MEDICAL POLICY STATEMENT

GEORGIA MEDICAID

Policy Name	Policy Number	Date Effective
Genetic Testing and Counseling	MM-0735	02/01/2021- 10/31/2021

Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

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.

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A. Subject

Genetic Testing and Counseling

B. Background

Recent advancements in our understanding of the human genome has 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 situations 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 of a cancer forming 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.

D. Policy

I. Prior authorization is required for genetic testing unless otherwise noted in other policies. This includes both somatic genetic mutation testing and inherited genetic mutation testing.

II. CareSource will review for medical necessity using published MCG criteria when available.

III. Genetic counseling is required for all inherited genetic mutation testing.
   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 considered.
   D. The clinician's credentials may include specialty genetic medicine training or non-geneticist clinician. (eg, Primary Care, Pediatrics, Obstetrics and Gynecology, Oncology)
   E. Medical necessity review will take into account 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 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.

V. Proprietary Panel 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.

E. Related Polices/Rules

Medical Necessity Determinations AD-0038

Cystic Fibrosis Carrier Testing AD-0842

F. Review/Revision History

DATE		ACTION
Date Issued	02/24/2015	New Policy
Date Revised	09/02/2020	Revised title, removed MCG table, condensed background
Date Effective	02/01/2021	
Date Archived	10/31/2021	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 August 10, 2020, from www.ncbi.nlm.nih.gov
2. *Genetic Tests*. (2019, August 15). Geonome.gov. Retrieved August 10, 2020, 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 August 10, 2020, from 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 –

GA-MED-P-274053 Date Issued 02/24/2015 DCH Approved 10/28/2020