Cell-Free Fetal DNA Testing (for Ohio Only)

Policy Number: CS085OH.D
Effective Date: January 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

DNA-based noninvasive prenatal tests of fetal aneuploidy are 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
0327U	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed

CPT Code	Description
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
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
81420	Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21
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
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy

Diagnosis Code	Description
O09.00	Supervision of pregnancy with history of infertility, unspecified trimester
O09.01	Supervision of pregnancy with history of infertility, first trimester
O09.02	Supervision of pregnancy with history of infertility, second trimester
O09.03	Supervision of pregnancy with history of infertility, third trimester
O09.10	Supervision of pregnancy with history of ectopic pregnancy, unspecified trimester
O09.11	Supervision of pregnancy with history of ectopic pregnancy , first trimester
O09.12	Supervision of pregnancy with history of ectopic pregnancy , second trimester
O09.13	Supervision of pregnancy with history of ectopic pregnancy , third trimester
O09.211	Supervision of pregnancy with history of pre-term labor, first trimester
O09.212	Supervision of pregnancy with history of pre-term labor, second trimester
O09.213	Supervision of pregnancy with history of pre-term labor, third trimester
O09.219	Supervision of pregnancy with history of pre-term labor, unspecified trimester
O09.291	Supervision of pregnancy with other poor reproductive or obstetric history, first trimester
O09.292	Supervision of pregnancy with other poor reproductive or obstetric history, second trimester
O09.293	Supervision of pregnancy with other poor reproductive or obstetric history, third trimester
O09.299	Supervision of pregnancy with other poor reproductive or obstetric history, unspecified trimester
O09.30	Supervision of pregnancy with insufficient antenatal care, unspecified trimester
O09.31	Supervision of pregnancy with insufficient antenatal care, first trimester
O09.32	Supervision of pregnancy with insufficient antenatal care, second trimester
O09.33	Supervision of pregnancy with insufficient antenatal care, third trimester
O09.40	Supervision of pregnancy with grand multiparity, unspecified trimester
O09.41	Supervision of pregnancy with grand multiparity, first trimester
O09.42	Supervision of pregnancy with grand multiparity, second trimester
O09.43	Supervision of pregnancy with grand multiparity, third trimester
O09.511	Supervision of elderly primigravida, first trimester
O09.512	Supervision of elderly primigravida, second trimester

Diagnosis Code	Description
O09.513	Supervision of elderly primigravida, third trimester
O09.519	Supervision of elderly primigravida, unspecified trimester
O09.521	Supervision of elderly multigravida, first trimester
O09.522	Supervision of elderly multigravida, second trimester
O09.523	Supervision of elderly multigravida, third trimester
O09.529	Supervision of elderly multigravida, unspecified trimester
O09.611	Supervision of young primigravida, first trimester
O09.612	Supervision of young primigravida, second trimester
O09.613	Supervision of young primigravida, third trimester
O09.619	Supervision of young primigravida, unspecified trimester
O09.621	Supervision of young multigravida, first trimester
O09.622	Supervision of young multigravida, second trimester
O09.623	Supervision of young multigravida, third trimester
O09.629	Supervision of young multigravida, unspecified trimester
O09.70	Supervision of high risk pregnancy due to social problems, unspecified trimester
O09.71	Supervision of high risk pregnancy due to social problems, first trimester
O09.72	Supervision of high risk pregnancy due to social problems, second trimester
O09.73	Supervision of high risk pregnancy due to social problems, third trimester
O09.811	Supervision of pregnancy resulting from assisted reproductive technology, first trimester
O09.812	Supervision of pregnancy resulting from assisted reproductive technology, second trimester
O09.813	Supervision of pregnancy resulting from assisted reproductive technology, third trimester
O09.819	Supervision of pregnancy resulting from assisted reproductive technology, unspecified trimester
O09.821	Supervision of pregnancy with history of in utero procedure during previous pregnancy, first trimester
O09.822	Supervision of pregnancy with history of in utero procedure during previous pregnancy, second trimester
O09.823	Supervision of pregnancy with history of in utero procedure during previous pregnancy, third trimester
O09.829	Supervision of pregnancy with history of in utero procedure during previous pregnancy, unspecified trimester
O09.891	Supervision of other high risk pregnancies, first trimester
O09.892	Supervision of other high risk pregnancies, second trimester
O09.893	Supervision of other high risk pregnancies, third trimester
O09.899	Supervision of other high risk pregnancies, unspecified trimester
O09.90	Supervision of high risk pregnancy, unspecified, unspecified trimester
O09.91	Supervision of high risk pregnancy, unspecified, first trimester
O09.92	Supervision of high risk pregnancy, unspecified, second trimester
O09.93	Supervision of high risk pregnancy, unspecified, third trimester
O09.A0	Supervision of pregnancy with history of molar pregnancy, unspecified trimester
O09.A1	Supervision of pregnancy with history of molar pregnancy, first trimester
O09.A2	Supervision of pregnancy with history of molar pregnancy, second trimester
O09.A3	Supervision of pregnancy with history of molar pregnancy, third trimester
O26.20	Pregnancy care for patient with recurrent pregnancy loss, unspecified trimester
O26.21	Pregnancy care for patient with recurrent pregnancy loss, first trimester
O26.22	Pregnancy care for patient with recurrent pregnancy loss, second trimester
O26.23	Pregnancy care for patient with recurrent pregnancy loss, third trimester

Diagnosis Code	Description
O26.841	Uterine size-date discrepancy, first trimester
O26.842	Uterine size-date discrepancy, second trimester
O26.843	Uterine size-date discrepancy, third trimester
O26.849	Uterine size-date discrepancy, unspecified trimester
O26.851	Spotting complicating pregnancy, first trimester
O26.852	Spotting complicating pregnancy, second trimester
O26.853	Spotting complicating pregnancy, third trimester
O26.859	Spotting complicating pregnancy, unspecified trimester
O26.891	Other specified pregnancy related conditions, first trimester
O26.892	Other specified pregnancy related conditions, second trimester
O26.893	Other specified pregnancy related conditions, third trimester
O26.899	Other specified pregnancy related conditions, unspecified trimester
O26.90	Pregnancy related conditions, unspecified, unspecified trimester
O26.91	Pregnancy related conditions, unspecified, first trimester
O26.92	Pregnancy related conditions, unspecified, second trimester
O26.93	Pregnancy related conditions, unspecified, third trimester
O28.0	Abnormal hematological finding on antenatal screening of mother
O28.1	Abnormal biochemical finding on antenatal screening of mother
O28.2	Abnormal cytological finding on antenatal screening of mother
O28.3	Abnormal ultrasonic finding on antenatal screening of mother
O28.4	Abnormal radiological finding on antenatal screening of mother
O28.5	Abnormal chromosomal and genetic finding on antenatal screening of mother
O28.8	Other abnormal findings on antenatal screening of mother
O28.9	Unspecified abnormal findings on antenatal screening of mother
O30.001	Twin pregnancy, unspecified number of placenta and unspecified number of amniotic sacs, first trimester
O30.002	Twin pregnancy, unspecified number of placenta and unspecified number of amniotic sacs, second trimester
O30.003	Twin pregnancy, unspecified number of placenta and unspecified number of amniotic sacs, third trimester
O30.009	Twin pregnancy, unspecified number of placenta and unspecified number of amniotic sacs, unspecified trimester
O30.011	Twin pregnancy, monochorionic/monoamniotic, first trimester
O30.012	Twin pregnancy, monochorionic/monoamniotic, second trimester
O30.013	Twin pregnancy, monochorionic/monoamniotic, third trimester
O30.019	Twin pregnancy, monochorionic/monoamniotic, unspecified trimester
O30.021	Conjoined twin pregnancy, first trimester
O30.022	Conjoined twin pregnancy, second trimester
O30.023	Conjoined twin pregnancy, third trimester
O30.029	Conjoined twin pregnancy, unspecified trimester
O30.031	Twin pregnancy, monochorionic/diamniotic, first trimester
O30.032	Twin pregnancy, monochorionic/diamniotic, second trimester
O30.033	Twin pregnancy, monochorionic/diamniotic, third trimester
O30.039	Twin pregnancy, monochorionic/diamniotic, unspecified trimester
O30.041	Twin pregnancy, dichorionic/diamniotic, first trimester
O30.042	Twin pregnancy, dichorionic/diamniotic, second trimester

Diagnosis Code	Description
O30.043	Twin pregnancy, dichorionic/diamniotic, third trimester
O30.049	Twin pregnancy, dichorionic/diamniotic, unspecified trimester
O30.091	Twin pregnancy, unable to determine number of placenta and number of amniotic sacs, first trimester
O30.092	Twin pregnancy, unable to determine number of placenta and number of amniotic sacs, second trimester
O30.093	Twin pregnancy, unable to determine number of placenta and number of amniotic sacs, third trimester
O30.099	Twin pregnancy, unable to determine number of placenta and number of amniotic sacs, unspecified trimester
O35.00X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, unspecified, not applicable or unspecified
O35.01X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, agenesis of the corpus callosum, not applicable or unspecified
O35.02X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, anencephaly, not applicable or unspecified
O35.03X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, choroid plexus cysts, not applicable or unspecified
O35.04X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, encephalocele, not applicable or unspecified
O35.05X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, holoprosencephaly, not applicable or unspecified
O35.06X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, hydrocephaly, not applicable or unspecified
O35.07X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, microcephaly, not applicable or unspecified
O35.08X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, spina bifida, not applicable or unspecified
O35.09X0	Maternal care for (suspected) other central nervous system malformation or damage in fetus, not applicable or unspecified
O35.10X0	Maternal care for (suspected) chromosomal abnormality in fetus, unspecified, not applicable or unspecified
O35.11X0	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 13, not applicable or unspecified
O35.12X0	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 18, not applicable or unspecified
O35.13X0	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 21, not applicable or unspecified
O35.14X0	Maternal care for (suspected) chromosomal abnormality in fetus, Turner Syndrome, not applicable or unspecified
O35.15X0	Maternal care for (suspected) chromosomal abnormality in fetus, sex chromosome abnormality, not applicable or unspecified
O35.19X0	Maternal care for (suspected) chromosomal abnormality in fetus, other chromosomal abnormality, not applicable or unspecified
O35.2XX0	Maternal care for (suspected) hereditary disease in fetus, not applicable or unspecified
O35.AXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal facial anomalies, not applicable or unspecified
O35.BXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal cardiac anomalies, not applicable or unspecified
O35.CXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal pulmonary anomalies, not applicable or unspecified

Diagnosis Code	Description
O35.DXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal gastrointestinal anomalies, not applicable or unspecified
O35.EXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal genitourinary anomalies, not applicable or unspecified
O35.FXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal musculoskeletal anomalies of trunk, not applicable or unspecified
O35.GXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal upper extremities anomalies, not applicable or unspecified
O35.HXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal lower extremities anomalies, not applicable or unspecified
O99.210	Obesity complicating pregnancy, unspecified trimester
O99.211	Obesity complicating pregnancy, first trimester
O99.212	Obesity complicating pregnancy, second trimester
O99.213	Obesity complicating pregnancy, third trimester
O99.280	Endocrine, nutritional and metabolic diseases complicating pregnancy, unspecified trimester
O99.281	Endocrine, nutritional and metabolic diseases complicating pregnancy, first trimester
O99.282	Endocrine, nutritional and metabolic diseases complicating pregnancy, second trimester
O99.283	Endocrine, nutritional and metabolic diseases complicating pregnancy, third trimester
O99.284	Endocrine, nutritional and metabolic diseases complicating childbirth
O99.285	Endocrine, nutritional and metabolic diseases complicating the puerperium
O99.310	Alcohol use complicating pregnancy, unspecified trimester
O99.311	Alcohol use complicating pregnancy, first trimester
O99.312	Alcohol use complicating pregnancy, second trimester
O99.313	Alcohol use complicating pregnancy, third trimester
O99.320	Drug use complicating pregnancy, unspecified trimester
O99.321	Drug use complicating pregnancy, first trimester
O99.322	Drug use complicating pregnancy, second trimester
O99.323	Drug use complicating pregnancy, third trimester
O99.330	Smoking (tobacco) complicating pregnancy, unspecified trimester
O99.331	Smoking (tobacco) complicating pregnancy, first trimester
O99.332	Smoking (tobacco) complicating pregnancy, second trimester
O99.333	Smoking (tobacco) complicating pregnancy, third trimester
O99.340	Other mental disorders complicating pregnancy, unspecified trimester
O99.341	Other mental disorders complicating pregnancy, first trimester
O99.342	Other mental disorders complicating pregnancy, second trimester
O99.343	Other mental disorders complicating pregnancy, third trimester
O99.810	Abnormal glucose complicating pregnancy
O99.814	Abnormal glucose complicating childbirth
Q95.0	Balanced translocation and insertion in normal individual
Q95.1	Chromosome inversion in normal individual
Q95.2	Balanced autosomal rearrangement in abnormal individual
Q95.3	Balanced sex/autosomal rearrangement in abnormal individual
Q95.5	Individual with autosomal fragile site
Q95.8	Other balanced rearrangements and structural markers
Q95.9	Balanced rearrangement and structural marker, unspecified
Z34.00	Encounter for supervision of normal first pregnancy, unspecified trimester

Diagnosis Code	Description
Z34.01	Encounter for supervision of normal first pregnancy, first trimester
Z34.02	Encounter for supervision of normal first pregnancy, second trimester
Z34.03	Encounter for supervision of normal first pregnancy, third trimester
Z34.80	Encounter for supervision of other normal pregnancy, unspecified trimester
Z34.81	Encounter for supervision of other normal pregnancy, first trimester
Z34.82	Encounter for supervision of other normal pregnancy, second trimester
Z34.83	Encounter for supervision of other normal pregnancy, third trimester
Z34.90	Encounter for supervision of normal pregnancy, unspecified, unspecified trimester
Z34.91	Encounter for supervision of normal pregnancy, unspecified, first trimester
Z34.92	Encounter for supervision of normal pregnancy, unspecified, second trimester
Z34.93	Encounter for supervision of normal pregnancy, unspecified, third trimester
Z36.0	Encounter for antenatal screening for chromosomal anomalies
Z36.1	Encounter for antenatal screening for raised alphafetoprotein level
Z36.2	Encounter for other antenatal screening follow-up
Z36.3	Encounter for antenatal screening for malformations
Z36.4	Encounter for antenatal screening for fetal growth retardation
Z36.5	Encounter for antenatal screening for isoimmunization
Z36.81	Encounter for antenatal screening for hydrops fetalis
Z36.82	Encounter for antenatal screening for nuchal translucency
Z36.83	Encounter for fetal screening for congenital cardiac abnormalities
Z36.89	Encounter for other specified antenatal screening
Z36.8A	Encounter for antenatal screening for other genetic defects
Z36.9	Encounter for antenatal screening, unspecified
Z3A.09	9 weeks gestation of pregnancy
Z3A.10	10 weeks gestation of pregnancy
Z3A.11	11 weeks gestation of pregnancy
Z3A.12	12 weeks gestation of pregnancy
Z3A.13	13 weeks gestation of pregnancy
Z3A.14	14 weeks gestation of pregnancy
Z3A.15	15 weeks gestation of pregnancy
Z3A.16	16 weeks gestation of pregnancy
Z3A.17	17 weeks gestation of pregnancy
Z3A.18	18 weeks gestation of pregnancy
Z3A.19	19 weeks gestation of pregnancy
Z3A.20	20 weeks gestation of pregnancy
Z3A.21	21 weeks gestation of pregnancy
Z3A.22	22 weeks gestation of pregnancy
Z3A.23	23 weeks gestation of pregnancy
Z3A.24	24 weeks gestation of pregnancy
Z3A.25	25 weeks gestation of pregnancy
Z3A.26	26 weeks gestation of pregnancy
Z3A.27	27 weeks gestation of pregnancy
Z3A.28	28 weeks gestation of pregnancy
Z3A.29	29 weeks gestation of pregnancy
Z3A.30	30 weeks gestation of pregnancy

Diagnosis Code	Description
Z3A.31	31 weeks gestation of pregnancy
Z3A.32	32 weeks gestation of pregnancy
Z3A.33	33 weeks gestation of pregnancy
Z3A.34	34 weeks gestation of pregnancy
Z3A.35	35 weeks gestation of pregnancy
Z3A.36	36 weeks gestation of pregnancy
Z3A.37	37 weeks gestation of pregnancy
Z3A.38	38 weeks gestation of pregnancy
Z3A.39	39 weeks gestation of pregnancy
Z3A.40	40 weeks gestation of pregnancy
Z3A.41	41 weeks gestation of pregnancy
Z3A.42	42 weeks gestation of pregnancy
Z3A.49	Greater than 42 weeks gestation of pregnancy

Description of Services

Historically, screening tests for trisomy 13, 18, and 21 have included first-trimester screening (which involves an ultrasound and a blood test) and maternal serum screening (a blood test) in addition to a high-resolution ultrasound evaluation in the second trimester. In the past decade, prenatal screening performed using cell-free DNA (cfDNA) has become more common. During pregnancy, cfDNA from the placenta circulates in the birthing person'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 trisomy 13, 18 or 21, but they cannot diagnose, confirm, or exclude the possibility of a chromosomal disorder. Only conventional prenatal diagnosis [i.e., chorionic villus sampling (CVS) or amniocentesis] can definitively diagnose fetal trisomies (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 prenatal tests for trisomy 21, 18, and 13 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 February 7, 2024)

Additional Product Information (Not All Inclusive)

- Harmony™ Prenatal Test (Roche)
- MaterniT21® PLUS (LabCorp®)
- Panorama™ Prenatal Test (Natera™ Inc.)
- PreSeek™ (Baylor Genetics)
- QNatal® Advanced (Quest Diagnostics™)
- SensiGene (Sequenom Laboratories)
- UNITY Screen™ (Billion to One)
- Vanadis™ NIPT Test (Revvity)
- verifi® Prenatal Test (Illumina® Inc.)
- Vistara™ (Natera™ Inc.)

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 21, 2024.

Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Applicable Codes** • Added CPT codes 0488U, 0489U, and 0494U **Supporting Information** • Archived previous policy version CS085OH.C

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.