


MEDICAL POLICY STATEMENT		
Effective Date	Next Annual Review Date	Last Review / Revision Date
7/20/2004	7/2012	7/2011
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CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which 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.

A. SUBJECT

Genetic Testing

B. BACKGROUND

This document is to establish a policy to review the medical necessity for genetic testing.

Genes have sequence variants (mutations) that may be either benign or deleterious, but it is often unclear as to which variants are harmful. Most genetic tests are made available without any formal review and approval process and without regulatory oversight. Most genetic tests are individual laboratory tests and the individual lab is responsible for validating the tests. Evidence based reviews are critical in determining the validity and utility of genetic testing, but such reviews are lacking for most tests at this point in time. Genetic tests have one or more purposes:

1. Reduction in morbidity or mortality of the person tested
2. Provision of information relevant to the health of the person tested
3. Assistance in reproductive decision making

CareSource has contracted with Hayes Inc., an industry recognized independent review organization that includes consultants who are experts in the field, to gain access to their expertise and evidence-based assessment of genetic testing. Hayes evaluates genetic testing based on:

1. Analytic validity
2. Clinical validity
3. Clinical utility
4. Ethical, legal and social implications

Based on defined standards that require a minimum of 3 or more published studies that clearly establish phenotype/genotype relationship of the condition and one or more published studies on clinical validity, Hayes has established a rating system to grade the clinical appropriateness of genetic tests. Based on the most current and definitive clinical evidence available, genetic tests are graded as defined in the table below:

Rating	Description
A	Established Benefit
B	Some Proven Benefit
C	Potential but Unproven Benefit
D 1	No Proven Benefit – health outcomes
D 2	No Proven Benefit – insufficient evidence

C. POLICY

For Special Needs Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD).

Because of the limited validity and specificity of many genetic tests unproven genetic tests can increase the risks of false positives or negatives and lead to inappropriate decision making. Only genetic tests that have clinical validity and have been documented in clinical studies to be analytically sound will be considered medically necessary.

CareSource considers genetic testing as medically necessary under the following conditions:

1. The member displays clinical features, or is at direct risk of having inherited the mutation in question (presymptomatic); **AND**
2. The result of the test will directly impact definitive treatment being considered for the member; **AND**
3. After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain; **AND**
4. The genetic test requested has reasonable validity and evidence based analytic validity to be considered for an A rating by Hayes Inc.

Genetic tests that are assigned a B rating by Hayes Inc. will not be considered as medically necessary unless there are compelling history and/or physical findings in conjunction with a strong familial predisposition for the condition. B rated tests have only 'some proven benefit' and should not be considered for a general screening test.

Genetic testing may be medically necessary and required for pre-determination for the use of certain pharmacotherapy. Requests for such genetic tests will be authorized only for A or B rated tests that meet the criteria above.

Requests for genetic tests will be accepted only from the treating physician or the member's primary care physician and supporting clinical information must be provided with the request. Requests from providing laboratories will not be authorized without an accompanying request from the treating or primary care physician.

For Medicare LCD Number L24308

<https://www.codemap.com/content.cfm?id=7280&lcd=24308&sid=129>

D. REVIEW / REVISION HISTORY

Date Issued: 7/20/2004

Date Revised: 6/2009, 1/2010

Date Reviewed: 1/2010, 7/2011

E. REFERENCES

1. American Society of Clinical Oncology. Statement of the American Society of Clinical Oncology: Genetic Testing for Cancer Susceptibility. J Clin Oncol. 2003; 21:2397-406.
2. Doherty RA. National Institutes of Health consensus development conference statement on genetic testing for cystic fibrosis. J Med Screen. 1997;4(4):179-180.
3. Whittaker L. Clinical applications of genetic testing: Implications for the family physician. Am Fam Physician. 1996; 53(6):2077-2084.

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