

MEDICAL POLICY STATEMENT INDIANA MEDICALD PolicyName PolicyNumber Date Effective Genetic Testing and Counseling MM-0737 01/01/2022-09/30/2022 PolicyType MEDICAL Administrative Pharmacy Reimbursement

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Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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Effective Date: 01/01/2022



Genetic Testing and Counseling

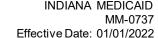
B. Background

Recent advancements in our understanding of the human genome have contributed to the rapid expansion of identified genetic mutations. Supported by new technologies and available measurement tools, there are now an ever-expanding number of genetic assays available for the purpose of genetic testing. In some clinical situ ations the results may be linked to proven diagnostic and /or therapeutic results

C. Definitions

- Genetic Counseling: is the process of education and recommendations provided by a professional and is a specialized skill set that can be performed by clinicians who receive appropriate training and have core competencies. This is not limited to genetic medicine, as non-genetic sub specialties including primary care have created core competencies for physicians and other healthcare professionals that is relevant to their area of practice.
- Genetic Screening: is the process used to uncover genetic disorders or the potential for transmission of genetic disorders in specific populations determined to be at risk.
- Genetic Testing: for clinical purposes, is the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect alterations or disease related genotypes, mutations, phenotypes or karyotypes related to a heritable or acquired disorder.
- **Somatic Gene Mutation:** a type of genetic mutation that is acquired in the process and may form cancer and is not present at birth. This can also be referred to as an acquired mutation.
- Inherited Genetic Mutation: a type of genetic mutation inherited from a mother or father that is present at birth. This also can be referred to as a Germline mutation or hereditary mutation.
- **Precision Medicine:** field of medicine that uses targeted therapy for somatic gene mutation in cancer patients.
- Human Leukocyte Antigen (HLA) Typing: used to identify certain individual variations in a person's immune system. This is typically used to identify which people can safely donate bone marrow, cord blood, or organ.
- Genetics: the study of heredity and the variation of inherited characteristics.
- **Genomics:** the study of genes and their functions, and related techniques. In general, genomics tends to focus more on how genes are involved in cancer growth and response (or lack of response) to chemotherapy or other types of oncologic drugs such as targeted therapies. Genomics also focuses on complex disease management such as diabetes, asthma, heart disease and mental health disorders.







- Prior authorization may be required for genetic testing. This includes both somatic genetic mutation testing and inherited genetic mutation testing.
- CareSource will review for medical necessity using published MCG criteria when available.
- Genetic counseling is required for all inherited genetic mutation testing. III.
 - A. Genetic counseling for inherited genetic testing should be completed and provided with the prior authorization request, prior to testing.
 - B. The clinician should provide documentation of a family history, pretest counseling, and a fully informed consent.
 - C. Counseling is required to be provided by a healthcare professional who has received training in the genetic issues that are relevant to the genetic tests being
 - D. The clinician's credentials may include specialty genetic medicine training or nongeneticist clinician. (eg, Primary Care, Pediatrics, Obstetrics and Gynecology, Oncology)
 - E. Medical necessity review will consider the complexity of the genetic test request. Certain types of genetic tests have sufficient complexity (ex. Multigene panels. whole exome sequencing, whole genome sequencing) that obtaining informed consent, preparing the patient for potentially uninformative results, and interpreting the returned results may require a trained geneticist or genetics counselor.
- IV. Somatic genetic mutation testing (for example but not limited to non-small cell lung cancer, metastatic colon cancer) will be reviewed using published MCG criteria and the Medical Necessity Determinations Administrative Policy.
 - A. Somatic genetic testing does not require genetic counseling described above.
- Proprietary Pane (for example but not limited to Gensight Psychotropic Test) testing requires evidence-based documentation per Medical Necessity Determinations Administrative Policy.
 - A. Individual genetic testing may be requested separately based on the Medical Necessity Determinations Administration Policy, for panels not meeting medical necessity requirements.

NOTE: HLA Typing is not part of the Genetic testing policy and does not require pre authorization.

NOTE: CareSource recognizes while most inherited genetic testing should only need to be performed once in a life time, based on advancement in technology or extraordinary circumstances there will be times when an inherited genetic test could be performed again. This type of test will be considered with the proper medical necessity documentation.



Effective Date: 01/01/2022



F. Review/Revision History

	DATE	ACTION
Date Issued	10/01/2018	New Policy
Date Revised	09/02/2020 09/17/2021	Revised title, removed MCG table, condensed background Added examples of somatic and proprietary genetic tests, updated definitions
Date Effective	01/01/2022	Effective Date
Date Archived	09/30/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

G. References

- 1. Home Genetic testing registry (GTR) NCBI. (n.d.). National Center for Biotechnology Information. Retrieved June 25, 2021, from www.ncbi.nlm.nih.gov
- 2. *Genetic Tests*. (2019, August 15). Geonome.gov. Retrieved June 25, 2021, from .gov/about-genomics/policy-issues/Coverage-Reimbursement-of-Genetic-Tests
- 3. MCG Care Guidelines Ambulatory Care Guidelines for Genetic Medicine (24th Edition, 2020)
- 4. What is a Genetic Mutation and How Does it Occur? (2020, August 4). U.S National Library of Medicine. Retrieved June 25, 2021, f rom ghr.nlm.nih.gov

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review - 10/2019

IN-MED-P-762553 Issue Date 10/01/2018 Approved OMPP 10/15/2021

