

MEDICAL ASSOCIATES HEALTH PLANS AND HEALTH CHOICES HEALTH CARE SERVICES POLICY AND PROCEDURE MANUAL

POLICY TITLE: GENETIC TESTING

POLICY STATEMENT: A genetic test is the analysis of human DNA, RNA, chromosomes, proteins or metabolites in order to detect alterations related to an inheritable or acquired disease or disorder. Genetic tests are conducted for a number of purposes, including predicting disease risk, newborn screening, determining clinical management, identifying carriers, and establishing prenatal or clinical diagnoses or prognoses in individuals, families, or populations.

Types of Genetic Tests

- Diagnostic – symptomatic individual to confirm clinical diagnosis
- Carrier – family member, asymptomatic
- Predictive/Presymptomatic – at risk to develop disorder in future
- Predisposition – also at risk but not 100% penetrant (breast cancer)
- Prenatal – fetus at risk for genetic disorder
- Newborn Screening – testing for a panel of treatable biochemical disorders at birth

NOTE: Health insurer shall not release genetic information pertaining to an individual without prior written authorization from the individual. Written authorization shall be required for each disclosure and shall include the person to whom the disclosure is being made.

The following exceptions apply to the requirement:

- (a) Individuals participating in research settings, including individuals governed by the federal policy for the protection of human research subjects.
- (b) Tests conducted purely for research, tests for somatic as opposed to heritable mutations and testing for forensic purposes.
- (c) Newborn screening.
- (d) Paternity testing.
- (e) Criminal investigations.

POLICY:

MAHP considers genetic testing medically necessary to establish a molecular diagnosis of an inheritable disease or disorder when the member meets all of the following criteria:

- The member displays clinical features or is at direct risk of inheriting the mutation in question; **and**
- The result of the test will directly impact the treatment being delivered to the member; **and**
- After history, physical examination, pedigree analysis, genetic counseling by a qualified and appropriately trained practitioner (can be primary care practitioner), and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain.

Genetic testing of children to confirm current symptomatology or predict the adult onset of disease is not considered medically necessary unless direct medical benefit would be lost by waiting until the child has reached adulthood. It is generally accepted that unless useful medical intervention can be offered to children as a result of the testing, formal testing should

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wait until the child is old enough to understand the consequences of testing and request it for him or herself.

MAHP would not provide coverage for the genetic testing if the member has already been diagnosed with the disease or disorder. Testing is also excluded from coverage if the testing is performed primarily for the medical management of other family members who are not covered under the member's benefit plan.

There must be reasonable expectation based on family history, pedigree analysis, risk factors and/or symptomatology that a genetically inherited condition exists.

The genetic molecular testing must be conducted in a laboratory certified, at a minimum, under Clinical Laboratory Improvement Amendments (CLIA).

If appropriate, according to the recognized standards of care, there must be documentation that the patient has received pre-test counseling from a qualified professional and has given informed consent for the test as appropriate. There must also be a plan for providing post-test counseling.

The genotypes to be detected by the genetic test must be shown by scientific valid methods to be associated with the occurrence of the disease and analytical and clinical validity of the test must be established.

Genetic testing will require Pre-certification and will be reviewed for medical necessity utilizing Nationally Developed Criteria and MAHP's current vendor.

References: Nationally Developed Criteria and MAHP's current vendor
Other Major Health Plan Policy Statements

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