Subject: Genetic Testing*

Effective Date: October 22, 2013

Department(s): Utilization Management

Policy: Genetic testing is reimbursable under QualCare, provided that conditions in the Procedure below are met.

Objective: To ensure proper and consistent reimbursement and appropriate use of specific diagnostic procedure.

Procedure: Genetic testing is performed for purposes of diagnosing disorders due to germline (inherited) or somatic (non-inherited) genetic alterations; prediction of risk of a future disorder; detection of the carrier state of a known genetic disorder; prognostic testing for a diagnosed disease; identification of genetic variants that alter response to treatment or an environmental factor. For each category of testing the following general criteria are used to assess medical necessity.

Genetic counseling- Pre-testing and post-testing genetic counseling is reimbursable for members recommended for genetic testing.

Genetic testing requested must be cleared or approved by the U.S. Food and Drug Administration, or performed by a Clinical Laboratory Improvement Amendment (CLIA) –certified laboratory.

If the genetic test category criteria below are not satisfied for a specific requested test, it will be considered investigational or not medically necessary.
Criteria according to test category:

A. **Diagnostic**-

1. The history and/or physical exam indicates features of an inherited mutation, or there is risk of an inherited mutation.

2. Pedigree analysis and genetic counseling support the risk of an inherited mutation for which an association with a disorder is established.

3. Conventional diagnostic testing for the suspected condition has not provided a definitive diagnosis.

4. The genetic testing results will have direct impact on the clinical management of the member.

B. **Prediction of risk**-

1. The genetic variant to be tested for has an established association with development of the disorder.

2. Testing will result in surveillance and/or management interventions that will improve health outcomes.

3. Genetic counseling as per section A above.

C. **Carrier testing**-

1. The genetic variant to be tested for has an established association with the disorder.

2. The disorder is associated with adverse effects on health.

3. Test results will impact reproductive decision making.

4. Genetic counseling as per section A above.
D. Prognostic testing-

1. The natural history of the condition is known to be impacted by the genetic variant.

2. Test results will lead to changes in clinical management.

3. Genetic counseling as per section A above.

E. Genetic variants altering treatment response

1. There is an established association for the genetic variant with adverse drug effects or efficacy that will impact clinical management to improve health outcomes.

   OR

2. There is an established association for a genetic variant to a specific drug response for which the member is a treatment candidate.

The number of commercially available genetic tests is very large and increasing at a rapid pace. Therefore this policy will not list all available genetic tests but provides examples of those considered medically necessary when the category criteria are met. These are listed below. Some tests may fall into more than one category.

Genetic testing for diagnosis-
- Familial adenomatous polyposis coli (APC)
- Charcot-Marie Tooth Neuropathy (PMP-22)
- Catecholaminergic polymorphic ventricular tachycardia
- Ehlers-Danlos syndrome
- Familial Mediterranean fever (MEFV)
- Factor V Leiden—see also medical policy on Infertility Diagnostic testing
- Fragile X
- Hereditary hemochromatosis (HFE)
- Hereditary non-polyposis colorectal cancer (HNPCC)—see medical policy on Colorectal Cancer Screening
- Hereditary Pancreatitis (PRSS1)
- Long QT syndrome
- Li-Fraumeni syndrome (TP53)
- Marfan syndrome (FBN1)
• Maturity onset diabetes of the young (MODY)
• Neurofibromatosis
• Primary dystonia (DYT1)
• Spinal muscular atrophy
• Shox-related short stature

Prediction of risk testing-

• CADASIL
• Cadherin-1 for hereditary diffuse gastric cancer
• Huntington Disease
• Hereditary Pancreatitis (PRSS1)
• Hypertrophic cardiomyopathy
• Hereditary hemochromatosis
• Long QT syndrome

Carrier-testing-

• Ashkenazi Jewish testing panel
• Cystic fibrosis
• Fragile X
• Neurofibromatosis
• Osteogenesis Imperfecta
• Spinal muscular atrophy

Prognostic testing-

• Breast cancer gene expression testing - see separate medical policy – Breast Cancer gene Expression Assays

Genetic testing for altered treatment response-

• KRAS for colon cancer
• CYP2C19 polymorphism testing for the use of clopidogrel (Plavix)

Note- this policy does not address molecular pathology (CPT code range 81400-81408) analysis for genetic alterations in tissue, cytogenetic testing or pre-implantation genetic diagnosis.
CPT Codes: Specific gene analysis testing can be reported from the range 81200-81355, however not all tests in this range may be considered medically necessary. For example, CPT code 81256-hemochromatosis gene analysis for common variants would be considered medically necessary if criteria in sections A or B above are met. Alternatively, cytochrome P450 enzyme CYP2D6 gene analysis when used for tamoxifen treatment –CPT 81266- is considered investigational as the current literature does not meet the criteria in sections D and E above.

Codes outside this range may be used if there is not a specific code for the testing.

References:


American College of Medical Genetics and Genomics-Policy Statement: Points to consider in the clinical application of Genomic Sequencing. Accessed online at ACMG.org on 10/03/13.


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*Consistent with Summary Plan Description (SPD). If there is discordance with the SPD, provisions of the SPD take precedence.