Medical Coverage Policy

Genetic Testing

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

Effective Date:	6/15/2007	Policy Last Updated:	6/18/2013

☒ **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 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

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.

Note: Per CMS policy, Jurisdiction of payment and coverage requests for laboratory services furnished by an independent laboratory, lies within the area in which the laboratory test is performed.- Example ,Laboratory that performs the test is in California. The LCD for California region is used

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
- Preimplantation Genetic Diagnosis

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

- Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis In Patients With Breast Cancer
- Array Comparative Genomic Hybridization (aCGH) for the Genetic Evaluation of Patients with Developmental Delay/Mental Retardation or Autism Spectrum Disorder
- Genetic Testing: Alzheimer's Disease
- Genetic Testing: Congenital Long QT Syndrome
- Genetic Testing: FMR1 mutations (including Fragile X Syndrome)
- Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
- Genetic Testing: Helicobacter pylori Treatment
- Genetic Testing: Hereditary Hemochromatosis
- Genetic Testing: Initial Warfarin Dose
- Genetic Testing: Rett Syndrome
- Genetic Testing for Assays of Genetic Expression to Determine Prognosis of Breast Cancer
- Genetic Testing for Hereditary Breast and Ovarian Cancer
- Genetic Testing for Cytochrome p450 Genotyping
- Genetic Testing to Determine Trisomy 21 from Maternal Plasma DNA
- Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer
- Genetic Counseling
- Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
- Genetic Testing: Epidermal Growth Factor Receptor (EGFR) Mutation Analysis for Patients with Non-Small Cell Lung Cancer (NSCLC)
- Genetic Testing: Multi-Gene Expression Assay for Predicting Recurrence in Colon Cancer

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:

Code	*Related Medical Policy (if available)*
81161	
81200	Germline Mutations of the RET Protooncogene in Medullary Thyroid Cancer
81201	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81202	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81203	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81205	
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81211	Genetic Testing for Hereditary Breast and Ovarian Cancer
81212	Genetic Testing for Hereditary Breast and Ovarian Cancer
81213	Genetic Testing for Hereditary Breast and Ovarian Cancer
81214	Genetic Testing for Hereditary Breast and Ovarian Cancer
81215	Genetic Testing for Hereditary Breast and Ovarian Cancer
81216	Genetic Testing for Hereditary Breast and Ovarian Cancer
81217	Genetic Testing for Hereditary Breast and Ovarian Cancer
81220	
81221	
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81225	Genetic Testing: Helicobacter pylori Treatment
81228	Array Comparative Genomic Hybridization (aCGH) for the Genetic Evaluation of Patients with Developmental Delay/Mental Retardation or Autism Spectrum Disorder
81240	
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81243	Genetic Testing: FMR1 mutations (including Fragile X Syndrome)
81244	Genetic Testing: FMR1 mutations (including Fragile X Syndrome)
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81256	Genetic Testing: Hereditary Hemochromatosis
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81280	Genetic Testing: Congenital Long QT Syndrome
81281	Genetic Testing: Congenital Long QT Syndrome
81282	Genetic Testing: Congenital Long QT Syndrome
81290	
81291	
81292	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81293	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81294	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81295	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81296	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81297	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81298	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81299	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81300	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81301	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81302	Genetic Testing: Rett Syndrome
81303	Genetic Testing: Rett Syndrome
81304	Genetic Testing: Rett Syndrome
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81315	
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81317	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81318	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
81319	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
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81355	Genetic Testing: Initial Warfarin Dose
81401	Genetic Testing: Alzheimer's Disease
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83890	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
83892	
83894	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
83898	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
83902	
83903	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
83904	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
83905	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
83906	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
83912	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
86316	
86305	
89290	Preimplantation Genetic Diagnosis
89291	Preimplantation Genetic Diagnosis
92235	
92240	

HCPCS Codes:

G9143-Q0	Genetic Testing: Initial Warfarin Dose
G9143	Genetic Testing: Initial Warfarin Dose
S3721	Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer
S3818	
S3828	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
S3829	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
S3830	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
S3831	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
S3833	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
S3834	Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
S3840	Genetic Testing: Germline Mutations of the RET Protooncogene in Medullary Carcinoma of the Thyroid
S3852	Genetic Testing: Alzheimer's Disease
S3855	Genetic Testing: Alzheimer's Disease
S3854	Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis In Patients With Breast Cancer
S3861	Genetic Testing: Congenital Long QT Syndrome

Also known as:
None

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

History:
June 2013 - stacking codes added

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