Last Review Date: 09/21

Genetic Testing for Health Plan Members Policy

PURPOSE

The purpose of this policy is to describe the decision-making process when performing an evaluation of a wide range of different Genetic Testing to determine if a request is Medically Necessary.

POLICY

It is policy that Genetic Testing is a covered benefit when Medically Necessary criteria is met.

SCOPE

This policy applies to Sutter Health, and any legal entity for which Sutter Health or an affiliate is the sole member or controls at least 51% of the voting power if that entity performs delegated Utilization Management (UM) for specific benefit/services, as indicated in Health Plan contract, for Health Plan Members on behalf of any Sutter Bay Medical Foundation and Sutter Valley Medical Foundation (herein after referred to as "Sutter").

Sutter is not responsible for reviewing and/or making a final determination on a request that has been identified as Health Plan responsibility to review.

DEFINITIONS

Genetic Testing is the use of a laboratory test to look for genetic variations associated with a disease.

Health Plan means health care service plans, Health Maintenance Organizations (HMOs), and other purchasers of covered services that arrange for the provision of health care services for their Members.

Medically Necessary means health care services or supplies needed to diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.

Member is a person covered under a Health Plan, either the enrollee or eligible dependent.

Qualified Health Care Professional (QHCP) is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who

performs a professional service within their scope of practice and independently reports that professional service.

Utilization Management (UM) means the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provisions of the applicable health benefits plan, sometimes called 'utilization review'.

PROCEDURE

A. Genetic Testing service requests are considered Medically Necessary by the reviewing QHCP, when all of the following criteria are met:
    1. There is a reasonable deduction based on family history, risk factors, and symptomatology that a genetically inherited condition exists.
    2. Diagnostic results from physical examination, family history, and standard testing are inconclusive and a definitive diagnosis is uncertain.
    3. The clinical benefit of all requested Genetic Testing is established (including all gene mutations in a panel test, if applicable). This is established when:
        a. Genetic test results will guide decisions regarding disease prevention, treatment, or management. An example of this would be when a test result will help the Member to avoid unnecessary treatment for an incorrect diagnosis.
        b. Treatment decisions could not otherwise be made without the results of the genetic test.
    4. Genetic Testing is performed in a Clinical Laboratory Improvement Amendments (CLIA) - approved laboratory.
    5. There is evidence in the published peer-reviewed medical literature that the test is clinically valid and can be adequately interpreted.

B. Genetic Testing is considered Medically Necessary for indications other than determining risk or establishing a diagnosis for a genetically inherited disease (e.g. genotyping for drug selection and dosing) when all of the following criteria are met:
    1. Results of Genetic Testing will be used to guide management decisions.
    2. Diagnostic results from physical examination and standard testing are inconclusive.
    3. Health outcomes are improved as a result of treatment decisions based on genetic test results as supported by evidence in the peer-reviewed scientific literature.
    4. Testing is performed in a CLIA-approved laboratory.

C. In the absence of specific advances in the knowledge of the gene variant for a particular disorder, genetic tests for inherited conditions only need to be conducted once in a

Member's lifetime, unless changes in technology or treatments indicate that test results or a Member's outcomes would change as a result of a repeat test.

D. Members must receive pre and post-test genetic counseling from a qualified professional when testing is performed to diagnose or predict susceptibility for inherited diseases, due to the complexity of interpreting genetic test results. Benefits and risks of Genetic Testing must be fully disclosed to Members prior to testing.

E. Milliman Care Guidelines (MCG®™) should be used to facilitate decisions during review of medical necessity of genetic test requests.

F. Global genetic tests to determine risks, including tests distributed directly to consumers (e.g. 23andMe®) and genomic "next generation sequencing" panels (e.g. Myriad's myRisk®) are not considered Medically Necessary, because they do not meet the criteria that is outlined above. However, individual components of the panels might be considered Medically Necessary upon review when performed for specific indications as noted above.

REFERENCE

- Centers for Disease Control and Prevention (CDC): Evaluating Genomic Tests.
- Centers for Disease Control and Prevention (CDC): Genomics and Precision Health
- National Health and Medical Research Council: Medical Genetic Testing - Information for Health Professionals
- MCG®™ Care Guidelines, 2021.

ATTACHMENTS

None