Medical Policy

Genetic Testing	
MEDICAL POLICY NUMBER	MED_Clin_Ops_003
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local CoverageDeterminations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

The purpose of this policy is to establish clinical review criteria to support the determination the medical necessity of genetic testing.

POLICY

For IFP and SG products, MCG criteria must be referenced before applying this policy. If there are MCG criteria available related to the authorization request for genetic testing, MCG criteria will supersede this policy.

Genetic testing of Brand New Day/Central Health Medicare Plan members is excluded from coverage if the testing is performed primarily for the medical management of other family members who are not covered under a Brand New Day/Central Health Medicare Plan.

Clinical Review Criteria

I. Single gene and multi-gene panel testing

A. Diagnosis and/or prediction of risk for inheritable diseases

Single gene and multi-gene panel testing for diagnosis and/or prediction of risk for inheritable diseases may be authorized when documentation in the medical record indicates that the member meets **ALL** of the following criteria:

1. Medical records document a detailed family history/pedigree and pre-test genetic counseling by **ONE** of the following:
    a) A board-certified medical geneticist or genetic counselor not affiliated with the commercial laboratory performing the testing.
    b) Other qualified healthcare professional with specialized education and training in medical genetics not affiliated with the commercial laboratory performing the testing.
2. The member has **ONE** of the following:
    a) Current signs and/or symptoms suggesting a genetic disease**.**
    b) Family history indicating that the member is at high risk for a genetic disease.
    c) Medical records document how the test(s) will lead to changes in treatment decisions (e.g., initiate a new course of therapy, alter existing therapy, determine/change level of surveillance, or make reproductive decisions) or health outcome for the member being tested.

B. Carrier status of inheritable diseases

Single gene and multi-gene panel testing for carrier status of inheritable diseases may be authorized when documentation in the medical records indicates that the member meets **ALL** of the following criteria:

1. Medical records document a detailed family history/pedigree and pre-test genetic counseling by one of the following:
    a) A board-certified medical geneticist or genetic counselor not affiliated with the commercial laboratory performing the testing**.**
    b) Other qualified healthcare professional with specialized education and training in medical genetics not employed by or contracted with the commercial laboratory performing the testing.
2. The member is currently pregnant or contemplating pregnancy and is at high risk of being a carrier of a specific genetic disorder based on family history. Examples may include, but are not limited to:
    a) One parent is a known carrier of a clinically significant X-linked recessive, or autosomal recessive disease (e.g., hemophilia, cystic fibrosis, Duchenne muscular dystrophy, sickle cell anemia, or Tay Sachs disease). Gaucher disease, Tay-Sachs disease, Hemophilia A,

Von Hippel-Lindau syndrome, Hereditary hemochromatosis.

b) A child of the member has been identified with an autosomal recessive or X- linked disorder.

c) One or both parents have a first or second-degree relative who is affected by a specific genetic disorder or the first-degree relative has an affected child with an autosomal recessive or X-linked disorder.

d) There is a maternal history of two or more fetal losses.

e) Prenatal carrier panel testing for recessive conditions commonly associated with ethnicity will only be covered for persons of those ethnicities.

   i. African American, Caribbean, West-Indian, West African, Hispanic Caribbean, Mediterranean, Asian, Middle Eastern and other individuals who may be at risk for hemoglobinopathies including sickle cell anemia, alpha and/or beta thalassemia based on ethnicity.

   ii. Ashkenazi disease screen, for individuals of Jewish descent (e.g., Tay Sachs, Canavan's Disease, etc.)**.**

f) The test results will affect reproductive choices.

II. Single and multigene molecular and genomic pathology testing (Cancer)

A. Single and multigene molecular and genomic pathology testing for **cancer management** may be authorized when documentation in the medical record indicates that the member meets **ALL** the following criteria:

1. The test is ordered by a board-certified pathologist, geneticist, or oncologist/hematologist not affiliated with the commercial laboratory performing the testing.
2. Medical records document how the test(s) will lead to increased precision in diagnosis and treatment.

III. Pharmacogenetic testing

A. Pharmacogenetic testing for **drug metabolism** may be authorized when testing for a specific gene biomarker is required by the U.S. Food and Drug Administration (FDA) prior to initiating therapy with a drug as noted in the section heading "Indications and Usage" of the FDA-approved prescribing label. Pharmacogenetic testing for all other indications may be medically necessary when documentation in the medical record indicates that **ALL** the following criteria are met:

1. The member is a candidate for a targeted drug therapy associated with a specific gene biomarker or gene mutation.
2. There is reliable evidence that a specific genetic biomarker or mutation is directly linked to a specific therapeutic drug target.
3. Medical records document how the test results will lead to changes

in treatment decisions and/or health outcome for the member being tested.

IV. Preimplantation genetic diagnosis

Preimplantation genetic diagnosis (PGD), including the oocyte polar body or cleavage stage embryo biopsy procedure, associated genetic testing, and pre- and post-test genetic counseling associated with PGD, may be authorized *(see member benefits)* when the results of the genetic test will impact clinical decision-making or clinical outcome. Please refer to the appropriate plan documents for further information as this may not be a covered benefit. If In-vitro fertilization is a covered benefit, preimplantation genetic diagnosis is not covered.

V. Unauthorized or Investigational Tests

A. Genetic testing for the following conditions is considered NOT medically necessary including but not limited to:

1. Familial Alzheimer Disease.
2. Amyotrophic lateral sclerosis.
3. Age-related macular degeneration.
4. Narcolepsy.
5. Scoliosis.
6. Depression.
7. Mood disorders.
8. Bipolar disorders.
9. Anxiety disorders.
10. Attention deficit hyperactivity disorder.
11. Anorexia nervosa.

B. Brand New Day/Central Health Medicare Plan considers the following tests investigational and will not be authorized (Exceptions may be made on an individual case basis):

1. Cytochrome P450 (including CYP2D6 and CYP2D19);
2. deCODE AF, deCODE Breast Cancer, deCODE Glaucoma, deCODE MI, deCODE PrCa; deCODE T2;
3. EpiSEEK test for epilepsy/seizures;
4. Genetic Addiction Risk Score (GARSPREDX™);
5. Home genetic tests;
6. MTHFR genetic testing;
7. Multigene panels to predict risk of several cancers (e.g., BreastNext; BROCA Cancer Risk Panel; CancerNext; CancerNext Expanded; ColoNext; Coloseq; Invitae Common Hereditary Cancers Panel; Invitae Gastric Cancer Panel; Invitae Hereditary Cancer Syndromes Panel; Invitae Hereditary

Paraganglioma-Pheochromocytoma Panel; Invitae Melanoma Panel; Invitae Melanoma-Pancreatic Cancer Panel; Invitae Multi-Cancer Panel; Invitae Pancreatic Cancer Panel; Invitae Thyroid Cancer Panel; myRisk Hereditary Cancer Panel; OncoGeneDx Comprehensive Cancer Panel; OncoGeneDx Custom Panel; OncoGeneDx High/Moderate Risk Panel; OncoGeneDx Pancreatic Cancer Panel; OvaNext; PancNext; Panexia; VistaSeq Hereditary Cancer Panel);

8. Nuclear encoded mitochondrial genomic sequencing panel;
9. Plasminogen activator inhibitor-1 (PAI-1) for inherited thrombophilia;
10. POLG1 for mitochondrial recessive ataxia syndrome;
11. Single nucleotide polymorphisms for breast cancer (Oncovue, Brevagen);
12. SLCO1B1 testing for statin induced myopathy;
13. SLIT1 testing for Asperger syndrome;
14. Whole exome sequencing, exceptions may be made on a case by case basis to avoid a diagnostic cascade;
15. Whole genome sequencing;
16. Whole mitochondrial genome sequencing.

BACKGROUND

There are numerous commercially available genetic tests, including those used to guide intervention in symptomatic or asymptomatic individuals, to identify individuals at risk for future disorders, to predict the prognosis of diagnosed disease and to predict treatment response. This this policy offers a framework for evaluating the appropriate use and utility of genetic tests, by classifying the types of genetic tests into clinically relevant categories and developing criteria that can be used for evaluating tests in each category.

DEFINITIONS

1. **Authorization:** A decision by Brand New Day/Central Health Medicare Plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary or meets other member contract terms. Sometimes called prior authorization, prior approval or precertification. Brand New Day/Central Health Medicare Plan requires preauthorization for certain services before a member receives them, except in an emergency. Authorization is not a promise that Brand New Day/Central Health Medicare Plan will cover the cost.

2. **Genetic counseling**: is primarily aimed at patients who are at risk for inherited disorders, and experts recommend formal genetic counseling in most cases when genetic testing for an inherited condition is considered. The interpretation of the results of genetic tests and the understanding of risk factors can be difficult and complex. Therefore, genetic counseling assists individuals in understanding the possible benefits and harms of genetic testing, including the possible impact of the information on the

individual's family. Genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

3. **Genetic testing**: Genetic testing involves the analysis of chromosomes, DNA (deoxyribonucleic acid), RNA (ribonucleic acid), genes or gene products to detect inherited (germline) or non-inherited (somatic) genetic variants related to disease or health. Limitations of genetic testing include:
    - The testing methods may not detect all the mutations that may occur in a gene.
    - Genetic testing may identify variants of unknown clinical significance.
    - Genetic testing may not determine the clinical outcome.
    - Different genes can cause the same disease (genetic heterogeneity).
    - A mutation in a gene may cause different phenotypes (phenotypic heterogeneity).
    - Some disease-causing genes may not be identified yet.
    - Genetic testing is subject to laboratory error.

4. **Carrier testing**: A carrier of a genetic disorder has one abnormal allele for a disorder. When associated with an autosomal recessive or X-linked disorder, carriers of the mutation are typically unaffected. When associated with an autosomal dominant disorder, the individual has one normal and one mutated copy of the gene, and may be affected with the disorder, may be unaffected but at high risk of developing the disease later in life, or the carrier may remain unaffected because of the sex-limited nature of the disease. Carrier testing may be offered to individuals who:
    - Have family members with a genetic condition.
    - Have family members who are identified carriers.
    - Are members of ethnic or racial groups known to have a higher carrier rate for a condition.

5. **Germline mutations**: These mutations are present in the DNA of every cell of the body, from the moment of conception. These include cells in the gonads (testes or ova) and could be passed on to offspring.

6. **Somatic mutations**: Somatic variations that occur with the passage of time, and are restricted to a specific cell or cells derived from it. If these variations are limited to cells that are not in the gonads, these variations will not be passed on to offspring.

7. **Pharmacogenomics**: The study of how an individual's genetic makeup affects the body's response to drugs.

CODING CPT CODES

N/A

EVIDENCE-BASED REFERENCES

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POLICY HISTORY

Original Effective Date	April 18, 2018
Revised Date	December 18, 2018 – Updated to include new 2019 markets April 29, 2019 – Annual review, no changes noted February 1, 2020 – Updated to include appropriate 2020 markets December 20, 2020 – Small Group added as applicable product April 15, 2021 – Annual review; template updates, clarified existing criteria, updates to list of unauthorized tests August 19, 2021 – Updated to reflect that MCG criteria must be referenced for Commercial products August 18, 2022 – Annual review March 01, 2023 – Adopted by MA UMC

Approved by the Utilization Management Committee