



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.

Subject Genetic Testing For Cystic Fibrosis

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Genetic Counseling
Genetic Testing of Heritable Disorders
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Coverage Policy

CIGNA covers genetic testing for cystic fibrosis (CF) using the American College of Medical Genetics (ACMG) mutation core panel as medically necessary for ANY of the following indications:

- Confirmation of a diagnosis in ANY of the following situations:
 - Individual who exhibits symptoms of CF but has a negative sweat test
 - infant with meconium ileus or other symptoms indicative of CF who is too young to produce adequate volumes of sweat for a sweat chloride test
 - infant with an elevated immunoreactive trypsinogen (IRT) value on newborn screening
 - male with congenital bilateral absence of vas deferens (CBAVD)
- Preconception or prenatal genetic testing to determine carrier status of an individual who is pregnant or a prospective biologic parent with the capacity and desire to reproduce
- Prenatal testing of a fetus (i.e., amniocentesis or chorionic villus sampling [CVS]) or preimplantation genetic diagnosis (PGD) in EITHER of the following situations:
 - embryo or at-risk fetus when either parent has a diagnosis of CF, is a known carrier of a cystic fibrosis transmembrane regulator (CFTR) mutation, or has a family history of CF
 - fetus when fetal echogenic bowel has been identified on ultrasound

All individuals undergoing genetic testing for any reason should have both pre- and post-test genetic counseling with a physician or a licensed or certified genetic counselor.

CIGNA does not cover genetic testing for CF for ANY the following indications because it is not medically necessary (this list may not be all-inclusive):

- carrier screening in the general population
 - routine genetic mutation screening in a newborn
 - testing using extended mutation panels (i.e., mutation panels that extend beyond the standard mutation panel recommended by the ACMG)
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General Background

Cystic fibrosis (CF) is a chronic, progressive, genetic disorder in which defective chloride transport across cell membranes causes dehydrated secretions. The dehydration may cause abnormally high sweat chloride levels and lead to thick, tenacious mucus in the lungs, pancreas, liver, reproductive organs, and/or intestines. Manifestations of CF include congenital bilateral absence of the vas deferens (CBAVD), neonatal meconium ileus, chronic sinusitis, nasal polyps, liver disease, and pancreatitis (Moskowitz, et al., 2008; Grosse, et al., 2004; Richards, et al., 2002).

The presence of CF may be suspected or diagnosed based on clinical presentation and/or family history and is identified in 70% of patients by age two years. The sweat test (i.e., sweat electrolytes, iontophoretic sweat test) is the established, standard test for CF. A sweat chloride level of > 60 milliequivalents per liter (mEq/L) is considered diagnostic for the disease. Other diagnostic studies include the measurement of the level of immunoreactive trypsinogen (IRT), an enzyme produced by the pancreas, and DNA analysis for cystic fibrosis transmembrane regulator (CFTR) mutations. Newborn screening for CF consists of multiple protocols and algorithms and varies from state to state (Moskowitz, et al., 2008; Grosse, et al., 2004).

Genetic Testing of the Cystic Fibrosis Transmembrane Regulator (CFTR) Gene

To date, over 1500 CFTR mutations have been identified; however, the vast majority of mutations are at a frequency of < 0.1% in the CF population. The most prevalent mutation, delta (Δ) F508, is responsible for 80% of CF mutations in Caucasians of Northern European descent and is considered the most severe form in terms of clinical presentation. The presence of two CF-causing mutations in the CFTR gene is considered diagnostic for the disease (Goetzinger and Cahill, 2010; Farrell, et al., 2008; Langfelder-Schwind, et al., 2005; Grosse, et al., 2004; Richards, et al., 2002).

Genetic testing may be indicated to confirm a diagnosis of CF in infants with an elevated immunoreactive trypsinogen (IRT) value on newborn screening or infants with meconium ileus or other CF symptoms but are too young to produce adequate volumes of sweat for a sweat chloride test. CF testing may also be necessary in males with congenital bilateral absence of vas deferens (CBAVD) and individuals exhibiting symptoms of CF but have a negative sweat test.

Carrier screening is recommended in a subset of individuals to aid in the identification of autosomal recessive family members who themselves do not have CF but are at risk for producing affected children. The test is offered to patients of reproductive age who have the capacity and intend to have children or who are pregnant. The results of the test may assist couples in making informed reproductive choices and/or aid in the diagnosis of fetal abnormalities. With autosomal recessive disorders such as CF, the risk of having an affected child is 25% for each pregnancy when both parents are carriers. The sensitivity of CF testing varies from 49%–97% based on the ethnicity of the individual being tested (Goetzinger and Cahill, 2010; Farrell, et al., 2008; Moskowitz, et al., 2008; Langfelder-Schwind, et al., 2005; Grosse, et al., 2004; Richards, et al., 2002).

Genetic testing may be indicated for prenatal analysis of embryos, at risk-fetuses, or for pre-implantation genetic diagnosis (PGD). When either parent has a diagnosis of CF, is a known carrier of a CFTR mutation, or has a family history of CF, testing is warranted. A diagnosis of echogenic bowel seen on fetal ultrasound is also an indication for testing. (For additional information on PGD, please refer to the Coverage Policy on Pre-Implantation Genetic Diagnosis.)

Routine genetic screening for CF mutations in all newborns is generally not recommended. Screening of healthy infants with no known history of familial CF may be associated with false positives affecting the infant-parent relationship, give false reassurance from negative tests delaying treatment in CF infants, or cause needless treatment to be given to infants with mild disease who would otherwise not have required treatment. Southern, et al. (2009) conducted a systematic review of randomized and quasi-randomized trials to determine if newborn screening for CF improved clinical outcomes, quality of life, and survival. Two trials involving 1,124,483 neonates (210 with CF) met inclusion criteria. Follow-ups ranged from one to 16 years. The trials compared newborn screening (n=552,354) to clinical diagnosis (572,129). Due to the varying study designs, various outcomes and summary measures, only data from one study were analyzed. Severe malnutrition was less common among screened babies and the screened babies had better diagnostic chest radiograph scores. However, the scores worsened over time and the screened babies became colonized with *Pseudomonas aeruginosa* earlier than the control babies.

Mutation Panels

In an effort to standardize the laboratory approach to screening, the Subcommittee on Cystic Fibrosis Screening, American College of Medical Genetics (ACMG) and American College of Obstetricians and Gynecologists (ACOG) recommended the use of a pan-ethnic panel that included all mutations with an allele frequency $\geq 0.1\%$ in the general United States (U.S.) population. Initially, 25 mutations were included in the standard core mutation analysis of the CFTR gene. This panel was predicted to identify about 97% of mutations in Ashkenazi Jewish individuals, 80% in European Caucasians, 69% in African Americans, and 57% in Hispanic Americans (Grody, et al., 2001). A 2004 update to the ACMG cystic fibrosis carrier screening statement recommended no additions and two deletions (I148T, 1078delT) to the initial panel of mutations and variants. The ACMG mutation panel is considered the standard testing for population-based carrier testing and is performed in Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories. As such, the test does not require FDA approval (Moskowitz, et al., 2008; ACOG, 2005; ACMG, 2004; Gregg, 2002; Richards, et al., 2002).

Strom et al. (2010) retrospectively reviewed 2,975,649 CF screening tests, 1310 prenatal diagnostic tests, and 2400 CF sequencing analyses to compare the performance of the ACMG 23-mutation panel to an expanded mutation panel. A total of 87,776 mutations were detected and 98.4% were in the core ACMG panel. Mutations identified by the ACMG panel represented an 84% detection rate of CF carriers in US pan-ethnic population. A combined frequency of 1:25 individuals self-identified as white or Ashkenazi Jewish represented close to 100% of carriers. Of 62 newborns with positive sweat tests and IRTs, only two would have been identified using an expanded mutation panel. In 250 sequencing analyses of patients with known CF, a single rare variant was not detected more than three times, indicating that "there are no frequent founder mutations in the US population not represented on the ACMG core panel that should be added to the current panel." The authors stated that no changes in the core ACMG panel or its use were indicated.

Extended Mutation Panels

Because of the ethnic diversity in the U.S. population, the use of extended panels to test for additional mutations has been proposed. Proponents of extended panels contend that the ACMG 23-mutation panel may miss certain CF carriers who possess rarer mutations, especially in African American and Hispanic individuals. These larger panels include testing for the 23-ACMG panel plus various numbers of additional mutations (e.g., 16 additional mutations) up to testing the full-length CFTR gene sequence (i.e., > 1500 mutations).

The specific circumstances under which extended CF mutation panels should be employed, and which additional mutations should be analyzed for which specific individuals have not been established. There are limited data on the penetrance of the rarer mutations and the impact on health outcomes. The clinical utility of extended mutation panels, including full-length CFTR gene sequencing, has not been established. The ACMG does not recommend the routine use of extended panels (Grody, et al., 2001).

Extended panels are approved by the U.S Food and Drug Administration (FDA) as 510(k) Class II devices. An example of an extended CFTR panel is the Tag-It™ Cystic Fibrosis Kit (Tm Bioscience Corporation, Toronto, Ontario). DNA from a blood sample is mixed with the Tag-It reagents and the Tag-It system processes the DNA, testing for 43 mutations, and reports the results using the Luminex® 100xMAP™ IS (Integrated System). The test is intended to "simultaneously detect and identify a panel of mutations and variants in the cystic fibrosis transmembrane conductance regulator (CFTR) gene in human blood specimens". The Tag-It™ "is a "qualitative genotyping test which provides information intended to be used for carrier testing in adults of reproductive age,

as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children. The kit is not indicated for use in fetal diagnostic or pre-implantation testing.” Because it detects a limited number of mutations, the kit is not recommended as a stand-alone test (FDA, 2009; FDA, 2005). Other FDA approved extended panels include the xTAG[®] Cystic Fibrosis 39 kit v2 (Luminex Molecular Diagnostics, Inc. Toronto, Ontario) and the Verigene[®] CFTR and Verigene[®] CFTR PolyT Nucleic Acid Tests (Nanosphere, Inc., Northbrook, IL).

Professional Societies/Organizations

American College of Obstetricians and Gynecologists (ACOG): In their recommendations for preconception and prenatal carrier screening in individuals of Eastern European Jewish descent, the ACOG Committee on Genetics (2009) stated that carrier screening for CF “should be offered to Ashkenazi Jewish individuals before conception or during early pregnancy so that a couple has an opportunity to consider prenatal diagnostic testing options. If the woman is already pregnant, it may be necessary to screen both partners simultaneously so that the results are obtained in a timely fashion to ensure that prenatal diagnostic testing is an option.” If only one of the couple is Ashkenazi Jew, that person should be screened first. Carrier screening should be offered if there is a positive family history of CF.

In their discussion of carrier screening for CF, the ACOG Committee on Genetics (2005) stated that “because it is becoming increasingly difficult to assign a single ethnicity, it is reasonable to offer carrier screening to all pregnant women.” Complete analysis of the CFTR gene is not appropriate for routine carrier screening. Initial screening should be performed on the patient and if the patient is a carrier, then the partner should be tested. When both partners are of Caucasian, European, or Ashkenazi Jewish ethnicity, screening should be offered before conception or early in pregnancy. The ACOG recommendations stated “For individuals with a family history of cystic fibrosis, medical records indicating the CFTR mutation in the affected family member should be obtained whenever possible. If the mutation has not been identified, screening with an expanded panel of mutations or, in some cases, complete analysis of the CFTR gene by sequencing may be indicated.” The recommendations also stated that “individuals who have a reproductive partner with cystic fibrosis or congenital bilateral absence of the vas deferens may benefit from screening with an expanded panel of mutations or, in some cases, a complete analysis of the CFTR gene by sequencing.” ACOG stated that genetic counseling may be beneficial in managing these patients.

Cystic Fibrosis Foundation: The Cystic Fibrosis Foundation guidelines for diagnosis of CF in newborns through older adults (Farrell, et al., 2008) stated that of the 1547 mutations listed in the CF Mutation Database, 225 are designated sequence variants that have no resulting clinical effect. “Of the remaining 1322 potential CF-causing mutations, only 23 have been demonstrated by direct or empirical evidence to cause sufficient loss of CFTR function to confer CF disease and thus can be recommended as conclusive genetic evidence for diagnostic purposes. These mutations account for the defects in both CFTR genes in 85% of the CF population.” The Foundation discouraged making prognostic predictions based on genotype information.

American College of Medical Genetics (ACMG): In a practice guideline for carrier screening in individuals of Ashkenazi Jewish descent, the ACMG (2008) recommended that carrier screening for CF along with genetic counseling be offered to all individuals of Ashkenazi Jewish descent who are pregnant or considering pregnancy. If only one of the couple is an Ashkenazi Jew, ideally that individual would be tested first. If that test is positive, then the partner should be tested.

The ACMG (Richards, et al., 2002) recommendations for CF genetic testing include:

- diagnostic testing, possible diagnosis of CF
- diagnostic testing, definite diagnosis of CF
- diagnostic testing, infants with meconium ileus
- diagnostic testing, males with congenital bilateral absence of the vasa deferentia (CBAVD)
- carrier testing, partners of individuals with positive family history of CF
- carrier testing, partners of males with CBAVD
- carrier testing, general population of reproductive couples
- carrier testing, positive family history
- carrier testing, gamete donors
- preimplantation testing

- prenatal diagnostic testing, positive family history or for couples having a CF mutation in both partners
- prenatal diagnostic testing, echogenic bowel fetus during second trimester
- newborn screening*

*(Note: there is insufficient evidence in the published, peer-reviewed, scientific literature to support the use of routine genetic screening for CF in all newborns.)

In their laboratory standard and guidelines for CF screening (Grody, et al., 2001), the ACMG stated, "After careful consideration, the Committee recommends that an extended panel should not be offered routinely (e.g., to couples testing positive/negative with the standard panel) since it would have the effect of increasing the patients' anxiety, would appear to endorse an alternative mutation panel beyond the standard panel defined here as the "standard of care" and would provide very low additional yield, leaving such couples who test positive/negative with essentially the same level of uncertainty as they had before".

Summary

Evidence in the published, peer-reviewed, scientific literature, as well as support from various specialty societies and organizations, indicates that genetic testing for cystic fibrosis mutations using the American College of Medical Genetics (ACMG) mutation panel is generally considered to be medically appropriate for carrier detection, prenatal testing, pre-implantation embryo testing, and diagnostic/confirmatory testing in a specific subset of patients.

Carrier screening in the general population, routine genetic screening of all newborns and testing using extended mutation panels are considered not medically necessary.

Coding/Billing Information

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

Covered when medically necessary:

CPT [®] * Codes	Description
83890	Molecular diagnostics; molecular isolation or extraction, each nucleic acid type (ie: DNA or RNA)
83891	Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (ie: DNA or RNA)
83892	Molecular diagnostics; enzymatic digestion, each enzyme treatment
83893	Molecular diagnostics; dot/slot blot production, each nucleic acid preparation
83894	Molecular diagnostics; separation by gel electrophoresis (eg, agarose, polyacrylamide), each nucleic acid preparation
83896	Molecular diagnostics; nucleic acid probe, each
83897	Molecular diagnostics; nucleic acid transfer (eg, Southern, Northern), each nucleic acid preparation
83898	Molecular diagnostics; amplification, target, each nucleic acid sequence
83900	Molecular diagnostics; amplification, target, multiplex, first two nucleic acid sequences
83901	Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (List separately in addition to code for primary procedure)
83902	Molecular diagnostics; reverse transcription
83903	Molecular diagnostics; mutation scanning, by physical properties (eg, single strand conformational polymorphisms (SSCP), heteroduplex, denaturing gradient gel electrophoresis (DGGE), RNA'ase A), single segment, each
83904	Molecular diagnostics; mutation identification by sequencing, single segment, each segment
83905	Molecular diagnostics; mutation identification by allele specific transcription, single segment, each segment

83906	Molecular diagnostics; mutation identification by allele specific translation, single segment, each segment
83907	Molecular diagnostics; lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue), each specimen
83908	Molecular diagnostics; amplification, signal, each nucleic acid sequence
83909	Molecular diagnostics; separation and identification by high resolution technique (eg, capillary electrophoresis), each nucleic acid preparation
83912	Molecular diagnostics; interpretation and report
83913	Molecular diagnostics; RNA stabilization
83914	Mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay (OLA), single base chain extension (SBCE), or allele-specific primer extension (ASPE))

HCPCS Codes	Description
S3835	Complete gene sequence analysis for cystic fibrosis

ICD-9-CM Diagnosis Codes	Description
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
V82.71 [†]	Screening for genetic disease carrier status

†Note: Covered when used for preconception or prenatal genetic testing to determine carrier status of an individual who is pregnant or a prospective biologic parent with the capacity and desire to reproduce.

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	1/15/2008	0022	Genetic Testing for Cystic Fibrosis
Great-West Healthcare	2/20/2007	05.273.02	Genetic Testing for Cystic Fibrosis

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