



**DIAGNOSTIC AND PREDICTIVE
GENETIC TESTING
HS-021**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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WellCare Health Insurance of Arizona, Inc.*

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WellCare Prescription Insurance, Inc.

**Diagnostic and Predictive
Genetic Testing**

Policy Number: HS-021

Original Effective Date: 5/9/2008

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8/2/2011**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Genetic testing can be performed for several reasons; predominantly among these reasons are 1) using genetic testing as a diagnostic tool, and 2) using testing as a mechanism for predicting the presence of a specific disease in those with a familial history.

Diagnostic/Confirmatory Testing in Symptomatic Individuals

This testing is done to rule out, identify, or confirm a suspected genetic disorder in an affected individual. Diagnostic testing may be performed to help determine the course of the disease or choice of the relevant treatment.

Predictive Testing in Pre-Symptomatic Individuals

Predictive testing is used to determine whether individuals who have a family history of a disease but no current symptoms have the gene alteration associated with the disease. Predictive genetic testing includes pre-symptomatic testing and predispositional testing. When a specific mutation is identified through pre-symptomatic testing, the patient will eventually develop symptoms of a disease (e.g., testing for Huntington's disease before symptoms are present). In predispositional testing, eventual development of symptoms is likely but not certain when the gene mutation is present (e.g., breast cancer).

Genetic Counseling and Informed Consent

Individuals who are considering genetic testing should receive detailed counseling from a qualified professional prior to and following testing so that they are able to make informed decisions. Patients should be advised that genetic testing is a multi-step process that includes risk assessment, pretesting education and follow-up counseling after the test results are known. While genetic counseling should provide sufficient information to allow the individual and family to make well-informed decisions about the benefits, risks, limitations, and implications of genetic testing, it should also be nondirective in nature. Once the results of the test are known, the implications of either a positive or a negative test should be reviewed.

POSITION STATEMENT

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

1. The member displays clinical features, or is at risk of inheriting the mutation in question (pre-symptomatic); **AND**
2. The result of the test will directly impact the treatment being delivered to the member; **AND**
3. After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain, and an inheritable disease is suspected.

In the absence of specific information regarding advances in the knowledge of mutation characteristics for a particular disorder, genetic tests for inherited disease need only be conducted once per lifetime of the member.

WellCare will cover genetic testing for inheritable disorders in non-WellCare members only when ALL of the following conditions are met:

1. The information is needed to adequately assess risk in the WellCare member; **AND**
2. The information will be used in the immediate care plan of the WellCare member; **AND**
3. The non-WellCare member's benefit plan, if any, will not cover the test (a copy of the denial letter* from the non-WellCare member's benefit plan must be provided).

WellCare may also request a copy of the certificate from the non-member's health insurance plan if: (1) the denial letter from the non-member's insurance carrier fails to specify the basis for non-coverage; (2) the denial is based on a specific plan exclusion; or (3) the genetic test is denied by the non-member's insurance carrier as not medically necessary and the medical information provided to WellCare does not make clear why testing would not be of significant medical benefit to the non-member.

CODING

Coding/Billing Information - Covered when medically necessary

Applicable CPT®* Codes - This list of codes may not be all-inclusive.

83890	Molecular diagnostics; molecular isolation or extraction
83891	Molecular diagnostics; isolation or extraction of highly purified nucleic acid
83892	Molecular diagnostics; enzymatic digestion
83893	Molecular diagnostics; dot/slot blot production
83894	Molecular diagnostics; separation by gel electrophoresis (e.g., agarose, polyacrylamide)
83896	Molecular diagnostics; nucleic acid probe, each
83897	Molecular diagnostics; nucleic acid transfer (e.g., Southern, Northern)
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 (e.g., 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)
83908	Molecular diagnostics; amplification signal, each nucleic acid sequence
83909	Molecular diagnostics; separation and identification by high resolution technique (eg, capillary electrophoresis)
83912	Molecular diagnostics; interpretation and report
83913	Molecular diagnostics; RNA Stabilization

Applicable CPT®* Codes - This list of codes may not be all-inclusive.

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))
88230	Tissue culture for non-neoplastic disorders; lymphocyte
88233	Tissue culture for non-neoplastic disorders; skin or other solid tissue biopsy
88235	Tissue culture for non-neoplastic disorders; amniotic fluid or chorionic villus cells
88237	Tissue culture for neoplastic orders; bone marrow, blood cells
88239	Tissue culture for neoplastic orders; solid tumor
88240	Cryopreservation, freezing and storage of cells, each cell line
88241	Thawing and expansion of frozen cells, each aliquot
88245	Chromosome analysis for breakage syndromes; baseline Sister Chromatid Exchange (SCE), 20-25 cells

- 88248** Chromosome analysis for breakage syndromes; baseline breakage, score 50100 cells, count 20 cells, 2 karyotypes (eg, for ataxia telangiectasia, Fanconi anemia, fragile X)
- 88249** Chromosome analysis for breakage syndromes; score 100 cells, clastogen stress (eg, diepoxybutane, mitomycin C, ionizing radiation, UV radiation)
- 88261** Chromosome analysis; count 5 cells, 1 karyotype, with banding
- 88262** Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding
- 88263** Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding
- 88264** Chromosome analysis; analyze 20-25 cells
- 88267** Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding
- 88269** Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding
- 88271** Molecular cytogenetics; DNA probe, each (eg, FISH)
- 88272** Molecular cytogenetics; chromosomal in situ hybridization, analyze 3-5 cells (eg, for derivatives and markers)
- 88273** Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (eg, for microdeletions)
- 88274** Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells
- 88275** Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells
- 88280** Chromosome analysis; additional karyotypes, each study
- 88283** Chromosome analysis; additional specialized banding technique (eg, NOR, C-banding)
- 88285** Chromosome analysis; additional cells counted, each study
- 88289** Chromosome analysis; additional high resolution study
- 88291** Cytogenetics and molecular cytogenetics, interpretation and report
- 88384** Array based evaluation of multiple molecular probes; 11 through 50 probes.
- 88385** Array based evaluation of multiple molecular probes; 51 through 250 probes.
- 88386** Array based evaluation of multiple molecular probes; 251 through 500 probes.
- 96040** Medical genetics and genetic counseling service, each 30 minutes face-to-face with patient/family

Applicable HCPCS Codes This list of codes may not be all-inclusive.

- S0265** Genetic counseling, under physician supervision, each 15 minutes
 - S3818** Complete gene sequence analysis; BRCA1 gene
 - S3819** Complete gene sequence analysis; BRCA 2 gene
 - S3820** Complete BRCA1 and BRCA2 gene sequence analysis for susceptibility to breast and ovarian cancer
 - S3822** Single mutation analysis (in individual with a known BRCA1 or BRCA2 mutation in the family) for susceptibility to breast and ovarian cancer
 - S3823** Three-mutation BRCA1 and BRCA2 analysis for susceptibility to breast and ovarian cancer in Ashkenazi individuals
 - S3828** Complete gene sequence analysis; MLH1 gene
 - S3829** Complete gene sequence analysis; MLH2 gene
 - S3830** Complete MLH1 and MLH2 gene sequence analysis for hereditary nonpolyposis colorectal cancer (HNPCC) genetic testing
- S- Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes**

Applicable HCPCS Codes continued This list of codes may not be all-inclusive.

- S3831** Single-mutation analysis (in individual with a known MLH1 and MLH2 mutation in the family) for hereditary nonpolyposis colorectal cancer (HNPCC) genetic testing
- S3833** Complete APC gene sequence analysis for susceptibility to familial adenomatous polyposis (FAP) and attenuated FAP
- S3834** Single-mutation analysis (in individual with a known APC mutation in the family) for susceptibility to familial adenomatous polyposis (FAP) and attenuated FAP
- S3835** Complete gene sequence analysis for cystic fibrosis genetic testing
- S3837** Complete gene sequence analysis for hemochromatosis genetic testing

- S3840** DNA analysis for germline mutations of the ret proto-oncogene for susceptibility to multiple endocrine neoplasia type 2
 - S3841** Genetic testing for retinoblastoma
 - S3842** Genetic testing for von hippel-lindau disease
 - S3843** DNA analysis of the f 5 gene for susceptibility to Factor V Leiden Thrombophilia
 - S3844** DNA analysis of the connexin 26 gene (GJB2) for susceptibility to congenital, profound deafness
 - S3845** Genetic testing for alpha-thalassemia
 - S3846** Genetic testing for hemoglobin e beta-thalassemia
 - S3847** Genetic testing for Tay-Sachs disease
 - S3848** Genetic testing for Gaucher disease
 - S3849** Genetic testing for Niemann-Pick disease
 - S3850** Genetic testing for sickle cell anemia
 - S3851** Genetic testing for Canavan disease
 - S3853** Genetic testing for Myotonic muscular dystrophy
 - S3852** DNA Analysis for APOE epsilon 4 allele for susceptibility to Alzheimer's disease
 - S3853** Genetic testing for myotonic muscular dystrophy
 - S3854** Gene expression profiling panel for use in the management of breast cancer treatment
 - S3855** Genetic testing for detection of mutations in the presenilin – 1 gene
 - S3860** Genetic testing, comprehensive cardiac ion channel analysis, for variants in 5 major cardiac ion channel genes for individuals with high index of suspicion for familial Long QT Syndrome (LQTS) or related syndromes
 - S3861** Genetic testing, sodium channel, voltage-gated, type V, alpha subunit (SCN5A) and variants for suspected Brugada Syndrome
 - S3862** Genetic testing, family specific ion channel analysis, for blood-relatives of individuals (index case) who have previously tested positive for a genetic variant of a cardiac ion channel syndrome using either one of the above test configurations or confirmed results from another laboratory.
 - S3865** Comprehensive gene sequence analysis for hypertrophic cardiomyopathy
 - S3866** Genetic analysis for specific gene mutation for hypertrophic cardiomyopathy (HCM) in an individual with a known HCM mutation in the family
 - S3870** Comparative genomic hybridization (CGH) microarray testing for development delay, autism, spectrum disorder and/or mental retardation
- S- Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes**

Applicable ICD-9-CM Procedure Codes - No specific codes

Applicable ICD-9-CM Diagnosis Codes - This list of codes may not be all-inclusive

- V26.31** Testing of female for genetic disease carrier status
- V26.32** Other genetic testing of female
- V26.33** Genetic Counseling
- V26.34** Testing of male for genetic disease carrier status
- V26.39** Other genetic testing of male

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

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HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
8/2/2011	<ul style="list-style-type: none">• Approved by MPC. No changes.