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VP Clinical
Services
Area Medical Policy
Lines Of Business Commercial,
Mountain
Health Trust,
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+ 1 more

Non-invasive Prenatal Testing (NIPT) - Cell-Free DNA

PURPOSE:

This policy is designed to discuss the medical necessity criteria for Noninvasive Prenatal Testing, specifically Cell-Free DNA Screening.

DEFINITIONS:

Amniocentesis: A procedure in which amniotic fluid and cells are taken from the uterus for testing. The procedure uses a needle to withdraw fluid and cells from the sac that holds the fetus.

Aneuploidy: Having an abnormal number of chromosomes. Types include trisomy, in which there is an extra chromosome, or monosomy, in which a chromosome is missing. Aneuploidy can affect any chromosome, including the sex chromosomes. Down syndrome (trisomy 21) is a common aneuploidy. Others are Patau syndrome (trisomy 13) and Edwards syndrome (trisomy 18).

Cell-free DNA: The small amount of DNA that is released from the placenta into a pregnant woman's bloodstream.

Chorionic Villus Sample (CVS): A procedure in which a small sample of cells is taken from the placenta and tested.

Down Syndrome (Trisomy 21): A genetic disorder that causes abnormal features of the face and body, medical problems such as heart defects, and mental disability. Most cases of Down syndrome are caused by an extra chromosome 21 (trisomy 21).

Edwards Syndrome (Trisomy 18): A genetic condition that causes serious problems. It causes a small head, heart defects, and deafness.

Nuchal Translucency Screening: A test to screen for certain birth defects, such as Down syndrome, Edwards syndrome, or heart defects. The screening uses ultrasound to measure fluid at the back of the fetus's neck.

Patau Syndrome (Trisomy 13): A genetic condition that causes serious problems. It involves the heart and brain, cleft lip and palate, and extra fingers and toes.

PROCEDURE:

Noninvasive prenatal genetic screening includes serum screening with or without nuchal translucency (NT) ultrasound or cell-free DNA. Either option may be considered medically necessary for all pregnant individuals.

Cell-free DNA testing may be considered medically necessary if any of the following situations:

- The individual has requested a preference for cell-free DNA testing after being offered both non-invasive options; OR
- Maternal age 35 years or older at delivery; OR
- Fetal ultrasonographic findings indicating increased risk of aneuploidy; OR
- History of previous pregnancy with a trisomy; OR
- Standard serum screening test positive for aneuploidy; OR
- Parental balanced Robertsonian translocation with increased risk of fetal trisomy 13 or trisomy 21; OR
- Significant family history of chromosomal abnormalities.

If an individual chooses to have cell-free DNA screening performed for any of the above reasons, the screening may be considered medically necessary if all the following criteria are met:

- The individual has reached at least 9 weeks gestation in either a singleton or twin pregnancy; AND
- Counseling is provided before and after testing by an OB/GYN provider or genetic counselor; AND
 - Counseling must include the following:
 - Information on cell-free DNA being a screening test, and is not equivalent to diagnostic testing; AND
 - In the event of a positive cell-free DNA test, chorionic villus sampling (CVS) or amniocentesis is required in order to make a diagnosis; AND
 - That there is a potential for false-positive and false-negative results.

Note: Individuals should select one prenatal screening approach. It is not recommended to have multiple screening testing performed simultaneously.

Non-Coverage Statement:

Noninvasive prenatal testing (NIPT) is considered not medically necessary for pregnant women who

have previously had a multiple serum marker screening test with or without fetal nuchal translucency ultrasound that is negative for fetal aneuploidy during the current pregnancy.

CPT Code	Description
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
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
81509*	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score
81510*	Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
81511*	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood
0252U	Fetal aneuploidy short tandem-repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy
0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic dna genomic sequence analysis for aneuploidy, and a mitochondrial dna score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy
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

Note: All codes with "*" require an authorization.

Covered Diagnosis Codes:

ICD-10 Code	Description
Z33.1	Pregnant state, incidental
Z33.3	Pregnant state, gestational carrier
O30.001 –	Twin Pregnancy

O30.099	
O26.20-O26.23	Pregnancy care for patient with recurrent pregnancy loss
O09.00-O09.3	Supervision of pregnancy with history of Infertility, Unspecified trimester, first trimester, second trimester, or third trimester
O09.10-O09.13	Supervision of pregnancy with history of ectopic pregnancy, unspecified trimester, first trimester, second trimester, third trimester
O09.211-O09.213	Supervision of pregnancy with history of preterm labor, First trimester, second trimester, third trimester, unspecified trimester

Note: This is not an all-inclusive list.

Non-covered Diagnosis Codes:

ICD-10 Code	Description
O30.101 – O30.93	Twin, Triplet, and Multiple Gestation Unspecified
O31.00X0–O31.8X99	Complications specific to multiple gestation - Non-covered for multiple gestations of triplets or more

REFERENCES:

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Palomaki GE, Messerlian GM, Halliday JV. Prenatal screening for common aneuploidies using cell-free DNA. UpToDate [online serial]. Waltham, MA: UpToDate. Last updated October 11, 2022. Accessed October 13, 2022.

Ormond KE, Borensztein MJ, Hallquist MLG, et al. Defining the Critical Components of Informed Consent for Genetic Testing. *J Pers Med*. 2021;11(12):1304. Published 2021 Dec 5. doi:10.3390/jpm11121304. Accessed October 11, 2023.

RELATED POLICIES

Proprietary Laboratory Testing 17229055

POLICY HISTORY:

DATE	DESCRIPTION
10/26/2022	Title changed from "Cell Free DNA Genetic Testing for Identification of Chromosomal Aneuploidy" to "Non-invasive Prenatal Testing (NIPT) - Cell -Free DNA". Added criteria covering cell-free DNA for all singleton/twin pregnancy's, and that genetic counseling is required and the it must be after 9 weeks of gestation. Reformatted entire policy. Renamed "Medical Necessity" section to "Procedure". Removed codes 81508, 81509, 81510, 81511, 81512, and 88271, and placed codes into table. Added Reference, Policy History, Post-Payment Audit Statement, and Disclaimer sections.
10/25/2023	Annual Review: Updated references. Added codes 81509, 81510, 81511.
02/03/2025	Annual review. Deleted codes 0168U Added codes 0252U, 0254U, and 0327U. Added non-coverage statement. Added additional diagnosis codes 009.00-009.3, 009.10-009.13, and 009.211-009. 213.

POST-PAYMENT AUDIT STATEMENT:

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by THP at any time pursuant to the terms of your provider agreement.

DISCLAIMER:

This policy is intended to serve as a guideline only and does not constitute medical advice, any guarantee of payment, plan pre-authorization, an explanation of benefits, or a contract. This policy is intended to address medical necessity guidelines that are suitable for most individuals. Each individual's unique clinical situation may warrant individual consideration based on medical records. Individual claims may be affected by other factors, including but not necessarily limited to state and federal laws and regulations, legislative mandates, provider contract terms, and THP's professional judgment. Reimbursement for any services shall be subject to member benefits and eligibility on the date of

service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification, and utilization management guidelines. Unless otherwise noted within the policy, THP's policies apply to both participating and non-participating providers and facilities. THP reserves the right to review and revise these policies periodically as it deems necessary in its discretion, and it is subject to change or termination at any time by THP. THP has full and final discretionary authority for its interpretation and application. Accordingly, THP may use reasonable discretion in interpreting and applying this policy to health care services provided in any particular case.

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All Revision Dates

3/3/2025, 2/12/2024, 12/14/2022, 11/3/2020

Approval Signatures

Step Description	Approver	Date
EMT Approval	Mumtaz Ibrahim, MD: Chief Medical Officer	3/3/2025
PAC Approval	Robert Wetzel, MD: Medical Director	2/28/2025
Medical Directors Oversight Committee	Robert Cross, MD: Medical Director	2/28/2025
	Heather Jones: VP Clinical Services	2/18/2025

Lines Of Business

Commercial, Mountain Health Trust, PEIA, Self-Funded