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. Minuteman Health, Inc. (MHI) utilizes evidence-based research or McKesson InterQual© 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.
8. Genetic testing requests may be submitted by the inplan provider and/or the inplan lab. Clinical notes from the ordering physician must be attached. Anything from an out of area lab must be submitted by the inplan provider who ordered the test.

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. Genetic tests for an inherited disease need only be done once per lifetime of the member, unless there is documentation of recent advances in the knowledge of mutation characteristics of a particular disorder.

C. Genetic testing of the individual’s genome for inherited diseases using panels of genes, including but not limited to whole genome and whole genome exome sequencing, is considered investigational and not medically necessary.

D. Genetic Testing that is used to inform the medical management of an individual’s family member is not covered.

E. Genetic Testing to confirm a diagnosis that can be established through other clinical evaluations is not covered.

F. Repeat genetic testing is not covered. 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.

G. Genetic Testing for the following conditions is considered NOT medically necessary:
   - Familial Alzheimer Disease
   - Amyotrophic lateral sclerosis (ALS)
   - Age-related macular degeneration
   - Narcolepsy
   - Kabuki Syndrome
   - Scoliosis
• Stickler Syndrome
• Testing to determine fetal sex

III. References

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

Medicare Local Coverage Determination (LCD) L24308, Genetic Testing

Memorandum Report: Coverage and Payment for Genetic Laboratory Tests; Office of Inspector General, OEI-07-11-00011, 2/15/17


IV. Summary of Changes

06/29/2017
• I., Criteria for Approval: Added 8., Genetic testing requests may be submitted by the in-plan provider and/or the in-plan lab. Clinical notes from the ordering physician must be attached. Anything from an out of area lab must be submitted by the inplan provider who ordered the test.
• Multiple reasons for non-coverage
• Once per lifetime testing for an inherited disease
• Under II., What is Not Covered: Removed the list of genetic tests that was located at the end of the policy
• Added disclaimer, updated references and last accessed dates

V. Review Dates

HNE Review Dates: 11/10/2015, 6/14/16, 5/9/17
MHI Review Dates: 2/2/2016, 6/30/16, 10/20/2016, 06/29/2017
Medical Guideline Disclaimer
The treating physician or primary care provider must submit to Minuteman the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Minuteman will not be able to properly review the request for prior authorization. The clinical review criteria expressed herein reflects how Minuteman determines whether certain services or supplies are medically necessary. Minuteman established the clinical review criteria based upon a review of currently available clinical information (including, without limitation clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). Minuteman expressly reserves the right to revise these criteria as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by Minuteman. If there is a discrepancy between this policy and a member’s benefit program, the benefit program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the federal government or the Centers for Medicare & Medicaid Services (CMS). Minuteman has adopted the herein policy in providing management, administrative and other services to its members.