MN.008.C	Genetic Testing

Title: Genetic Testing **Policy #:** MN.008.C **Type:** Medical **Sub-Type:** Medical Necessity [MN]	**Original Implementation Date:** 10/16/2016 **Version [C] Date:** 7/1/2020 **Last Reviewed:** 6/17/2020

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PRODUCT VARIATIONS

This policy applies to all Health Partners Plans (HPP) product lines unless noted below.

POLICY STATEMENT

Genetic testing may be considered medically necessary when ALL the following criteria are met:

1. The test is either U.S. Food and Drug Administration (FDA) approved or performed in a Clinical Laboratory Improvement Amendment (CLIA)-certified laboratory as a lab developed test
2. Peer-reviewed literature has established the test's analytic validity, clinical validity and clinical utility
3. The member has not previously had the same genetic test, except for genetic testing of cancer cells
4. Pre- and post-test genetic counseling are performed for any individual undergoing genetic testing for any indication
5. The member meets criteria as either symptomatic or asymptomatic, as listed below

Genetic testing of a symptomatic (affected) member may be considered medically necessary when ALL the following criteria are met:

1. The member has symptoms of the suspected disease
2. After history, physical examination, pedigree analysis, counseling from the physician directing care and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain or testing is needed to provide prognostic benefits, such as need for treatment or testing
3. Results of the test will directly impact the affected member by changing the treatments, testing or test frequency offered to the member

4. Reliable medical evidence shows that changes in treatment or testing is likely to improve the health outcome of the member

Genetic testing of an asymptomatic member for screening ***may be medically necessary*** when ALL the following are met:

1. One of the following applies:
    a) There is a pre-symptomatic phase of the suspected disease in which treatments are available.
    b) Testing is in a pregnant member and one of the following:
        i. Test results will impact the decision of a pregnant member to continue with the pregnancy
        ii. Test results will impact the care of the fetus
2. One of the following interventions in the pre-symptomatic phase of the disease is likely to improve outcomes by:
    a) Allowing earlier treatment, which is more effective
    b) Allowing discontinuation of unwarranted interventions
3. The condition has either reduced life expectancy or increased morbidity.
4. The member is at risk for a heritable disease as demonstrated by one of the following:
    a) Family pedigree
    b) Known family mutation
    c) The member is from an ethnic group where there is a known statistically significant increased risk of the disease
    d) When screening of the general population is considered standard of care according to nationally recognized guidelines published by expert professional societies (such as ACOG, ACC, USPSTF, etc.) even in the absence of an increased risk for the disease

For assisted reproductive technology (ART) where either parent is known to have a chromosomal abnormality, results of testing must impact reproductive treatment and planning (e.g., in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), artificial insemination). ART is also known as pre-implantation genetic testing [PGT] or pre-implantation genetic diagnosis [PGD].

Note: ART is applicable only under those products that include infertility benefits.

Panels—including but not limited to multiple genes and/or multiple conditions and in cases where a tiered approach/method is clinically available—may be medically necessary only for the number of genes or tests deemed appropriate based on the criteria listed within this medical necessity policy. For a panel to be covered, every test within the panel must be medically necessary in accordance with the above listed criteria for genetic testing.

Genetic testing is considered ***not medically necessary*** when testing:

- Is not considered standard of care, such as when the clinical diagnosis can be made without the use of a genetic test.

- Is not clinically appropriate for the patient's condition, for example, when it would not change diagnosis and/or management.
- Is performed entirely for nonmedical (i.e., social) reasons, such as paternity testing.
- Is not expected to provide a definitive diagnosis that would obviate the need for further testing.
- Is performed primarily for the convenience of the member, a member's family member, physician or other health care provider.
- Is part of a clinical trial and is not considered usual care.
- Would result in outcomes that are equivalent to outcomes using an alternative strategy, and the genetic test is more costly.

Direct-to-consumer (DTC) genetic testing is considered ***investigational*** because there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this test.

POLICY GUIDELINES

Genetic testing is an eligible service for individuals when the genetic testing is used only for the covered individual's care. Testing of associated family members, who are not insured by HPP, is not eligible for reimbursement.

In the absence of specific information regarding advances in the knowledge of mutation characteristics for a particular disorder, the current literature indicates that genetic tests for inherited disease need only be conducted once per lifetime of the member.

Any state mandates for genetic testing take precedence over this clinical policy.

Physician interpretation and reporting for molecular pathology procedures is considered integral to the primary molecular pathology procedure/laboratory testing and not separately reimbursable.

CODING

The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that *may* be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.

This broad policy encompasses all possible reported codes representing genetic testing including but not limited to the following:

CPT Code	Description
81170-81383	Molecular pathology tests with specific CPT – Tier 1 codes.
81400-81408	Molecular pathology tests with less specific coding – Tier 2 codes.

81479	Unlisted molecular pathology procedure.

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HCPCS Code	Description
N/A	N/A

ICD-10 Code	Description
N/A	N/A

BENEFIT APPLICATION

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the member's benefits, which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the member's applicable benefit contract on the date the service was rendered. Services determined by HPP to be investigational or experimental are excluded from coverage for all product lines.

DESCRIPTION OF SERVICES

The term "genetic testing" covers an array of techniques including analysis of human DNA, RNA, or protein. Genetic tests are used as a health care tool to detect gene variants associated with a specific disease or condition, as well as for non-clinical uses such as paternity testing and forensics. In the clinical setting, genetic tests can be performed to determine the genetic cause of a disease, confirm a suspected diagnosis, predict future illness, detect when an individual might pass a genetic mutation to his or her children, and predict response to therapy. They are also performed to screen newborns, fetuses, or embryos used in in vitro fertilization for genetic defects.

A genetic or genomic test involves an analysis of human chromosomes, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or gene products (e.g., enzymes and other types of proteins) to detect heritable or somatic mutations, genotypes, or phenotypes related to disease and health. There are several different types of genetic tests available today, including:

- **Carrier**: Tells people if they "carry" a genetic change that can cause a disease. Carriers usually show no signs of the disorder; however they can pass on the genetic variation to their children, who may develop the disorder or become carriers themselves
- **Diagnostic**: Identifies a genetic condition or disease that is making or in the future will make a person ill. The results of diagnostic testing can help in treating and managing the disorder
- **Newborn screening:** Used to test babies one or two days after birth to find out if they have certain disease known to cause problems with health and development

- **Pre-implantation**: Done in conjunction with in vitro fertilization to determine if embryos for implantation carry genes that could cause disease
- **Prenatal screening**: Offered during pregnancy to help identify fetuses that have certain diseases.
- **Direct- to Consumer Genetic Test (DTC):** Genetic testing that can be directly accessed by patients outside of the oversight of a healthcare professional.

POLICY BACKGROUND

Genetic test should be cleared or approved by the FDA or performed in a CLIA-certified laboratory. Peer-reviewed literature on the performance and indications for the test should be available. Evaluation of a genetic test focuses on three main principles:

1. Analytic validity, which refers to the technical accuracy of the test in detecting or excluding a mutation
2. Clinical validity, which refers to the diagnostic performance of the test (sensitivity, specificity, positive and negative predictive values) in detecting clinical disease (e.g., If the mutation is present, does the patient have disease?)
3. Clinical utility (i.e., how the results of the test will be used to change management of the patient and whether these changes in management lead to clinically important improvements in health outcomes)

LIMITATIONS OF GENETIC TESTING

- 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 necessarily 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.

DIRECT-TO-CONSUMER GENETIC TESTING

Direct-to-consumer genetic testing allows a person to receive genetic testing outside of the context of a physician-patient relationship. Use of direct-to-consumer testing often may not result in the realization of all the clinical benefits of testing. In addition, it can be difficult to determine the quality of a genetic test sold directly to the public. Some providers of direct-to-consumer genetic tests are not CLIA-certified, so it can be difficult to tell if tests are valid.[5]

Members should be fully informed regarding what the test can and cannot say about their health. Many direct-to-consumer genetic tests do not give a definitive answer regarding whether an individual will develop a given condition, but instead, only provide information about the risk or probability of developing a disease. The medical interpretation of such results is often complex and includes additional patient-specific information, such as prior medical and family history and other factors. This information needs to be incorporated and communicated to the consumer in the appropriate context and in an understandable fashion that is linguistically and culturally appropriate.[4]

DEFINITIONS

Analytic Validity: How well a genetic test predicts the presence or absence of a particular gene or genetic change.

Assisted Reproductive Technology: All fertility treatments in which both eggs and sperm are handled. Includes procedures involving surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory and returning them to the woman's body or donating them to another woman.

Asymptomatic: Showing no signs of a disease or sickness. In some cases, a disease can exist, but the patient shows no signs or symptoms.

Clinical Laboratory Improvement Amendment (CLIA): The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. The goal of CLIA is to ensure accuracy, reliability and timeliness of test results regardless of where the test was performed.

Clinical Utility: Whether a test can provide information about diagnosis, treatment, management or prevention of a disease that will be helpful to a consumer.

Clinical Validity: How well the genetic variant being analyzed is related to the presence, absence or risk of a specific disease.

Heritable Disease: A pathological condition caused by an absent or defective gene or by a chromosomal aberration, also called a hereditary disease.

Pedigree: A chart of an individual's ancestors used in human genetics to analyze Mendelian inheritance of certain traits, especially of familial diseases.

Symptomatic: Showing a change in the body or mind, which indicates that a disease is present.

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making.

POLICY HISTORY

Summary	Version	Version Date
2020 annual policy review. Pre and post genetic counseling added to policy statement.	C	7/1/2020
2019 annual policy review/reissue. Related Policies and Clinical Evidence sections were removed. Language in the coding section was revised.	B	5/01/2019

Edits made as part of HPP's annual review process include minor revisions to language in the Policy Statement section to improve readability; removal of language in the Clinical Evidence section; and updates to the References section.	B	5/1/2018
N/A – This is a new policy bulletin.	A	10/16/2016

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