



MEDICAL POLICY STATEMENT Marketplace

Policy Name & Number	Date Effective
Genetic Testing and Counseling-MP-MM-1322	GA, IN, KY, WV: 08/01/2023-06/30/2024 OH: 09/01/2023- 06/30/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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.

This policy applies to the following Marketplace(s):

☒ Georgia	☒ Indiana	☒ Kentucky	☒ Ohio	☒ West Virginia
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A. Subject

Genetic Testing and Counseling

B. Background

Advancements in technology have contributed to the rapid expansion of identified genetic variations. Some of these variations have been identified as disease-causing, while others are considered common variants with no clinical impact. With the ever-expanding number of genetic tests available, it can be clinically difficult to determine the most appropriate tests for a particular patient. When clinically appropriate, genetic testing may provide diagnostic and/or actionable therapeutic results which can impact a patient's outcome. Due to the complexity of genetic tests and their results, consultation with medical genetics professionals and counselors may be required to assist members.

According to the National Society of Genetic Counselors of the United States, genetic counseling is meant to integrate the following goals: 1) interpretation of family and medical histories to assess the chance of disease occurrence or recurrence; 2) education about the natural history of the condition, inheritance pattern, testing, management, prevention, support resources, and research; 3) counseling to promote informed choices in view of risk assessment, family goals, ethical and religious values; and 4) support to encourage the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of that disorder. Genetic counselors are healthcare professionals trained to provide this care; however, access issues may require other healthcare professionals to assume this role. Genetic counseling, whether provided by a certified genetic counselor or other qualified healthcare professional, is an integral component of genetic testing that is informative and supportive to members, both before and after they undergo testing.

C. Definitions

- **Genetic Screening** – The process of testing a population for a genetic disease to identify a subgroup of people who either have the disease or the potential to pass it on to offspring.
- **Genetic Testing** – A medical test that identifies changes in genes, chromosomes, or proteins to confirm or rule out a suspected genetic condition either hereditary or acquired.
- **Human Leukocyte Antigen (HLA) Typing** – A test used to match patients and donors for bone marrow or cord blood transplants.
- **Inherited Genetic Variant** – A type of DNA sequence change passed from parent to offspring (i.e., germline).
- **Precision Medicine** – A field of medicine that selects pharmacotherapies based on the patient's genetics.
- **Somatic Gene Variant** – A type of DNA sequence change that is not inherited from a parent but acquired during a person's life.

D. Policy

- I. Prior authorization may be required for genetic testing. This includes both somatic and germline genetic testing.
- II. CareSource will review for medical necessity using published MCG criteria when available and the Medical Necessity Determinations administrative policy.
- III. Proprietary Panel testing requires evidence-based documentation per the Medical Necessity Determinations administrative policy. Individual genetic tests may be requested separately based on the Medical Necessity Determinations administrative policy for panels not meeting medical necessity requirements.
- IV. Genetic counseling is required for all germline genetic testing, as indicated by **ALL** the following:
 - A. Counseling is provided by a healthcare professional with education and training in genetic issues relevant to the genetic tests under consideration;
 - B. Counselor is free of commercial bias and discloses all (potential and real) financial and intellectual conflicts of interest;
 - C. Process involves individual or family and is comprised of **ALL** the following:
 1. Calculation and communication of genetic risks after obtaining a 3-generation family history, when available;
 2. Discussion of natural history of genetic condition in question, including role of heredity;
 3. Discussion of possible impacts of testing (e.g., psychological, social, limitations of nondiscrimination statutes);
 4. Discussion of possible outcomes (i.e., positive, negative, variant of uncertain significance);
 5. Explanation of potential benefits, risks, and limitations of testing;
 6. Explanation of purpose of evaluation (e.g., to confirm, diagnose, or screen for a genetic condition);
 7. Identification of medical management issues, including available prevention, surveillance, and treatment options and implications; and
 8. Obtaining informed consent for genetic test.
- V. Somatic genetic testing does not require genetic counseling described above.
- VI. Human leukocyte antigen (HLA) typing is not part of the genetic testing policy and does not require pre-authorization.
- VII. While most inherited genetic testing is only necessary once in a lifetime, CareSource recognizes that a germline genetic test could be appropriately repeated in extraordinary circumstances due to changes in technology. This situation will be considered with the proper medical necessity documentation.

E. Conditions of Coverage

NA

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

F. Related Policies/Rules
Medical Necessity Determinations
Cystic Fibrosis Carrier Testing

G. Review/Revision History

DATE		ACTION
Date Issued	05/25/2022	New Policy
Date Revised	05/10/2023	Annual review: updated background, definitions, and references, rephrased genetic counseling process. Approved at Committee.
Date Effective	GA, IN, KY, WV: 08/01/2023 OH: 09/01/2023	
Date Archived	GA, IN, KY, WV:06/30/2024 OH: 06/30/2024	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.

H. References

1. Cohen SA, Bradbury A, Henderson V, et al. Genetic counseling and testing in a community setting: quality, access, and efficiency. *Am Soc Clin Oncol Educ Book*. 2019 Jan;e34-e44. doi:10.1200/EDBK_238937.
2. Crooke A, Jacobs C, Newton-John T, et al. Genetic counseling and testing practices for late-onset neurodegenerative disease: a systematic review. *J Neurol*. 2022;269(2):676-692. doi:10.1007/s00415-021-10461-5.
3. Kohlmann W, Slavotinek A. Genetic testing. UpToDate. Published October 7, 2022. Accessed April 11, 2023. www.uptodate.com.
4. MCG Care Guidelines Ambulatory Care Guidelines for Genetic Medicine 27th Edition. MCG Health, LLC. Accessed April 11, 2023. www.careweb.careguidelines.com.
5. Mundy J, Davies HL, Radu M, et al. Research priorities in psychiatric genetic counselling: how to talk to children and adolescents about genetics and psychiatric disorders. *Eur J Hum Genet*. 2023;31(3):262-264. doi:10.1038/s41431-022-01253-0.
6. National Center for Biotechnology Information (NCBI). Genetic Testing Registry (GTR) National Library of Medicine. Accessed April 11, 2023. www.ncbi.nlm.nih.gov.
7. National Human Genome Research Institute. Coverage and Reimbursement of Genetic Tests. National Institutes of Health. Published August 15, 2019. Accessed April 11, 2023. www.genome.gov.
8. National Human Genome Research Institute. Regulation of Genetic Tests. National Institutes of Health. Published February 2, 2022. Accessed April 11, 2023. www.genome.gov.

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

9. Raby BA, Kohlmann W. Genetic counseling: family history interpretation and risk assessment. UpToDate. Published January 31, 2022. Accessed April 11, 2023. www.uptodate.com.
10. Sarata AK. Genetic Testing: Background and Policy Issues. Congressional Research Service Report. RL33832. Published March 2, 2015. Accessed April 11, 2023. www.sgp.fas.org.
11. Senter L, Austin JC, Carey M, et al. Advancing the genetic counseling profession through research: Identification of priorities by the National Society of Genetic Counselors research task force. *J Genet Couns*. 2020;29(6):884-887. doi:10.1002/jgc4.1330.
12. White S, Jacobs C, Phillips J. Mainstreaming genetics and genomics: a systematic review of the barriers and facilitators for nurses and physicians in secondary and tertiary care. *Genet Med*. 2020;22(7):1149-1155. doi:10.1038/s41436-020-0785-6.

I. State-Specific Information

- A. Georgia
Effective: 08/01/2023
- B. Indiana
Effective: 08/01/2023
- C. Kentucky
Effective: 08/01/2023
- D. Ohio
Effective: 09/01/2023
- E. West Virginia
Effective: 08/01/2023

Independent medical review – 10/2019

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