Effective:	*2/13/2023*
Last Approved:	*12/14/2022*
Next Review:	*12/31/2023*
Lines Of Business:	*All Lines of Business*

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.

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
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood
0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy

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 – O30.099	Twin Pregnancy
O26.20-O26.23	Pregnancy care for patient with recurrent pregnancy loss

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:

American College of Obstetricians and Gynecologists (ACOG). Current ACOG Guideance: NIPT Summary of Recommendations. Copyright 2022. Accessed October 12, 2022.

American College of Obstetricians and Gynecologists (ACOG). Screening for Fetal Chromosomal Abnormalities. ACOG Practice Bulletin No. 226. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;136:e48–69. Accessed October 12, 2022.

American College of Obstetricians and Gynecologists (ACOG). Counseling about genetic testing and communication of genetic test results. Committee Opinion No. 693. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;129:e96–101. Accessed October 12, 2022.

American College of Obstetricians and Gynecologists (ACOG). Prenatal Genetic Screening Tests: FAQs. FAQ 165. Last updated October 2020, last reviewed December 2021. Accessed October 12, 2022.

Taylor-Phillips S, Freeman K, Geppert J, et al. Accuracy of non-invasive prenatal testing using cell-free DNA for detection of Down, Edwards and Patau syndromes: a systematic review and meta-analysis. *BMJ Open*. 2016;6(1):e010002. Published 2016 Jan 18. doi:10.1136/bmjopen-2015-010002. Accessed October 13, 2022.

Iwarsson E, Jacobsson B, Dagerhamn J, Davidson T, Bernabé E, Heibert Arnlind M. Analysis of cell-free fetal DNA in maternal blood for detection of trisomy 21, 18 and 13 in a general pregnant population and in a high risk population - a systematic review and meta-analysis. *Acta Obstet Gynecol Scand*. 2017;96(1):7-18. doi:10.1111/aogs.13047. Accessed October 13, 2022.

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.

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 tabled. Added Reference, Policy History, Post-Payment Audit Statement, and Disclaimer sections.

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.

All revision dates: 12/14/2022, 11/3/2020