Cell-Free Fetal DNA Testing (for Ohio Only)

Policy Number: CS085OH.E
Effective Date: August 1, 2025

➲ Instructions for Use

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Related Policies

- Chromosome Microarray Testing (Non-Oncology Conditions) (for Ohio Only)
- Preimplantation Genetic Testing and Related Services (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

Cell-Free Fetal DNA testing using maternal plasma to determine fetal genotype is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Molecular Diagnostics, Noninvasive Prenatal Screening (NIPS).

Click here to view the InterQual® criteria.

Genetic Counseling

Genetic counseling is strongly recommended prior to fetal screening or prenatal diagnosis in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person.

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
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood
0488U	Obstetrics (fetal antigen noninvasive prenatal test), cell-free DNA sequence analysis for detection of fetal presence or absence of 1 or more of the Rh, C, c, D, E, Duffy (Fya), or Kell (K) antigen in alloimmunized pregnancies, reported as selected antigen(s) detected or not detected

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CPT Code	Description
0489U	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA sequence analysis of 1 or more targets (e.g., CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants, and relative mutation-dosage analysis based on molecular counts to determine fetal inheritance of maternal mutation, algorithm reported as a fetal risk score for the condition (e.g., cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia)
0494U	Red blood cell antigen (fetal RhD gene analysis), next-generation sequencing of circulating cell-free DNA (cfDNA) of blood in pregnant individuals known to be RhD negative, reported as positive or negative
0536U	Red blood cell antigen (fetal RhD), PCR analysis of exon 4 of RHD gene and housekeeping control gene GAPDH from whole blood in pregnant individuals at 10+ weeks gestation known to be RhD negative, reported as fetal RhD status
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood
81479	Unlisted molecular pathology procedure

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Description of Services

During pregnancy, cell-free DNA (cfDNA) from the placenta circulates in a pregnant individual's blood. Fetal cfDNA from this blood can be screened for aneuploidies and other genetic anomalies, with testing offered as early as 10 weeks gestation. Available tests use different methodologies and algorithms for data analysis. These tests may identify women with an increased risk of having a child with a genetic disorder, but they cannot conclusively diagnose, confirm, or exclude the possibility of a genetic condition. Only conventional prenatal diagnosis [i.e., chorionic villus sampling (CVS) or amniocentesis] can definitively diagnose fetal genetic conditions (ACOG, 2020).

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 DNA-based tests are regulated by the FDA under the Clinical Laboratory Improvement Amendments. Refer to the following website for more information: https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia. (Accessed March 3, 2025)

A list of nucleic acid-based tests that have been cleared or approved by the FDA Center for Devices and Radiological Health is available at: https://www.fda.gov/medical-devices/in-vitro-diagnostics/nucleic-acid-based-tests. (Accessed March 4, 2025)

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 March 19, 2025.

Policy History/Revision Information

Date	Summary of Changes
08/01/2025	**Coverage Rationale** • Replaced language indicating "*DNA-based noninvasive prenatal tests* of fetal *aneuploidy are* proven and medically necessary in certain circumstances" with "*Cell-Free Fetal* DNA *testing using maternal plasma to determine* fetal *genotype is* proven and medically necessary in certain circumstances" **Applicable Codes** • Added CPT code 0536U • Removed CPT codes 0327U, 81420, and 81507

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Date	Summary of Changes
	• Removed list of applicable ICD-10 diagnosis codes: O09.00, O09.01, O09.02, O09.03, O09.10, O09.11, O09.12, O09.13, O09.211, O09.212, O09.213, O09.219, O09.291, O09.292, O09.293, O09.299, O09.30, O09.31, O09.32, O09.33, O09.40, O09.41, O09.42, O09.43, O09.511, O09.512, O09.513, O09.519, O09.521, O09.522, O09.523, O09.529, O09.611, O09.612, O09.613, O09.619, O09.621, O09.622, O09.623, O09.629, O09.70, O09.71, O09.72, O09.73, O09.811, O09.812, O09.813, O09.819, O09.821, O09.822, O09.823, O09.829, O09.891, O09.892, O09.893, O09.899, O09.90, O09.91, O09.92, O09.93, O09.A0, O09.A1, O09.A2, O09.A3, O26.20, O26.21, O26.22, O26.23, O26.841, O26.842, O26.843, O26.849, O26.851, O26.852, O26.853, O26.859, O26.891, O26.892, O26.893, O26.899, O26.90, O26.91, O26.92, O26.93, O28.0, O28.1, O28.2, O28.3, O28.4, O28.5, O28.8, O28.9, O30.001, O30.002, O30.003, O30.009, O30.011, O30.012, O30.013, O30.019, O30.021, O30.022, O30.023, O30.029, O30.031, O30.032, O30.033, O30.039, O30.041, O30.042, O30.043, O30.049, O30.091, O30.092, O30.093, O30.099, O35.00X0, O35.01X0, O35.02X0, O35.03X0, O35.04X0, O35.05X0, O35.06X0, O35.07X0, O35.08X0, O35.09X0, O35.10X0, O35.11X0, O35.12X0, O35.13X0, O35.14X0, O35.15X0, O35.19X0, O35.2XX0, O35.AXX0, O35.BXX0, O35.CXX0, O35.DXX0, O35.EXX0, O35.FXX0, O35.GXX0, O35.HXX0, O99.210, O99.211, O99.212, O99.213, O99.280, O99.281, O99.282, O99.283, O99.284, O99.285, O99.310, O99.311, O99.312, O99.313, O99.320, O99.321, O99.322, O99.323, O99.330, O99.331, O99.332, O99.333, O99.340, O99.341, O99.342, O99.343, O99.810, O99.814, Q95.0, Q95.1, Q95.2, Q95.3, Q95.5, Q95.8, Q95.9, Z34.00, Z34.01, Z34.02, Z34.03, Z34.80, Z34.81, Z34.82, Z34.83, Z34.90, Z34.91, Z34.92, Z34.93, Z36.0, Z36.1, Z36.2, Z36.3, Z36.4, Z36.5, Z36.81, Z36.82, Z36.83, Z36.89, Z36.8A, Z36.9, Z3A.09, Z3A.10, Z3A.11, Z3A.12, Z3A.13, Z3A.14, Z3A.15, Z3A.16, Z3A.17, Z3A.18, Z3A.19, Z3A.20, Z3A.21, Z3A.22, Z3A.23, Z3A.24, Z3A.25, Z3A.26, Z3A.27, Z3A.28, Z3A.29, Z3A.30, Z3A.31, Z3A.32, Z3A.33, Z3A.34, Z3A.35, Z3A.36, Z3A.37, Z3A.38, Z3A.39, Z3A.40, Z3A.41, Z3A.42, and Z3A.49 **Supporting Information** • Updated *Description of Services* and *FDA* sections to reflect the most current information • Archived previous policy version CS085OH.D

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.

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