MEDICAL MUTUAL®

Medical Policy

Policy:	**201303**	**Initial Effective Date:**	**11/05/2013**
SUBJECT:	**Genetic Testing and Genetic Counseling General Policy**	**Annual Review Date:**	**05/23/2023**
		Last Revised Date:	**08/15/2023**

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

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.

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

To access the MCG Care 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 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 follows MCG Care Guidelines for genetic counseling requirements. If MCG Care Guidelines for a genetic test do not include genetic counseling requirements, then no genetic counseling is necessary. MCG Care Guidelines list the following criteria for genetic counseling:

- Counseling is provided by healthcare professional with education and training in genetic issues relevant to the genetic tests under consideration.
- Counselor is free of commercial bias and discloses all (potential and real) financial and intellectual conflicts of interest.
- Process involves individual or family and is comprised of **ALL** of the following:
    - Calculation and communication of genetic risks after obtaining 3-generation family history
    - Discussion of natural history of condition in question, including role of heredity
    - Discussion of possible impacts of testing (eg, psychological, social, limitations of nondiscrimination statutes)
    - Discussion of possible test outcomes (ie, positive, negative, variant of uncertain significance)
    - Explanation of potential benefits, risks, and limitations of testing
    - Explanation of purpose of evaluation (eg, to confirm, diagnose, or exclude genetic condition)
    - Identification of medical management issues, including available prevention, surveillance, and treatment options and their implications
    - Obtaining informed consent for genetic test

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 MCG Care Guidelines*** 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. MCG Care Guidelines).

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
- 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.**

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).

NOTE: For coverage criteria related to ClonoSEQ please refer to CMP 201923: Next Generation Sequencing for Detection and Quantification of Lymphoid Cancers. For coverage criteria related to OncotypeDX AR-V7 please refer to CMP 201924: OncotypeDX AR-V7 Nucleus Detect Assay for Men with Metastatic Castration-Resistant Prostate Cancer.

See Addendum for Not Medically Necessary molecular and 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.

NOTE: After reviewing the relevant documentation, the Company reserves the right to apply this policy to the procedure performed regardless of how the procedure was coded by the Provider.

Sources of Information:

- American College of Medical Genetics and Genomics (ACMG). ACMG Policy Statement. Clinical utility of genetic and genomic services: a position statement of the American College of Medical Genetics and Genomics. https://www.acmg.net. Published March 12, 2015. Accessed May 11, 2023.
- Centers for Disease Control and Prevention. (June, 2022). *Genetic Counseling.* Retrieved from: https://www.cdc.gov/genomics/gtesting/genetic_counseling.htm.
- Genetic Conditions: Explore the signs and symptoms, genetic cause, and inheritance pattern of various health conditions. (Accessed May 11, 2023). U.S. National Library of Medicine. Retrieved from: http://ghr.nlm.nih.gov/.
- Hayes, Inc., Lansdale, PA: Author. Health Technology Assessments.
- Kohlmann, W. Slavotinek, A. Genetic Testing. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed October 2022.
- Manning, M., & Hudgins, L. (2010). Array-based technology and recommendations for utilization in medical genetics practice for detection of chromosomal abnormalities. *Genet Med, 12*(11), 742-745.
- Pagon, R. A., Adam, M. P., Ardinger, H. H., Bird, T. D. Dolan, C. R., Fong, C., Smith, R. J., Stephens, K. (1993-2014). GeneReviews (Internet). Univerisity of Washington, Seattle. Retrieved from: http://www.ncbi.nlm.nih.gov/books/NBK1116/.
- Raby, B., Kohlmann, W., & Hartzfeld, D. Genetic counseling: Family history interpretation and risk assessment. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed January 2022.
- Rehm, H. L., Bale, S. J., Bayrak-Toydemir, P., Berg, J. S., Brown, K. K., Deignan, J. L., …Funke, B. H. (2013). ACMG clinical laboratory standards for next-generation sequencing. *Genet Med, 15*(9), 733-747.

Applicable Code(s):

CPT: **There are many medical codes that may be used to reimburse for molecular and genetic testing. All claims submitted for genetic testing must include a Z-code identifier.**

HCPCS:

ICD10 Procedure Codes:

MEDICAL MUTUAL®

Medical Policy

ADDENDUM

Not Medically Necessary Tests

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

Not Medically Necessary Testing	Example (Manufacturer)
Biomarker Test for Alzheimer Disease	AD-Detect (Quest Diagnostics Inc.)
Blood test to predict risk for premature delivery	PreTRM (Sera Prognostics)
Ductal Carcinoma In Situ (DCIS) Test to Predict Radiation Therapy Benefit	DCISionRT (PreludeDX)
Gene or Protein expression profiling for Breast Cancer	BluePrint (Agendia, Inc.); TheraLink HER Family Assay (Theranostics Health Inc.)
Gene or Protein expression profiling for Cancer	PancraGEN (Interpace Diagnostics); miRInform Thyroid (Asuragen Inc.); ThyGeNEXT, ThyroMIR (InterpaceDiagnostics Group Inc.); ChemoFx (Helomics Corp.); MI Profile, MI Tumor Seek (Caris Life Sciences); FoundationOne Liquid, FoundationOne Heme (Foundation Medicine); CANCERPLEX (KEW Inc.); Tempus xF, Tempus xG, Tempus xT (Tempus Labs Inc.); Colon Cancer Hotspot Panel v2 NGS (Thermo Fisher Scientific); Colvera (ClinicalGenomics); Signatera (Natera Inc.)
Gene or Protein expression profiling for Prostate Cancer	Prostate Core Mitomic (Mitomics Inc); ConfirmMDx for Prostate Cancer (MDxHealth); 4Kscore Test (OPKO Health Inc.); SelectMDx Urine Test for Prostate Cancer (MDx Health); ExoDx Prostate IntelliScore (ExosomeDx); IsoPSA (Cleveland Diagnostics Inc.)

Inherited intrahepatic choleostasis	JaundiceChip (Cinncinati Children's Hospital Molecular Genetics Laboratory)
Mitochontrial/metabolic microarray analysis	MitoMet (Baylor College of Medicine Medical Genetics Laboratories)
Monoclonal antibody treatment monitoring	Anser ADA, Anser IFX, Anser VDZ, Anser UST (Prometheus, Inc.);
Multi-marker test for IBD diagnosis and differentiation	IBD sgi Diagnostic (Prometheus, Inc.)
Pharmacogenetic Testing	BTK Resistance Mutation (C481S); PrismRA (Scipher Medicine); GeneSight Psychotropic (Myriad Genetics)
Transplant Rejection Testing	AlloSure (CareDx); Prospera (Natera, Inc.)