



Clinical Review Criteria Related to Genetic Testing

I. Criteria for Approval

- A. Due to the rapidly evolving field of genetic tests, this policy is not inclusive of all known genetic tests.
- B. MHI utilizes evidence-based research or eviCore Criteria when available for specific testing. Clinical policy is not intended to pre-empt the judgement of the reviewing medical director.
- C. In addition to :B” above, all of the criteria must be met to satisfy coverage requirements for genetic testing:
 - 1. The test is to be used for the diagnosis or determination of risk for a suspected disease for a plan member who is either:
 - a. Symptomatic (e.g., exhibiting signs and symptoms of a disease), or;
 - b. Pre-symptomatic, but at an increased risk of disease, as determined by current scientific literature which may be due to family history, ethnicity, or gender.
 - 2. The results of the test will be clinically useful to the medical management of the patient (e.g., initiate a new course of therapy, alter an existing therapy or determine level of surveillance).
 - 3. There is a sufficient amount of evidence in the scientific literature to support the validity and predictive accuracy of the test.
 - 4. The patient/family has consulted with a genetic practitioner to discuss their questions and concerns about the test and how the results will be used. Documentation of that visit must be included with the request.
 - 5. Prior written consent has been obtained.
 - 6. All testing must be at a contracted facility when available.
 - 7. In regard to panel testing, if any tests included in the panel do not meet criteria the entire panel may be denied.
- D. The above criteria apply to all genetic testing whether or not disease-specific criteria are available.

II. What is not Covered

- A. Genetic Testing performed that does not meet the above criteria.
- B. Repeat genetic testing is not covered.



- C. MHI does not cover direct-to-consumer genetic testing, including, but not limited to, “home-testing kits” or genetic tests ordered by patients over the telephone or Internet. The American College of Medical Genetics recommends that genetic testing should only be provided by a qualified health care professional who is responsible for both ordering and interpreting the genetic tests as well as pretest and post-test counseling of individuals and families regarding the medical significance of the test results and the need for follow-up, if any.

REFERENCES

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

Medicare Local Coverage Determination (LCD) L24308, Genetic Testing
<https://www.cms.gov/medicare-coverage-database/details/lcd> last accessed 6/10/15

Memorandum Report: Coverage and Payment for Genetic Laboratory Tests; Office of Inspector General, OEI-07-11-00011, June 2012
<http://oig.hhs.gov/oei/reports/oei-07-11-00011.pdf>

Genetic testing insurance coverage trends: a review of publicly available policies from the largest US payers. Michael Graf, Denise Needham, Nicole Teed and Trisha Brown. Personalized Medicine, Vol 10, No 3, Pages 235-243