



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject Genetic Counseling

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- Down Syndrome Screening
- Genetic Testing for Canavan Disease
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- Genetic Testing for Cystic Fibrosis
- Genetic Testing for Factor V Leiden Thrombophilia
- Genetic Testing for Gaucher Disease
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- Genetic Testing of Heritable Disorders
- Genetic Testing for Long QT Syndrome (LQTS)
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- Genetic Testing for Susceptibility to Breast and Ovarian Cancer (BRCA1 & BRCA2)
- Genetic Testing for Susceptibility to Colorectal Cancer
- Genetic Testing for Tay-Sachs Disease
- Genetic Testing for von Hippel-Lindau Disease
- Preimplantation Genetic Diagnosis

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Coverage for genetic counseling is dependent on benefit plan language. Many benefit plans limit coverage of genetic counseling to three (3) visits per contract year for both pre and post genetic testing. Please refer to the applicable benefit plan language to determine benefit availability and terms, conditions and limitations of coverage.

If coverage is available for genetic counseling, the following conditions of coverage apply.

CIGNA covers pre- and post-test genetic counseling with a physician or a licensed or certified genetic counselor as medically necessary for an individual recommended for covered heritable genetic testing.

General Background

Genetic counseling services span the life cycle from preconception counseling to infertility evaluation, prenatal genetic screening and diagnosis, and include predisposition evaluation and genetic diagnosis for a growing number of adult onset conditions (Edwards, 2010). A genetics consultation involves evaluation of an individual or family for one or more of the following:

- confirming, diagnosing or ruling out a heritable genetic condition
- identifying medical management issues
- calculating and communicating genetic risks
- providing or arranging for psychosocial support

The National Society of Genetic Counselors defines genetic counseling as “The process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease. This process integrates:

- interpretation of family and medical histories to assess the chance of disease occurrence or recurrence.
- education about inheritance, testing, management, prevention, resources and research.
- counseling to promote informed choices and adaptation to the risk or condition.”

The National Cancer Institute ([NCI], 2010) notes “Central to the philosophy and practice of genetic counseling are the principles of voluntary utilization of services, informed decision making, attention to psychosocial and affective dimensions of coping with genetic risk, and protection of patient confidentiality and privacy. This is facilitated through a combination of rapport building and information gathering; establishing or verifying diagnoses; risk assessment and calculation of quantitative occurrence/recurrence risks; education and informed consent processes; psychosocial assessment, support, and counseling appropriate to a family’s culture and ethnicity; and other relevant background characteristics.”

Certification of individuals in the field of genetics and genetic counseling is primarily the responsibility of two organizations. The American Board of Medical Genetics (ABMG) certifies an individual who has an earned doctoral degree in the area of clinical genetics, medical genetics, clinical biochemical genetics, clinical cytogenetics or clinical molecular genetics, and who has completed required clinical training. The ABMG also accredits training programs in the field of human genetics. These individuals conduct physical examinations, make diagnoses of genetic disorders, manage the clinical care of these disorders, and contribute to the counseling and education of the patient and family. The clinical geneticist also serves as a resource person for other health care providers, and provides more detailed basic science and medical knowledge on a case-by-case basis.

The American Board of Genetic Counseling, Inc. (ABGC) certifies an individual who has completed an accredited graduate-level (i.e., Master’s degree) course of study in genetics and requisite clinical training. The ABGC also provides accreditation of genetics training programs. Diplomates of this Board hold the Certified Genetics Counselor® designation. Data indicate that there are greater than 3000 certified genetic counselors (ABGC, 2011). Licensure for genetic counselors is currently required in only a few states. The National Society of Genetic Counselors (NSGC) is a professional society representing genetic counselors.

In 1969, the World Health Organization Expert Committee on Genetic Counseling endorsed the nondirective approach to genetic counseling, an attitudinal strategy that has become universally accepted by all professionals providing genetic counseling services. The counselor makes clear from the onset that the process is educational and that no decisions will be made for the patient. The counselor tries to remain impartial and objective in providing information that will allow patients to make their own rational decisions commensurate with their private concerns and desires, although complete nondirective counseling is probably unrealistic.

The mainstay of any counseling session is the ability to obtain accurate family information from the collection of a thorough and accurate pedigree. The medical information gathered for purposes of genetic counseling may be historical or as a result of a recently performed physical exam or laboratory procedure.

Good genetic advice requires certainty of diagnosis. Even the best counseling cannot compensate for an inaccurate diagnosis. In addition to taking a detailed family history, the practitioner should examine the proband, as well as other family members at risk. If the proband is no longer living, the appropriate medical records should be obtained and reviewed. The possibility of nonpaternity must also be considered. Laboratory studies needed to establish the diagnosis may include chromosome analysis, deoxyribonucleic acid (DNA) studies, or biochemical tests of blood, urine or cultured cells. Improved techniques now permit DNA analysis of archival specimens (e.g., paraffin-embedded tissue blocks) in some cases. Because nongenetic factors can mimic genetic factors in the production of disease (i.e., phenocopies), an accurate history and various clinical and laboratory studies may help resolve questionable cases. Laboratory genetic testing is available for an increasing number of diseases, and locating a laboratory to perform the test is necessary (Agan, 2002).

Mendelian inheritance patterns, multifactorial disease estimates, gonadal mosaicism and Bayesian analysis are available methods that allow counselors to refine disease or recurrence risk estimates. Implicit in each of these is a general knowledge of the inheritance pattern of the disease or disorder in question (Plunkett, 2002).

A number of heritable conditions are addressed in related Coverage Policies (please see related Coverage Policy section). If genetic testing is covered, genetic counseling may be appropriate for the following heritable conditions including, but not limited to:

Condition
Susceptibility to breast and ovarian cancer
Canavan disease
Cystic fibrosis
Congenital profound deafness
Colorectal cancer: <ul style="list-style-type: none"> • Familial adenomatous polyposis (FAP); includes Gardner syndrome, Turcot syndrome • Attenuated familial adenomatous polyposis (AFAP) • Hereditary nonpolyposis colorectal cancer (HNPCC)/Lynch syndrome; includes Muir-Torre syndrome • MYH-associated polyposis (MAP)
Down syndrome
Factor V Leiden thrombophilia
Fragile X syndrome
Gaucher disease
Hemochromatosis
Hemoglobinopathies: <ul style="list-style-type: none"> • Alpha-thalassemia • E beta-thalassemia • Sickle cell
Long QT syndrome

Mitochondrial disorders: <ul style="list-style-type: none"> • Kearns-Sayre syndrome (KSS) • Pearsons syndrome • Progressive external ophthalmoplegia (PEO) • Neurogenic muscle weakness, ataxia, and retinitis pigmentosa (NARP) • Leigh syndrome (LS) • Leber hereditary optic neuropathy (LHON) • Mitochondrial encephalomyopathy with lactic acidosis and stroke-like episodes (MELAS) • Myoclonic epilepsy with ragged-red fibers (MERRF)
Myotonic dystrophy
Neimann-Pick disease
Retinoblastoma
RET proto-oncogene germline testing for medullary thyroid carcinoma: <ul style="list-style-type: none"> • Multiple endocrine neoplasia type 2A (MEN2A); includes Sipple syndrome • Multiple endocrine neoplasia type 2B (MEN2B); includes mucosal neuroma syndrome • Familial medullary thyroid carcinoma (FMTC)
Rhett's disorder
Tay-Sachs disease and variants (e.g., Sandoff disease)
Thiopurine Methyltransferase (TPMT) for the management of inflammatory bowel disease
von Hippel-Lindau syndrome

Pretest counseling precedes genetic testing. The genetic counselor interviews the patient, assembling a large amount of information about family medical history, ethnicity, the patient's concerns and expectations of genetic testing, and potential future consequences.

Pretest counseling involves the following:

- construction of a family history and pedigree showing all medical problems
- analysis of the family history for potentially inherited and congenital diseases
- verification of the family history (often a process that is pursued after the first counseling session by contacting relatives and obtaining medical records)
- assessment and interpretation of the risk for occurrence (or recurrence) of genetic conditions in the family
- discussion of the nature of the conditions, including the contribution of heredity
- discussion of the options available to reduce risks, including available testing; sometimes this involves planning which family member should be tested first to give the most informative results
- brief discussion of the meaning of various possible results of genetic testing
- presentation of risks and benefits of each option, with careful attention to patient comprehension
- assistance in selecting the option most appropriate for the person consulting, with consideration for the family
- provision of supportive or psychological counseling or referral to community resources, when appropriate
- coordination of testing, when indicated
- composition of a summary letter to the patient or referring physician which documents the counseling session and outlines the plan of care

Post-test counseling involves providing the results of genetic testing to the person tested. The counselor presents a full explanation of test results and implications for further testing and management. Information is discussed regarding the implications for family members. Finally, post-test counseling involves emotional support, including referral to mental health professionals, when indicated, and often to condition-specific advocacy and self-help groups. Generally, the role of the consulting genetic counselor ends at this post-test session, although individuals can arrange follow-up visits as new questions arise or as more family members request information about the implications of the tests (Plunkett, 2002).

When the family history or other clinical information indicates further genetic assessment, the clinician and patient can discuss whether pursuing it makes sense at that time. Clinical utility is defined as the usefulness of a particular test in a specific clinical situation. The patient, test, and intrinsic disease factors drive clinical utility. Tests of high clinical utility are likely to be of more benefit for patients. Conversely, tests of lower clinical utility may be of no clinical value or may be harmful to patients. Characteristics of tests with higher clinical utility include the following (Martin, 2004):

- The test has high predictive power.
- The disease in question has highly effective and acceptable presymptomatic intervention.
- The pretest probability for detecting a disease-causing mutation is fairly high.
- The pretest probability increases based on the following familial factors:
 - high number of affected individuals
 - multiple generations affected
 - disease characterized by early age at diagnosis
 - recognized clustering of findings associated with the genetic disease (e.g., ovarian and breast cancers for breast cancer risk antigen (BRCA) mutations; uterine and colon cancers for hereditary non-polyposis colorectal cancer [HNPCC])
 - ethnicity in which the prevalence for genetic disease is increased
 - high perceived usefulness of the test to the patient and family

Genetic counseling sessions do not include any testing or procedures that the patient does not explicitly consent to, such as prescriptions, specific medical recommendations, or long-term psychological care.

Professional Societies/Organizations

American College of Medical Genetics (ACMG): On behalf of the ACMG, Williams et al. (2001) noted, “Genetic counseling is the process of explaining medical and scientific information about an inherited condition or birth defect to an individual or family. The goal of genetic counseling is for families and individuals to understand the information, participate in decision-making about their medical care, and be able to manage the associated problems in a way that is best for them and their families. Genetic counselors are health care professionals who have completed training in an accredited Masters degree program and have passed the certification examination administered by the American Board of Genetic Counseling. Genetic Counselors are trained to:

- Review family histories and medical records
- Discuss genetic conditions and how they are inherited
- Explain inheritance patterns
- Perform genetic risk assessments
- Review available testing options
- Discuss disease management, treatment and surveillance options
- Explore the impact of genetic disorders on both affected and unaffected family members and assist families and individuals as they adjust to the diagnosis

Most genetic counselors work in conjunction with a medical geneticist or as part of a department, program, or institution. They play a crucial role in health care delivery, particularly in the areas of prenatal diagnosis and cancer genetics.”

National Cancer Institute (NCI, 2010): The NCI notes, “The goal of genetic education and counseling is to help individuals understand their personal risk status, their options for cancer risk management, and to explore feelings regarding their personal risk status. Counseling focuses on obtaining and giving information, promoting autonomous decision-making, and facilitating informed consent if genetic testing is pursued.”

Summary

A genetics consultation involves evaluation of an individual or family for one or more of the following: confirming, diagnosing or ruling out a heritable genetic condition identifying medical management issues calculating and communicating genetic risks and providing or arranging for psychosocial support. Trained genetic practitioners include medical geneticists, genetic counselors and genetic nurses.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary only when coverage is available for genetic counseling. Many plans limit genetic counseling to three (3) visits per contract year for both pre and post genetic testing.

CPT®* Codes	Description
96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family

HCPCS Codes	Description
S0265	Genetic counseling, under physician supervision, each 15 minutes

ICD-9-CM Diagnosis Codes	Description
153.0 – 153.9	Malignant neoplasm of colon
154.0 – 154.8	Malignant neoplasm of rectum, rectosigmoid junction, and anus
182.0	Malignant neoplasm of body of uterus, Corpus uteri, except isthmus
190.5	Malignant neoplasm of retina
193	Malignant neoplasm of thyroid gland
211.3	Benign neoplasm of other parts of digestive system, colon
238.72	Progressive external ophthalmoplegia
258.02	Multiple endocrine neoplasia [MEN] type IIB
272.0	Pure hypercholesterolemia
272.7	Lipidosis
275.01	Hereditary hemochromatosis
277.87	Disorders of mitochondrial metabolism
277.00	Cystic fibrosis without mention of meconium ileus
277.01	Cystic fibrosis with mention of meconium ileus
277.02	Cystic fibrosis with pulmonary manifestations
277.03	Cystic fibrosis with gastrointestinal manifestations
277.09	Cystic fibrosis with other manifestations
282.41-282.49	Thalassemias
282.5	Sickle cell trait
282.60-282.69	Sickle cell disease
282.7	Other hemoglobinopathies
287.0	Allergic purpura
289.81	Primary hypercoagulable state
330.0	Leukodystrophy
330.1	Cerebral lipodosis
330.8	Other specified cerebral degenerations in childhood
359.21	Myotonic muscular dystrophy
359.29	Other specified myotonic disorder
377.16	Hereditary optic atrophy
389.10	Unspecified sensorineural hearing loss
389.18	Sensorineural hearing loss, bilateral
389.7	Deaf, nonspeaking, not elsewhere classifiable
426.82	Long QT syndrome
671.50-671.54	Other phlebitis and thrombosis in pregnancy and the puerperium

758.0	Down syndrome
759.6	Other hamartoses, not elsewhere classified
759.83	Fragile X syndrome
V18.51	Family history of colonic polyps
V18.9	Family history of genetic disease carrier
V19.1	Family history of other conditions; Other eye disorders
V19.2	Family history of other conditions; Deafness or hearing loss
V26.33	Genetic counseling
V84.01	Genetic susceptibility to malignant neoplasm of breast
V84.02	Genetic susceptibility to malignant neoplasm of ovary
V84.09	Genetic susceptibility to other malignant neoplasm

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2007	0297	Genetic Counseling
Great-West Healthcare	2/20/2007	05.271.02	Genetic Testing, Coverage Guidelines

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