MEDICAL COVERAGE POLICY	
SERVICE: Genetic Testing	
Policy Number:	**037**
Effective Date:	**09/01/2023**
Last Review:	**07/27/2023**
Next Review Date:	**07/27/2024**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Genetic (Genomic) Testing

PRIOR AUTHORIZATION: Required.

POLICY: Not all Plans cover non-mandated genetic/genomic testing. Please check the Plan documents for coverage limitations:

For Commercial and ASO plans please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination).

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

Where genetic/genomic testing is a benefit …
All genetic testing should be used for predictive, diagnostic or prognostic disease situations. Genetic testing for non-medical purposes, such as paternity, ancestry. genome-wide association studies (GWAS), and non-disease traits, such as baldness, eye color, are NOT medically necessary. Most genetic testing is once per lifetime or once per pregnancy (prenatal testing). When possible, testing should be performed at a contracted/network laboratory. If a non-contracted (out-of-network) laboratory is required, the member should be informed of difference in out-of-pocket charges. In addition, the provider should document the need for an out-of-network laboratory, e.g., targeted testing in another family member, gene not offered at contracted/network laboratory, etc. Finally, **medical necessity must be documented for every request.**

I. **For Medicaid plans**, please confirm coverage as outlined in the Texas Medicaid TMPPM. Then use InterQual® if further guidance is needed.

II. **For Commercial and Self-funded plans,** please confirm coverage and then use InterQual® for further guidance as needed

III. If an appropriate criterion set is not found in the resources above, the request will be processed using the overarching principles that follow:

Coverage for genetic/genomic testing and/or screening may be medically necessary when all

of the following criteria are met:

1. Appropriate genetic counseling occurs before and after testing.
   Members must have genetic counseling by a practitioner who has expertise in the genetic aspects of the condition being evaluated and who will discuss the results of the test and their clinical implications. Documentation of the counseling will accompany the preauthorization request.

   Evidence of genetic counseling should include, but is not limited to the following:
   - discussion of the types of test results (positive, negative, uncertain findings) that could be obtained,
   - identifying problems that are known to occur due to test methodology,
   - evaluation of the members risk for the specific disorder, the differential diagnosis, inheritance patterns, penetrance, variable expressivity and genetic heterogeneity
   - evidence of informed consent
   - a plan for posttest counseling

   Note: genetic counseling must be performed by practitioners NOT employed by testing companies due to conflict of interest.
2. There must be a reasonable expectation, based on family history, pedigree analysis, risk factors, and/or symptomatology, that a genetically inherited or acquired condition exists and the member displays clinical features, or is at direct risk of inheriting the mutation in question (pre-symptomatic) or comes from the appropriate disease-specific population. A three-generation pedigree **MUST** accompany the request for testing, where appropriate, to aid in coverage determination.
3. Knowledge of the presence or absence of the condition would **DIRECTLY** affect medical care of the member:
   a. The disease must be treatable and/or preventable AND
   b. The test results will lead to a change in the intensity of surveillance frequency and /or treatment for that disease.
4. There are often options for single gene testing, multiple gene testing and panel testing.
   a. If a single gene test meets other criteria and will answer the clinical question, SHWP will generally find such a test medically necessary.
   b. If a multigene panel is requested, there must be evidence that there are two or more genes responsible for a specific condition or that there is the possibility that several genes can cause multiple diseases within the family. Most of the genes on the panel should be plausible explanations for the disorder observed
   c. The smallest plausible gene panel will be authorized, to decrease variants of unknown significance. Broad multi-gene-based panels are not medically necessary when a more focused study is available.
   d. If a panel is chosen, the list of genes should be on the request and in the accompanying documentation to explain why that particular panel was chosen
   e. Multiple panels tested at the same time are not medically necessary
5. The test is performed in a CLIA certified laboratory, AND is FDA approved, AND is **recommended by recognized, national guidelines.**
6. The request MUST be submitted with the SWHP “Statement of Medical Necessity for Genetic Testing” located at the end of this policy, OR other documentation such as clinical documentation that addresses all of the questions in that document. In particular there must be a clear statement that explains how the test results will improve the medical management of the patient’s condition. The statement “… is medically necessary” does NOT meet the criteria since it does not explain the change in management or surveillance that would take place if the test is positive and if it were negative.

Note: Genetic/genomic testing for specific germline conditions or mutations is limited to once per lifetime for the specific mutation or panel. Exceptions may be considered if there is a change in guidelines for genes that have not been tested or need reinterpretation of results.

IV. Tests with specific policy guidance:

A. **Cell-free DNA screening tests for microdeletions** (CPT 81422) have **NOT** been validated and are not deemed medically necessary.

B. **Whole Genome Sequencing** may be medically necessary to identify or confirm the genetic etiology of a known or unknown disorder in clinically affected neonatal and pediatric patients. In most cases whole genome sequencing will not be found medically necessary unless more targeted studies have failed to identify a mutation.

V. Exclusions:

The following are examples of services that are not covered:

1. Routine, ongoing, or long-term genetic counseling.
2. Genetic testing to determine the paternity of a child.
3. Genetic testing to determine the sex of the child.
4. General population screening for genetic disorders (e.g., cystic fibrosis).

VI. Other information

Genetic Test codes with Prior Authorization (PA) diagnosis specifications:

81161	DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	No PA if Prenatal Dx present
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)	No PA if Prenatal Dx present
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; known familial variants	No PA if Prenatal Dx present
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants	No PA if Prenatal Dx present
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; full gene sequence	No PA if Prenatal Dx present
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; intron 8 poly-T analysis (eg, male infertility)	No PA if Prenatal Dx present
81229	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants	No PA if Prenatal Dx present
81238	F9 (coagulation factor IX) (eg, hemophilia B)	No PA if Prenatal Dx present
81243	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis	No PA if Prenatal Dx present
81259	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (eg, Southeast Asian, Thai, Filipino,	No PA if Prenatal Dx present
81302	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; full sequence analysis	No PA if Prenatal Dx present

81303	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; known familial variant	No PA if Prenatal Dx present
81304	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; duplication/deletion variants	No PA if Prenatal Dx present
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysi	No PA if Prenatal Dx present
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence	No PA if Prenatal Dx present
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)	No PA if Prenatal Dx present
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia)	No PA if Prenatal Dx present
88267	Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding	No PA if Prenatal Dx present
88269	Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding	No PA if Prenatal Dx present

Definitions:

First-degree relative – a blood relative with whom an individual shares approximately 50% of his or her genes, including parents, full siblings and children

Second-degree relative – a blood relative with whom an individual shares approximately 25% of his/her genes, including grandparents, grandchildren, aunts, uncles, nephews, nieces and half- siblings.

MANDATES: None

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
HCPCS Codes:	
ICD-10:	
ICD-10 Not covered:	

CMS: There is no NCD.

POLICY HISTORY:

Status	Date	Action
New	08/01/2010	New policy

Reviewed	12/06/2011	Reviewed.
Reviewed	12/06/2012	Revised. BRCA added. Criteria revised
Reviewed	11/14/2013	BRCA criteria updated.
Reviewed	04/24/2014	Minor updates made.
Reviewed	07/02/2015	Extensively re-written
Reviewed	09/08/2016	Clarified criteria; added pharmacogenetics section.
Update	06/27/2017	Updated criteria for NIPT.
Reviewed	08/22/2017	Set most testing limit to once per lifetime. Updated criteria. New request form.
Minor correction	11/28/2017	Removed discussion regarding FIT-DNA stool testing
Reviewed	06/26/2018	Significant revision of several coverage topics.
Addition	02/12/2019	InterQual® to be used instead of policy for five codes.
Major revision	09/26/2019	Policy re-written to direct reviews to InterQual®
Reviewed	05/28/2020	Redesign incorporating LCD and Palmetto GBA MolDX
Reviewed	04/22/2021	
Reviewed	05/26/2022	Reviewed without changes
Updated	07/27/2023	Re-wrote criteria referring primarily to IQ or Medicare/Medicaid guidelines

REFERENCES: The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence surrounding genetic testing and may modify this policy at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Calderon-Margalit R, Paltiel O. Prevention of Breast Cancer in Women Who Carry BRCA1 or BRCA2 Mutations: A Critical Review of the Literature. Int J Cancer. 2004 Nov 10;112(3):357- 64.
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3. National Cancer Institute. Genetics of Colorectal Cancer (PDQ®). Last Modified 03/24/2006. http://nci.nih.gov/cancertopics/pdq/genetics/colorectal/healthprofessional.
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8. High frequency of MYH gene mutations in a subset of patients with familial adenomatous polyposis. Gastroenterology. 2004 Jun; 126(7): 1681-5.
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11. Richards CS, Bradley LA, Amos J. et al. ACMG Technical Standards and Guidelines for CFTR Mutation Testing 2006 Edition. http://www.acmg.net/Pages/ACMG_Activities/stds¬2002/cf.htm

12. Moskowitz SM, Gibson RL, Sternen DL, Cheng E, Cutting GR. CFTR-Related Disorders. August 2005. Available at: www.genetests.org.
13. ACOG Committee Opinion 690, March 2017: Carrier screening in the age of genomic medicine
14. ACOG Practice Bulletin 102, March 2017 (reaffirmed 2016): Management of stillbirth
15. American College of Obstetricians and Gynecologists Committee Opinion No 691: Carrier screening for genetic conditions carrier screening for genetic conditions 2017
16. American College of Medical Genetics, Points to consider in the clinical application of genomic sequencing Genet Med 2012 Aug 14(8):759-61 Policy statement whole exome and whole genome testing
17. American College of Medical Genetics and Genomics Practice Guidelines

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SWHP Genetic Testing Prior Authorization Form

6/23/2022 version

Date of Request: ___/____/_____ Date, if procedure has been scheduled: ___/____/_____

Insured Member Information:

Name: _____ SWHP ID #: _____ Date of birth: ___/____/_____

Gender: M F

Provider Information:

Requesting Provider Name: _____ NPI: _____

Requesting Provider Address: _____

Office Contact Person: _____Telephone #: _____ Fax #: _____

Supplying Provider Information:

Supplying Provider Name: _____ NPI: _____

Supplying Provider Address: _____

Office Contact Person: _____Telephone #: _____ Fax #: _____

Genetic Test Information:

Requested Genetic Test:

☐	BRCA 1 and 2, HBOC	☐	Breast expression RNA	☐	Hereditary Hemochromatosis Gene Analysis
☐	Colon Cancer Lynch Syndrome (list genes)	☐	Cystic Fibrosis	☐	Fragile X Syndrome
☐	Huntington's Disease	☐	Janus Kinase 2(JAK2)	☐	Chromosomal Microarray
☐	Familial Adenomatous Polyposis /Assoc. Polyposis Conditions	☐	Cardiology Gene Expression (AlloMap)	☐	NIPS (non-invasive prenatal screen)
☐	Multigene panel: Please list genes requested				

ICD-10 Codes:				

CPT Code	Test	CPT Code	Test

Medical Information:

Provide information to justify each test requested. (May attach dictation if it contains requested information.)

1) Why is the test appropriate for the patient? _____

_____

_____

_____

2) Does the beneficiary exhibit clinical features of the mutation in question? If not, has a genetic variant been identified in a family member? (May attach dictation if it contains requested information.)

_____

_____

_____

3) Has the patient given informed consent to the genetic test? ☐Yes ☐No

4) Has genetic counseling occurred? ☐Yes ☐No By whom? _____

5) What is the validity of testing and is the testing scientifically sound? (reference or link)

_____

_____

6) Is the patient willing to undergo the increased interventions that may potentially be required because of testing?

☐Yes ☐No

7) How will the results specifically impact or alter medical management of the patient?

_____

_____

8) What is the cost of the test? _____

9) Is multigene panel testing more cost efficient than the combined reimbursement for single codes? _____

Signature of Requesting Provider: _____Date: ___/____/_____