



Medical Policy

Policy: 201303

Initial Effective Date: 11/05/2013

SUBJECT: Genetic Testing and Genetic Counseling General Policy

Annual Review Date: 03/01/2019

Last Revised Date: 03/01/2019

Prior Approval is required for some or all procedure codes listed in this Corporate Medical Policy

Genetic counseling is required prior to testing for inherited genetic disorders

Z-code identifiers are required for molecular diagnostic test claims submission

Definition: Genetic testing is the analysis of chromosomes, DNA, RNA, genes or gene products to identify heritable or non-heritable genetic variants related to health or disease. There are several different categories of genetic testing, including:

- **Predictive testing:** Predictive testing is used to determine whether asymptomatic individuals with a family history of an inherited genetic disorder have the genetic variation(s) associated with the disorder.
- **Diagnostic testing:** Diagnostic testing is used in symptomatic individuals to identify or confirm a suspected heritable genetic disorder. This type of testing may be performed to help predict the course of a disease or determine the choice of treatment.
- **Carrier testing:** Carrier testing is used to identify individuals carrying one copy of a gene mutation that, when present in two copies, allows a genetic disorder to become manifest. It may be offered to individuals with a family history of a genetic disorder or certain ethnic groups with an increased risk of a genetic condition, often to provide information about the risk of progeny having a genetic condition.
- **Prenatal testing:** Prenatal testing is performed during pregnancy to detect fetal gene or chromosome variations to identify possible inherited disorders or birth defects.
- **Newborn screening:** Newborn screening is performed just after birth to identify genetic disorders that require treatment early in life or that have long-term health effects.
- **Pharmacogenetic testing:** Pharmacogenetic testing identifies variations in genes that influence an individual's response to certain drugs. This type of testing can also include gene expression testing of tumor cells or tissue to predict responsiveness to, or appropriateness of, specific anti-cancer therapy. Testing information can then help guide treatment strategies and minimize adverse drug effects.

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There are numerous commercially available genetic tests in all of the above categories. Medical Mutual utilizes MCG Guidelines (22nd edition) as a frame of reference when making evidence-based medical necessity determinations for molecular and genetic tests.

To access the MCG guidelines, please click on the following link and follow access instructions:
<https://medmutual.access.mcg.com/index>

In addition, to better identify and evaluate what molecular diagnostic tests are being ordered and why, Medical Mutual is partnering with McKesson Diagnostics Exchange™ (DEX) to administer unique Z-code™ Identifiers. Claims for select molecular diagnostic tests (see Addendum II for applicable CPT Codes) for dates of service on or after January 11, 2016 cannot be processed and will be rejected if submitted without a Z-code Identifier. Please submit Z-code identifiers with prior approval requests for all molecular diagnostic tests.

Genetic Counseling

Genetic counseling is a service provided by trained, qualified professionals involving assessment and education of an individual about presence or absence of an **inherited** genetic disease. This process is intended to assist individuals in understanding and adapting to the medical, psychological and familial implications of genetic contributions to health risks, health conditions/disease and management/treatment responses.

Medical Mutual requires genetic counseling services for the following genetic tests when clinical criteria are met:

- Hereditary cardiomyopathies
- Hereditary cancers including breast, ovarian and colorectal cancers
- Comparative genomic hybridization and chromosomal microarray analysis

Medical Necessity: The Company considers genetic screening and/or testing **medically necessary** and eligible for reimbursement providing that **all** of the following are present:

- Pre-test genetic counseling is performed **when indicated** by a trained genetics specialist[†] and appropriate testing is recommended; and
- Documented informed consent occurs before testing; and
- Testing is FDA/CLIA approved; and
- Testing results will directly impact medical management; and
- Testing is supported by clinical criteria (e.g. InterQual® Molecular Diagnostics Criteria).

Based upon our findings, the Company considers genetic testing **not medically necessary** and **not** eligible for reimbursement for **any** of, but not limited to, the following:

- Routine, ongoing or long term genetic counseling; or

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- Determining paternity of a child; or
- Determining the sex of a child (except when medically indicated); or
- General population screening for genetic disorders (e.g., cystic fibrosis).

NOTE: The Company limits the frequency of genetic testing for inherited disease to **once** per condition per lifetime (in absence of specific clinical information regarding advances in the knowledge of mutation characteristics for a particular disorder.)

NOTE: The Company had determined that the laboratory tests not determined to be medically necessary using MCG Guidelines have not demonstrated equivalency or superiority to currently accepted standard means of testing. **The Company considers all other molecular diagnostic testing not medically necessary and not eligible for reimbursement.**

†Genetics specialists qualified to provide genetic counseling are defined by the Company as:

- Individual works independently from the laboratory performing the pertinent genetic test(s); and
- Individual maintains a current license to perform genetic counseling, if applicable within that state; or
- Active and current American Board of Genetic Counseling (ABGC) certification; or
- Active and current American Board of Medical Genetics (ABMG) certification; or
- A Genetics Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APNG) credentialed through the Genetics Nursing Credentialing Commission (GNCC).

NOTE: It is the genetics specialist's role to provide information to the individual and/or family regarding the genetic risk or condition to permit informed decision-making and to determine the most appropriate type of testing (e.g., full sequencing, single-site analysis, multi-site analysis).

See Addendum I for applicable CPT Codes.

See Addendum II for Not Medically Necessary genetic tests.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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Addendum I

Procedure Codes for Molecular and Genetic Tests

Molecular Pathology Tier 1:

CPT Codes 81105, 81111, 81112, 81161, 81162, 81200-81383

Molecular Pathology Tier 2:

CPT Codes 81400-81408

Molecular Pathology Miscellaneous:

CPT Code 81479

Genomic Sequencing Procedures:

CPT Codes 81410-81471

Multianalyte Assays with Algorithmic Analyses:

CPT Codes 81490-81599

Molecular Cytogenetics:

CPT Codes 88271-88275

HCPCS Codes G0452, S3840-S3870



ADDENDUM II

Not Medically Necessary Tests

The following tests are considered **not medically necessary** and **not** eligible for reimbursement. This list is **not** all-inclusive.

Investigational Testing	Example (Manufacturer)
Adalimumab treatment monitoring	Anser ADA (Prometheus, Inc.)
Age-related macular degeneration panel	Macula Risk PGx (ArcticDx Inc)
Apolipoprotein E (Apo E) genotype	Spectracell Laboratories
Bilateral frontoparietal polymicrogyria (BFPP)	GPR56 Sequencing (Claritas Genomics Inc)
Cytochrome P450 genotyping to predict response to antidepressant and antipsychotic medications	STA2R SureGene (SureGene LLC); Genelex Corp.
Cytochrome P450 genotyping to predict response to pain medications	Quest Diagnostics Laboratories Inc., Genelex Corp.,
ERCC1 expression analysis in non-small cell lung cancer	ERCC1 by immunohistochemistry (Integrated Oncology)
Fetal RHD genotyping	SensiGene (Sequenome Center for Molecular Medicine)
Gene expression profiling for Breast Cancer	BluePrint, TargetPrint (Agendia, Inc.); Mammostrat (Clariant Inc.); Breast Cancer Index (BioTheragnostics Inc.), BRCPlus (Ambry Genetics Corp.)
Gene expression profiling for Cancer	DecisionDx-GBM, DecisionDx-Melanoma, DecisionDx-UM (Castle Biosciences Inc); ResponseDX (Response Genetics Inc); PathFinderTG® Pancreatic Cancer (Red Path Integrated Technology); NexCourse CRC (Genoptix Medical Laboratory); Xpresys Lung (Integrated Diagnostics Inc.); miRInform Thyroid (Asuragen Inc.); ChemoFx (Precision Therapeutics); Molecular Intelligence (Caris Life Sciences); FoundationOne, FoundationOneHeme, FoundationOneCDx, FoundationAct (Foundation Medicine)

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Gene expression profiling for cardiovascular conditions	Corus™ CAD (CardioDx)
Gene expression profiling for Prostate Cancer	Prostate Core Mitomic (Mitomics Inc); ConfirmMDx for Prostate Cancer (MDxHealth); TheraLink HER Family Assay (Theranostics Health Inc.)
Cytochrome P450 (<i>CYP450</i>) Genotyping to Predict Response to Antidepressant and Antipsychotic Medications for Pharmacogenetic Testing	GeneSightRx®(Assurex Health Inc.) , various manufacturers
Infliximab treatment monitoring	Anser IFX (Prometheus, Inc.)
Inherited intrahepatic choleostasis	JaundiceChip (Cincinnati Children's Hospital Molecular Genetics Laboratory)
KIF6 genotype	KIF6 Genotyping (Berkeley HeartLab Inc.)
Mitochondrial/metabolic microarray analysis	MitoMet (Baylor College of Medicine Medical Genetics Laboratories)
Multi-marker test for IBD diagnosis and differentiation	IBD sgi Diagnostic (Prometheus, Inc.)
Neurology panels	Complete Ataxia Evaluation (Athena Diagnostics); epilepsy and seizure disorder panel EpiSEEK, nucSEEK (Courtagen Life Sciences Inc.); mitochondrial genome sequencing and deletion panel, mitochondrial nuclear gene panel; infantile epilepsy panel (GeneDx Inc)
Next generation sequencing panels to predict cancer risk	BROCA Cancer Risk Panel (University of Washington Laboratory Medicine); ColoNext, OvaNext, RenalNext, BreastNext, GYNPlus (Ambry Genetics Corp.)
Tumor Necrosis Factor Receptor–Associated Periodic Syndrome	Periodic Fever Syndromes Panel; <i>TNFRSF1A</i> Exons 2-5 (GeneDx Inc.)
Prognostic Test for Adolescent Idiopathic Scoliosis	ScoliScore Adolescent Idiopathic Scoliosis (AIS)(Transgenomic Inc.)

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Single nucleotide polymorphism (SNP) tests to predict autism spectrum disorder risk	ARISk2 (IntegraGen Inc)
Single nucleotide polymorphism (SNP) tests to predict cancer risk	BREVAGen (Phenogen Sciences, Inc.); OncoVue (InterGenetics, Inc.)
Statin-associated myopathy	SLCO1B1 genotype (Mayo Medical Laboratories)
Whole genome and whole exome sequencing	Clinical Diagnostic Exome (Ambry Genetics Corp.); MyGenome (Veritas Genetics)