



MEDICAL POLICY STATEMENT

Ohio Medicaid

| Policy Name & Number | Date Effective |
|---|----------------|
| Genetic Testing and Counseling-OH MCD-MM-0003 | 11/01/2023 |
| 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.

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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 their 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

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

G. Review/Revision History

| DATE | | ACTION |
|-----------------------|------------|--|
| Date Issued | 02/24/2015 | New Policy |
| Date Revised | 06/05/2019 | Revised title, removed MCG table, condensed background |
| | 09/03/2020 | |
| | 07/07/2021 | Reviewed, updated references |
| | 05/25/2022 | Annual review: updated definitions, background, and references, re-organized criteria |
| | 05/10/2023 | Annual review: updated background, definitions, and references, rephrased genetic counseling process. Approved at Committee. |
| Date Effective | 11/01/2023 | |
| Date Archived | | |

H. References

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

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Independent medical review – 10/2019

Approved by ODM 7/27/2023