benefit of genetic counseling. Additionally, some home kits purport to help consumers select an optimal diet, stop smoking, or maintain a youthful appearance. These claims lack sufficient scientific support to demonstrate their validity.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 81200, 81205, 81209, 81220, 81221, 81222, 81223, 81224, 81240, 81241, 81242, 81243, 81244, 81250, 81251, 81255, 81256, 81257, 81260, 81265, 81266, 81268, 81290, 81291, 81292, 81295, 81302, 81303, 81304, 81330, 81331, 81332, 81350, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 83890-83914, 88245-88249, 88261-88264, 88271-88275, 88280-88291, 88384-88386, 84999, 96040, S0265, S3842, S3844, S3845, S3846, S3849, S3850

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

National Institutes of Health (NIH). National Human Genome Research Institute. All About the Human Genome Project (HGP). Retrieved on July 18, 2011 from <http://www.genome.gov/10001772>

GeneTests: Medical Genetics Information Resource (database online). Copyright, University of Washington, Seattle. 1993-2011. Accessed July 27, 2011 from <http://www.genetests.org>

Centers for Disease Control and Prevention (CDC). Genetic Testing Policy. Accessed July 27, 2011 from <http://www.cdc.gov/dls/genetics/policy.aspx>

Policy Implementation/Update Information

8/16/11 New policy implemented. Genetic testing for non-malignant inherited disorders may be considered medically necessary when the following criteria are met: The genetic disorder is associated with significant disability or has a lethal natural history; **AND** The risk of the significant

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disability or lethality from the genetic disorder cannot be determined through other diagnostic testing, **AND** A specific mutation, or set of mutations, has been proven valid in the scientific literature to be reliably associated with the disease; **AND** The results of the genetic test could impact the medical management of the individual being tested; **AND** The genetic test will likely result in an anticipated improvement in net health outcomes for the individual being tested; (i.e. the disease is treatable or preventable) **AND** Testing is accompanied by genetic counseling **AND** Proper informed consent is obtained. Genetic testing for individuals not meeting the above criteria is considered not medically necessary. Whole genome sequencing in which an individual's entire DNA is sequenced is considered investigational. Use of home testing kits is considered investigational. Notice given 8/16/11 for effective date 11/22/11.(mco)

12/30/11 The following CPT codes added to the "Billing/Coding" section and will be effective 1/1/2012: 81200, 81205, 81209 , 81240, 81241, 81242, 81243, 81244, 81250, 81251, 81255, 81256, 81257, 81260,81265, 81266, 81268, 81290, 81291, 81302, 81303, 81304, 81330, 81332,81350, 81402, 81403, 81404, 81405, 81406, 81407, 81408 (mco)

1/24/12 Added new CPT code 81331 to "Billing/Coding" section. (mco)

3/6/12 Added codes 81220, 81221, 81222, 81223, 81224, 96040, S0265 to the "Billing/Coding" section. Added a reference to the following policy in the "Description" section: "Genetic Testing for Predisposition to Inherited Hypertrophic Cardiomyopathy." (mco)

3/30/12 Deleted the following codes from the "Billing/Coding" section: S3828, S3829, S3835, S3837, S3843, S3847, S3848, and S3851. Added the following codes to the "Billing/Coding" section: 81292, 81295. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.