



Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource

<b>MEDICAL POLICY STATEMENT</b>	
<b>North Carolina Marketplace</b>	
<b>Policy Name &amp; Number</b>	<b>Date Effective</b>
Genetic Testing and Counseling-NC-MP-MM-1375	01/01/2023-07/31/2023
<b>Policy Type</b>	
<b>MEDICAL</b>	

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.

### Table of Contents

A. Subject.....	2
B. Background.....	2
C. Definitions .....	2
D. Policy .....	2
E. Conditions of Coverage.....	3
F. Related Policies/Rules.....	3
G. Review/Revision History.....	3
H. References.....	4

## A. Subject

### **Genetic Testing and Counseling**

## B. Background

Recent 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. Medical genetics professionals and counselors may be required to help educate the patient and family members on the purpose and results of testing. When clinically appropriate, genetic testing may provide diagnostic and/or actionable therapeutic results which can impact a patient's outcome.

## C. Definitions

- **Genetic Counseling** – A service provided to patients and family members by clinicians who receive appropriate training and licensing. The service is designed to educate and provide recommendations/guidance regarding the patient's test results and continued care.
- **Genetic Screening** – The process of testing a population for a genetic disease to identify a subgroup of people that 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.
- **Somatic Gene Variant** – A type of DNA sequence change that is not inherited from a parent but acquired during a person's life.
- **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.
- **Human Leukocyte Antigen (HLA) Typing** – A test used to match patients and donors for bone marrow or cord blood transplants.
- **Genetics** – The study of genes and heredity.
- **Genomics** – The branch of molecular biology concerned with the structure, function, evolution, and mapping of genomes (an organism's complete DNA sequence).

## 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 administration policy for panels not meeting medical necessity requirements.

- IV. Genetic counseling is required for all germline genetic testing.
  - A. Genetic counseling 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 informed consent to testing.
  - C. Counseling must be provided by a healthcare professional who has received training in the genetic issues that are relevant to the genetic tests being considered.
  - D. The clinician’s credentials may include specialty genetic medicine training or non-geneticist clinician (e.g., 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 (e.g., 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 certified geneticist or genetic counselor.
- 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

F. Related Policies/Rules

Medical Necessity Determinations

Cystic Fibrosis Carrier Testing

G. Review/Revision History

DATE		ACTION
<b>Date Issued</b>	05/25/2022	
<b>Date Revised</b>		
<b>Date Effective</b>	01/01/2023	
<b>Date Archived</b>	07/31/2023	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.

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

## H. References

1. MCG Care Guidelines Ambulatory Care Guidelines for Genetic Medicine 26<sup>th</sup> Edition (v26). MCG Health, LLC 2022. Retrieved May 23, 2022 from [www.careweb.careguidelines.com](http://www.careweb.careguidelines.com).
2. National Center for Biotechnology Information (NCBI). (n.d.). Genetic Testing Registry (GTR) National Library of Medicine. Retrieved May 12, 2022 from [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov).
3. National Human Genome Research Institute. (2019 August 15). Coverage and Reimbursement of Genetic Tests. National Institutes of Health. Retrieved May 12, 2022 from [www.genome.gov](http://www.genome.gov).
4. National Human Genome Research Institute. (2022 February 2). Regulation of Genetic Tests. National Institutes of Health. Retrieved May 12, 2022 from [www.genome.gov](http://www.genome.gov).
5. Raby BA, Kohlmann W. (2020 July 14). Genetic testing. UpToDate. Retrieved May 12, 2022 from [www.uptodate.com](http://www.uptodate.com).
6. Raby BA, Kohlmann W. (2022 January 31). Genetic counseling: family history interpretation and risk assessment. UpToDate. Retrieved May 12, 2022 from [www.uptodate.com](http://www.uptodate.com).
7. Sarata AK. Genetic Testing: Background and Policy Issues. 2015 March 2. Congressional Research Service Report. RL33832. Retrieved May 12, 2022 from [www.sgp.fas.org](http://www.sgp.fas.org).

*Independent medical review – 10/2019*