Carrier Testing Panels for Genetic Diseases (for Ohio Only)

Policy Number: CS151OH.B
Effective Date: November 1, 2023

Instructions for Use

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Related Policies

- Cell-Free Fetal DNA Testing (for Ohio Only)
- Preimplantation Genetic Testing (for Ohio Only)

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Pre-test genetic counseling is strongly recommended in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person.

Carrier Screening is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Molecular Diagnostics:

- Bloom's Syndrome
- Canavan Disease
- Carrier Screening (Genetic) for General Population
- Cystic Fibrosis and Cystic Fibrosis Transmembrane Regulator (CFTR) Disorders
- Familial Dysautonomia (FD)
- Fanconi Anemia (FA)
- Gaucher Disease
- Glycogen Storage Disease Type I (GSDI)
- Maple Syrup Urine Disease (MSUD)
- Mucolipidosis IV (MLIV)
- Niemann-Pick Disease Type A and B
- Tay-Sachs Disease

Click here to view the InterQual® criteria.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service.

Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0400U	Obstetrics (expanded carrier screening), 145 genes by next1generation sequencing, fragment analysis and multiplex ligation1dependent probe amplification, DNA, reported as carrier positive or negative
81412	Ashkenazi Jewish associated disorders (e.g., Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1
81443	Genetic testing for severe inherited conditions (e.g., cystic fibrosis, Ashkenazi Jewish-associated disorders [e.g., Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (e.g., ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)
81479	Unlisted molecular pathology procedure

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Laboratories that perform genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988. More information is available at: https://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm. (Accessed April 20, 2022)

References

Ohio Administrative Code/5160/Chapter 5160-1-01. Medicaid medical necessity: definitions and principles. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-01. Accessed June 14, 2022.

Policy History/Revision Information

Date	Summary of Changes

11/01/2023	**Title Change**
	• Previously titled *Carrier Testing for Genetic Diseases (for Ohio Only)*
	Coverage Rationale
	• Revised language to indicate:
	  ○ Pre-test genetic counseling is strongly recommended in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person
	  ○ Carrier Screening is proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Molecular Diagnostics:
	  ▪ Bloom's Syndrome
	  ▪ Canavan Disease
	  ▪ Carrier Screening (Genetic) for General Population
	  ▪ Cystic Fibrosis and Cystic Fibrosis Transmembrane Regulator (CFTR) Disorders
	  ▪ Familial Dysautonomia (FD)
	  ▪ Fanconi Anemia (FA)
	  ▪ Gaucher Disease

Date	Summary of Changes
	▪ Glycogen Storage Disease Type I (GSDI) ▪ Maple Syrup Urine Disease (MSUD) ▪ Mucolipidosis IV (MLIV) ▪ Niemann-Pick Disease Type A and B ▪ Tay-Sachs Disease **Applicable Codes** • Added CPT code 0400U **Supporting Information** • Updated *References* section to reflect the most current information • Removed *Definitions*, *Description of Services*, and *Clinical Evidence* sections • Archived previous policy version CS151OH.A – P

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.