Medical Coverage Policy

Genetic Testing

☐ Device/Equipment ☐ Drug ☐ Medical ☐ Surgery ☒ Test ☐ Other

Effective Date:	6/15/2007	Policy Last Updated:	12/18/2012

☒ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☐ **Prospective review is not required.**

Description:
Medical tests which are used to identify changes in chromosomes, genes, RNA or DNA sequencing are called genetic tests. Genetic testing is a technique used to identify people at risk for a specific genetic disease, predict the possibility of future genetic disease, or to determine the risk for transmitting such a disease to their offspring. Testing may also be used as part of the process to identify, confirm, or predict the possibility of a specific medical condition and develop a treatment plan. Hundreds of genetic tests are currently being used.

Types of genetic tests and genetic diagnostics:

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. If both parents are tested, the test can provide information about a couple's risk of a having a child with a genetic condition.

Genetic screening: Genetic screening is used to identify individuals who do not currently exhibit signs or symptoms but might have an increased risk of developing or transmitting a specific genetic disorder. Screening is different from testing for in screening there is no current evidence or manifestation of a genetic disease.

Preimplantation Genetic Diagnosis: Preimplantation genetic diagnosis (PGD) is a technique used to detect specific genetic disorders using molecular analysis on single cells removed from an embryo prior to implantation in the uterus.

Prenatal diagnosis: Prenatal testing (e.g. prenatal blood testing) is used to identify disorders such as Down's syndrome, spina bifida, cystic fibrosis or Tay-Sachs disease.

Genetic Screening Panels: Genetic Screening Panels are genetic tests that screen for multiple conditions such as the Ashkenazi Jewish Panel.

Definitions:

Diagnostic or Confirmatory testing: Tests used to identify or confirm diagnosis of disease. As a confirmatory diagnosis, these tests are helpful in developing a treatment plan. Genetic testing may also be used to specify disease characteristics that affect therapeutic decision making including family planning.

Direct Risk: Direct risk is defined as documentation in the family history of a disorder involving an autosomal dominant inheritance that has been demonstrated in either the mother or father or evidence of a disorder inherited in an autosomal recessive or X-linked recessive manner with supporting documentation suggesting a family history of the suspected disorder.

Family: For the purpose of this policy a family is defined as:

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

Population Based screening: Population based screening is defined as a test offered systematically to all individuals in a defined target group within a framework of agreed policy, protocols, quality management, monitoring, and evaluation.

Preventable: Preventable diseases could possibly not been acquired if a specific action had been taken to stop it.

Prior to testing, we strongly urge all members to have genetic counseling to review their risk, to discuss possible findings from screening, and to discuss the relevance of these findings to the management of their health care. Documentation reported in the family history is advised.

Medical Criteria:

Genetic testing is considered medically necessary to establish a molecular diagnosis of an inheritable disease when all of the following are met:

- The member displays clinical features; and
- The genetic disorder is associated with a potentially significant disability or has a lethal natural history; and
- After history, physical examination, pedigree analysis, genetic counseling and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain; and
- The results of the test will be used specifically for diagnosis; and
- The disease is treatable or preventable; and
- The result of the test will directly influence the treatment being delivered to the patient, including increasing the intensity of surveillance/treatment of that disease including family planning; and
- The providing laboratory must be approved by the FDA or other governmental agencies; and
- Peer reviewed literature is available that provides evidence for the indications and performance of the test or the indication for the test is in accordance with the guidelines of the American College of Medical Genetics

Genetic Screening is considered medically necessary when all of the following are met:

- To determine if he member is at direct risk of inheriting the mutation in question; and
- The genetic disorder is associated with a potentially significant disability or has a lethal natural history; and
- A specific mutation, or set of mutations has been established in the scientific literature to be reliably associated with the disease; and
- The results of the test will be used specifically for diagnosis or the result of the test will directly influence the treatment being delivered to the patient, including increasing the intensity of surveillance/treatment of that disease or have an impact on family planning; and
- The providing laboratory must be approved by the FDA or other governmental agencies; and
- Peer-reviewed literature is available that provides evidence for the indications and performance of the test or the indication for the test is in accordance with the guidelines of the American College of Medical Genetics.

Carrier Testing is considered medically necessary when all of the following are met:

- To determine if the member is at direct risk of transmitting the mutation in question to their offspring; and
- The genetic disorder is associated with a potentially significant disability or has a lethal natural history; and
- A specific mutation, or set of mutations has been established in the scientific literature to be reliably associated with the disease; and
- The results of the test will have an impact on family planning; and
- The providing laboratory must be approved by the FDA or other governmental agencies; and
- Peer reviewed literature is available that provides evidence for the indications and performance of the test or the indication for the test is in accordance with the guidelines of the American College of Medical Genetics.

Medicare excludes all screening (not just genetic screening) with certain statutory exceptions. Blue CHiP for Medicare provides no additional benefits for genetic screening. Only if the patient exhibits signs or symptoms of the disease would the test not be considered screening. For all other members, genetic testing is considered covered ONLY as listed in our policies.

Medical Policy:
When a specific genetic testing policy is not available, genetic testing/screening is considered medically necessary for all products except BC for Medicare if the above criteria are met.

Population and Genetic Screening Panels:
Population and genetic screening panels are considered genetic screening and should be evaluated according to the screening criteria above, except as required per state or federal mandates.

Note: This policy does not include newborn or preimplantation genetic diagnosis testing. Please refer to the following medical policies for additional information on these topics:

- Newborn Metabolic, Endocrine, and Hemoglobinopathy, and the Newborn Hearing Loss Screening Programs Mandate
- Preimplantation Genetic Diagnosis (PGD)

This policy should only be used in the absence of a medical policy. Listed below are our current genetic policies:

- Assays of Genetic Expression to Determine Prognosis of Breast Cancer (e.g. Oncotype DX)--PREAUTH
- Genetic Counseling
- Genetic Testing: Alzheimer's Disease
- Genetic Testing: Congenital Long QT Syndrome
- Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer
- Genetic Testing for Helicobacter pylori Treatment
- Genetic Testing: Hereditary Hemochromatosis - PREAUTH
- Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
- Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
- Genetic Testing for Initial Warfarin Dose
- Genetic Testing: Noninvasive Prenatal Test for Trisomy 21
- Genetic Testing: Rett Syndrome - PREAUTH
- Immunoassay for Tumor Antigens (Tumor Markers)

- Newborn Metabolic, Endocrine, and Hemoglobinopathy, and the Newborn Hearing Loss Screening Programs Mandate
- Preimplantation Genetic Diagnosis (PGD)

Coverage:
Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable genetic testing coverage/benefits. Please see individual policies (below) as some may require prior authorization for BlueCHiP for Medicare and may be recommended for all other lines of business.

Coding:
Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable genetic testing coverage/benefits. Please see individual policies (below) as some may require prior authorization for BlueCHiP for Medicare and may be recommended for all other lines of business.

Note: Additional policies will be added to these lists soon.

Code	*Related Medical Policy (if available)*
81200	
81201	Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
81202	Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
81203	Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
81211	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81212	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81213	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81214	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81215	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81216	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81217	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81220	
81225	Genetic Testing for Helicobacter pylori Treatment
81228	
81243	
81244	
81252	
81253	
81254	
81256	
81280	Genetic Testing: Congenital Long QT Syndrome
81281	Genetic Testing: Congenital Long QT Syndrome
81282	Genetic Testing: Congenital Long QT Syndrome
81240	
81241	
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81321	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81322	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81323	Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
81324	
81325	
81326	
81331	
81355	Genetic Testing for Initial Warfarin Dose
81401	Genetic Testing: Alzheimer's Disease
83890	Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer
83892	

83894 Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer;
83898 Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer;
83902
83903 Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer
83904 Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer
83905 Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer
83906 Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer

83912 Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer
86316
86305
89290 Preimplantation Genetic Diagnosis (PGD)
89291 Preimplantation Genetic Diagnosis (PGD)
92235
92240

HCPCS Codes:

G9143-
Q0
G9143
S3721
S3818 Genetic Testing: Inherited BRCA1 or BRCA2 Mutations
S3828 Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
S3829 Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
S3830 Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
S3831 Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
S3833 Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
S3834 Genetic Testing: Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability-PREAUTH
S3840 Genetic Testing for Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer
S3852 Genetic Testing: Alzheimer's Disease
S3855 Genetic Testing: Alzheimer's Disease
S3854 Assays of Genetic Expression to Determine Prognosis of Breast Cancer (e.g. Oncotype DX)--PREAUTH
S3861 Genetic Testing: Congenital Long QT Syndrome

Also known as:
Not applicable

Published:
Provider Update, March 2013
Provider Update, November 2009
Provider Update, October 2008
Policy Update, January 2008
Policy Update, August 2006

policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.