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.

TABLE A: Genetic testing for diagnosis considered medically necessary when ALL of the above criteria in section A1-A4 are met

TEST	CODES	TEST	CODES	TEST	CODES	TEST	CODES
Alpha-1 antitrypsin deficiency	81332	*Familial adenomatous polyposis coli(APC)	81201, 81202, 81203	Hereditary hemochromatosis(HFE)	81256	Muscular dystrophies (DMD, BMD, EDMD, DM1, DM2, SM)	81161 81400 81401 81403 81404 81405 81406 81408 S3853
Canavan Disease	81200	Fragile X	81243 81244 81470 81471	*Hereditary non-polyposis colorectal cancer(HNPCC)-	81288,81292-81301, 81317-81319	Neurofibromatosis	81405 81406
Catecholaminergic polymorphic ventricular tachycardia	81413, 81414 81405 81408	*Factor V Leiden F2-hereditary hypercoagulability	81241 81240	Hereditary Pancreatitis(PRSS1)	81404	Niemann-Pick Disease	81330
Charcot-Marie Tooth Neuropathy(PMP-22)	81324,81325, 81326	Familial Mediterranean fever(MEFV)	81402 81404	Long QT syndrome	81413 81414 81406	Nuclear mitochondrial genes	81440
Cystic	81220	Familial	81401	*Li-	81405	Primary	81400

fibrosis	81221 81222 81223 81224	hypercholesterolemia (homozygous and heterozygous)	81405 81406	Fraumeni syndrome(TP53		dystonia(DYT1)	81404 81405
DFNB1 nonsyndromichearing loss and deafness	81430 81431 81254	Fragile X	81243 81244 81470 81471	Marfan syndrome(FBN1)	81410 81411 81405 81408	Retinoblastoma	S3841
Ehler-Danlos syndrome	81410 81411	Gaucher Disease	81251	Maturity onset diabetes of the young(MODY)	81403 81404 81405 81406	Rett syndrome	81302 81303 81304
Spinal muscular atrophy	81400 81404 81405	Shox-related short stature	81405	Tay Sachs disease	81255 81406	Von Hippel-Lindau disease	S3842
21-hydroxylase deficiency	No specific code	Connexin 26 and 30 gene for congenital hearing loss	81252 81253 81254				

*See related medical policies on Genetic testing for susceptibility to Colorectal cancer, Recurrent Pregnancy–Diagnostic, Topographic Genotyping, and Pre-implantation Genetic Diagnosis.

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.

Table B: Genetic testing for prediction of risk considered medically necessary when criteria in section B1-B3 above are met.

TEST	CODES	TEST	CODES	TEST	CODES	TEST	CODES
CADASIL (Notch-3)	No specific codes	Connexin 26 gene for susceptibility to	S3844	Hereditary hemochromatosis(HFE)	81256	Huntington Disease	81401

Cadherin-1 for hereditary diffuse gastric cancer	81406	Hereditary Pancreatitis(PRSS1)	81404	Hypertrophic cardiomyopathy	81403	Long QT syndrome-known familial mutation	No specific codes

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.

Table C: Genetic testing for carrier status considered medically necessary when criteria in section C1-C3 above are met.*

TEST	CODE	TEST	CODE	TEST	CODE	TEST	CODE
Ashkenazi Jewish testing panel	81412	Cystic Fibrosis	81220 81221 81222 81223 81224	Fragile X	81243 81244 81470 81471	Neurofibromatosis	81405 81406
Osteogenesis Imperfecta	81408	Sickle Cell Disease	S3850	Spinal Muscular Atrophy	81400 81404 81405		

*See related medical policy on Preconception Genetic Carrier Screening.

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.

*See QualCare Medical Policy on Breast Cancer gene Expression Assays.

E. Genetic variants altering treatment response (pharmacogenetics)-

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, including those noted to be clinically necessary prior to initiating therapy with the drug as noted within the section heading "Indications and Usage" of the U.S. Food and Drug Administration (FDA)-approved prescribing label. In addition, the clinical utility of a gene biomarker and specific drug target will be considered validated by a National Comprehensive Cancer Network Guidelines™ [NCCN Guidelines™]category 1, 2A or 2B level recommendation and is reimbursable.

Table E: Genetic testing for altered treatment response considered medically necessary when criteria in E1or E2 are met.

TEST	CODES	TEST	CODES	TEST	CODES	TEST	CODES
ALK for non-small cell lung	81401	BRAF for colon cancer and melanoma	81210	EGFR for non-small cell lung	81235	KRAS	81275 81276

cancer				cancer			

3. Pharmacogenetic screening in the general population is **not** considered medically necessary.
4. Multigene pharmacogenetics genotyping assays (such as metabolism of a wide range of therapeutic drug classes) is not reimbursable as it is considered experimental, investigational or unproven.

NOTE:
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. Some tests may fall into more than one category.

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References for specific conditions available at genetic Testing Registry, http://www.ncbi.nlm.nih.gov/gtr/

Drafted By/Date: M. McNeil, MD 10/11/13
Approved By/Date: QM Committee 10/22/13

Revised By/Date: MMcNeil, MD 12/06/17
Approved By/Date: QM Committee 12/19/17

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