Concert Genetic Testing: Prenatal Cell-Free DNA Testing

Other common names for this test include: Non-invasive Prenatal Testing (NIPT), Cell-free Fetal DNA Testing (cffDNA)

Reference Number: LA.CP.CG.15
Date of Last Revision 01/25

Coding implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

OVERVIEW

Prenatal cell-free DNA testing (prenatal cfDNA) is a sequencing test performed on placental cell-free DNA found in maternal serum and is most commonly used to screen for fetal aneuploidy (trisomy 21, trisomy 13, and trisomy 18). Sex chromosomes are also screened for fetal sex determination and sex chromosome aneuploidy. Prenatal cfDNA is a screening test and does not provide definitive diagnosis for a fetus. When prenatal cfDNA is positive, or high risk, for a genetic abnormality, the fetus is at increased risk for that condition. Further testing via karyotype, fluorescent in situ hybridization (FISH), or chromosomal microarray (CMA) would be necessary to exclude the possibility of a false-positive.

Before testing, guidelines recommend that pregnant people be counseled about the risk of a false-positive result. False-positive findings have been associated with several factors, including placental mosaicism, vanishing twin, or a confounding factor within the pregnant person (such as a genetic condition or malignancy).

Prenatal cfDNA testing has expanded to include microdeletion and microduplication syndromes, as well as single-gene disorders, although this is an area of ongoing research. Prenatal cfDNA has also expanded to predict twin zygosity (i.e., monozygotic versus dizygotic twins). Monozygotic twins have a higher risk for certain complications, such as twin-twin transfusion syndrome (TTTS).

Prenatal screening can also be performed via maternal serum screening (MSS), which examines levels of various analytes produced by the fetus and placenta and provides risks for certain genetic conditions and birth defects.

POLICY REFERENCE TABLE

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT is a registered trademark of the American Medical Association. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are

included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis. The non-covered codes will only be denoted in the table below and not throughout the policy. Please only reference the policy reference table for covered and non-covered codes.

The tests, associated laboratories, CPT codes, and ICD codes contained within this document serve only as examples to help users navigate claims and corresponding criteria; as such, they are not comprehensive and are not a guarantee of coverage or non-coverage. Please see the Concert Platform for a comprehensive list of registered tests.

Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Prenatal Cell-free DNA Testing for Chromosome 13, 18, 21, X and Y Aneuploidies	Vasistera (Natera)	0327U*	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0	1, 2, 3, 5, 6
	Panorama Prenatal Panel (with or without twin zygosity testing) (Natera)	81420, 0060U* (twin zygosity only)		
	Harmony Prenatal Test (BioReference Laboratories)	81507		
Prenatal Cell-free DNA Testing for Microdeletions	Panorama Extended Panel (Natera)	81422*	O09, O28, O35, Q90-Q99, Z34, Z36.0	3, 5
	MaterniT21 Plus Core + ESS (LabCorp)			
	Prequel Prenatal Screen: Microdeletions (Myriad Genetics)			
Prenatal Cell-free DNA Testing for Single-gene Disorders	Vistara - Single-Gene NIPT (Natera)	81302*, 81404*, 81405*, 81406*, 81407*, 81408*, 81442*	O09, O28, O30, O35, Q90-Q99, Z34, Z36.04	4
	PreSeek Non-invasive Prenatal Gene Sequencing Screen (Baylor Genetics, LLC)			

Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
	UNITY Fetal Antigen NIPT	0488U*		
	UNITY Fetal Risk Screen	0489U*		
Maternal Serum Screening (MSS)	First Trimester Maternal Screen, Serum (Mayo Clinic Laboratories)	81508*	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0	3
	Quad Screen (Quest Diagnostics)	81509*, 81510*, 81511*, 81512*		
	Serum Integrated Screen, Part 2 (Quest Diagnostics)			
	Penta Screen (Quest Diagnostics)	81512*		
Prenatal Cell-Free DNA Testing for Fetal RhD Genotyping	Fetal RhD NIPT (Natera) - 81479	81479		7, 8
	UNITY Fetal RhD NIPT (add on) (Billion to One) – 81403	81403*		

OTHER RELATED POLICIES

This policy document provides criteria for Prenatal Cell-free DNA Testing. Please refer to:

- ***Oncology: Circulating Tumor DNA and Circulating Tumor Cells (Liquid Biopsy)*** for criteria related to circulating tumor DNA (ctDNA) or circulating tumor cell testing performed on peripheral blood for cancer diagnosis, management and surveillance.
- ***Genetic Testing: Prenatal Diagnosis (via amniocentesis, CVS, or PUBS) and Pregnancy Loss*** for criteria related to prenatal and pregnancy loss diagnostic genetic testing.
- ***Genetic Testing: Prenatal and Preconception Carrier Screening*** for criteria related to carrier screening for genetic disorders.
- ***Genetic Testing: Preimplantation Genetic Testing*** for criteria related to genetic testing of embryos prior to in vitro fertilization.
- ***Genetic Testing: Multisystem Inherited Disorders, Intellectual Disability, and Developmental Delay*** for criteria related to diagnostic genetic testing in the postnatal period.
- ***Genetic Testing: General Approach to Genetic and Molecular Testing*** for criteria related to non-invasive prenatal screening that is not specifically discussed in this or other non-general policies, including known familial variant testing.

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CRITERIA

It is the policy of Louisiana Healthcare Connections that the specific genetic testing noted below is **medically necessary** when meeting the related criteria:

Prenatal Cell-free DNA Testing for Chromosome 13, 18, 21, X and Y Aneuploidies

I. Prenatal cell-free DNA testing for 13, 18, 21, X and Y aneuploidy (0327U, 81420, 81507) may be considered **medically necessary** when:

   A. The member/enrollee has a singleton or twin pregnancy, **AND**
   B. The member/enrollee has NOT previously had cell-free DNA screening in the current pregnancy.

II. Prenatal cell-free DNA testing to predict twin zygosity (0060U) is considered **investigational**.

III. Prenatal cell-free DNA testing is considered **investigational** for all other indications, including the following:

   A. For all other aneuploidies (other than trisomy 13, 18, and 21)
   B. For multiple gestation pregnancies (triplets or higher)
   C. Prenatal cell-free DNA performed simultaneously with maternal serum screening
   D. Use on a singleton pregnancy with a known vanishing twin
   E. For the sole purpose of fetal sex determination.

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Prenatal Cell-free DNA Testing for Microdeletions

I. Prenatal cell-free DNA testing for microdeletions and microduplications (81422) is considered **investigational**.

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Prenatal Cell-free DNA Testing for Single-gene Disorders

I. Prenatal cell-free DNA testing for mutations associated with single gene disorders (81302, 81404, 81405, 81406, 81407, 81408, 81442) is considered **investigational.**

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Maternal Serum Screening (MSS)

I. Maternal serum screening for aneuploidy using no more than one of the following one time per pregnancy is considered **medically necessary**:

   A. First trimester screening (free or total beta-HCG and PAPP-A) (81508)
   B. Second trimester screening (hCG, msAFP, uE3, and DIA) (81509, 81510, 81511, 81512)
   C. Integrated, stepwise sequential, or contingent sequential screening (81508, 81509, 81510, 81511, 81512)
   D. Penta screen (hCG, msAFP, uE3, DIA, ITA) (81512).

Prenatal Cell-Free DNA Testing for Fetal RhD Genotyping

I. Prenatal cell-free DNA testing for fetal RhD genotyping (81403, 81479) is considered **medically necessary** when:

   A. The member is pregnant, **AND**
   B. The member is confirmed to be RhD negative, **AND**
   C. The member is not planning to undergo amniocentesis, **AND**
   D. The member's practice setting is experiencing RhIg shortages.

II. Prenatal cell-free DNA testing for fetal RhD genotyping (81403, 81479) is **investigational** for all other indications.

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DEFINITIONS

1. **Prenatal Cell-free DNA Testing** is a screening test that is used to determine the risk of specific genetic disorders by analyzing traces of cell-free DNA (cfDNA) in a pregnant woman's blood.

2. **Sequencing tests** use 1 of 2 general approaches to analyze cell-free DNA. The most widely used technique to date uses massively parallel sequencing (MPS; also known as next-generation or "next gen" sequencing). The second general approach uses the single nucleotide polymorphism (SNP) method.

3. **Singleton pregnancy** is a pregnancy with one fetus.
4. **Twin zygosity** testing is used to predict the degree of genetic similarity within each pair (i.e., monozygotic versus dizygotic). Monozygotic (genetically identical twins) are at a higher risk for pregnancy complications, such as twin-twin transfusion syndrome (TTTS).

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BACKGROUND AND RATIONALE

Prenatal Cell-free DNA Testing for Chromosome 13, 18, 21, X and Y Aneuploidies

American College of Obstetricians and Gynecologists (ACOG) and Society for Maternal-Fetal Medicine (SMFM)

ACOG and SMFM (2020) released a joint practice bulletin (No. 226) with the following recommendations for screening for fetal chromosomal abnormalities:

"The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- Cell-free DNA is the most sensitive and specific screening test for the common fetal aneuploidies. Nevertheless, it has the potential for false-positive and false-negative results. Furthermore, cell-free DNA testing is not equivalent to diagnostic testing." (p. e63)

"The following recommendations and conclusions are based on limited and inconsistent scientific evidence (Level B)":

- "Cell-free DNA screening can be performed in twin pregnancies. Overall, performance of screening for trisomy 21 by cell-free DNA in twin pregnancies is encouraging, but the total number of reported affected cases is small. Given the small number of affected cases it is difficult to determine an accurate detection rate for trisomy 18 and 13. (p. e64)

Regarding prenatal screening for multiple gestation pregnancies of triplets or higher, Practice Bulletin No. 226 also states: "...there are no data available for serum screening for higher-order multiple gestations such as triplets and quadruplets." (p. e59)

Regarding screening a pregnancy with a vanishing twin: "In a patient with both a vanishing twin and a viable intrauterine pregnancy, cell-free DNA screening is not advised because of the high risk for aneuploidy in the nonviable sac or embryo, which can lead to false-positive results." (p. e53)

The Practice Bulletin No. 226 also notes that "[i]f screening is accepted, patients should have one prenatal screening approach, and should not have multiple screening tests performed simultaneously." (p. e49)

American College of Medical Genetics and Genomics (ACMG)

ACMG (2016) published a position statement on noninvasive prenatal screening (NIPS) for fetal aneuploidy.

ACMG recommends:

- Informing all pregnant women that NIPS is the most sensitive screening option for traditionally screened aneuploidies (i.e., T13, T18, and T21). (p. 1059)
- Referring patients to a trained genetics professional when an increased risk of aneuploidy is reported after NIPS. (p. 1059)
- Providers should make efforts to deter patients from selecting sex chromosome aneuploidy screening for the sole purpose of biologic sex identification in the absence of a clinical indication for this information (p. 1060)

Current ACMG practice guidelines (2022) "strongly recommends NIPS over traditional screening for all pregnant patients with singleton and twin gestations for fetal trisomies 21, 18, and 13 and strongly recommends NIPS be offered to patients to screen for fetal sex chromosome aneuploidy." (p. 1 and p. 5)

National Society for Genetic Counselors (NSGC)

The National Society for Genetic Counselors adopted the following statement updated in 2021 supporting prenatal cell-free DNA (cfDNA) screening as an option for pregnant patients:

> The National Society of Genetic Counselors believes that all pregnant patients, regardless of aneuploidy risk, should have access to prenatal aneuploidy screening using cell-free DNA (cfDNA)*. Healthcare providers should present cfDNA screening for aneuploidy within the context of other available prenatal screening and diagnostic testing options. Included in this discussion should be the option of pursuing diagnostic testing as a first line approach or declining all screening/testing. Pretest counseling should also include a discussion of the individual patient's values, preferences, and needs, as well as the benefits and limitations of cfDNA screening. Many factors influence cfDNA screening performance; therefore, it may not be appropriate for every clinical scenario. Additionally, some laboratories offer screening for conditions beyond common aneuploidies, so it is essential to consider the test's positive predictive value, particularly when the prevalence of the disorder is low.

> Patients who receive increased risk or inconclusive/atypical results should receive post-test genetic counseling with a knowledgeable healthcare provider, such as a genetic counselor. In such cases, confirmatory diagnostic testing may be indicated, and patients should be counseled that no irreversible actions should be taken based on the cfDNA screening alone.

Wojas, et al

In a 2022 study of 59,471 twin pregnancies, the authors stated: "Further research should determine the impact of the addition of first trimester zygosity assignment for twin pregnancies upon the accuracy of chorionicity assignment, and the differences in healthcare costs for pregnancies assigned either MZ [monozygotic] or DZ [dizygotic] genetic origin. Finally, there is limited information on the impact of zygosity (corrected for chorionicity) upon pregnancy outcome. Our study lays a foundation for such research, to better determine the degree to which these two factors contribute independently to complicated and normal outcomes." (p. 1239)

Prenatal Cell-free DNA Testing for Microdeletions

American College of Obstetricians and Gynecologists (ACOG) and Society for Maternal-Fetal Medicine (SMFM)

ACOG and SMFM (2020) released a joint practice bulletin (No. 226) with the following recommendations for screening for fetal chromosomal abnormalities:

> Screening for a limited number of microdeletions with cell-free DNA is available; however, this testing has not been validated clinically and is not recommended. Although microdeletions are relatively common when considered in aggregate, cell-free DNA panels only include a few specific clinically significant microdeletions and these are very rare. Therefore, the PPV for these disorders is much lower than for common trisomies. (p. e53)

American College of Medical Genetics (ACMG)

The ACMG 2022 practice guideline, Noninvasive prenatal screening (NIPS) for fetal chromosome abnormalities in a general-risk population: An evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG), includes a conditional recommendation, suggesting 22q11.2 deletion syndrome be offered to all patients. The guideline defines a conditional recommendation as follows: "most patients would request this testing and most clinicians would offer NIPS for this purpose, after a discussion about the benefits and limitations of screening and in the context of shared-decision making." (p. 5)

Concert Note

Overall, studies attempting to validate the clinical utility of microdeletion analysis via NIPS have overall shown low positive predictive values and higher false positive rates, likely because of the low prevalence of the individual targeted microdeletion syndromes in the general population.

At the present time, testing for microdeletions, including 22q11.2, via cell-free DNA testing has insufficient evidence in peer-reviewed publications to effectively result in improved health outcomes compared to the current standard of care.

Prenatal Cell-free DNA Testing for Single-gene Disorders

The American College of Obstetricians and Gynecologists (ACOG)

ACOG issued a practice advisory for the use of cell-free DNA to screen for single-gene disorders (February 2019, reaffirmed October 2022 and September 2023), which states the following:

> The continued innovation in cell-free technology combined with the desire for a maternal blood test to predict the risk for fetal genetic disorders during a pregnancy has broadened the application of cell-free DNA screening beyond aneuploidy to single-gene disorders. Examples of single-gene disorders include various skeletal dysplasias, sickle cell disease and cystic fibrosis. Although this technology is available clinically and marketed as a single-gene disorder prenatal screening option for obstetric care providers to consider in their practice, often in presence of advanced paternal age, there has not been sufficient data to provide information regarding accuracy and positive and negative predictive value in the general population. For this reason, single-gene cell-free DNA screening is not currently recommended in pregnancy.

Maternal Serum Screening (MSS)

The American College of Obstetricians and Gynecologists (ACOG)

ACOG provided an updated position statement (number 226) regarding Screening for Fetal Chromosomal Abnormalities.

Specifically, these guidelines state: “Prenatal genetic screening (serum screening with or without nuchal translucency [NT] ultrasound or cell-free DNA screening) and diagnostic testing (chorionic villus sampling [CVS] or amniocentesis] options should be discussed and offered to all pregnant women regardless of maternal age or risk of chromosomal abnormality.” (p. 862)

The use of multiple screening approaches performed independently (e.g., a first-trimester screening test followed by a quad screen as an unlinked test) is not recommended because it will

result in an unacceptably high positive screening rate and could deliver contradictory results. (p. 865)

Prenatal Cell-Free DNA Testing for Fetal RhD Genotyping

American College of Obstetrics and Gynecology (ACOG)

ACOG issued a practice advisory in March 2024 stating the following: "Although current ACOG guidance does not recommend routine use of noninvasive prenatal testing (NIPT) to determine fetal Rh(D) status based on cost-effectiveness analyses, the use of NIPT to prioritize use of RhIg and conserve RhIg supply is a reasonable consideration in the practice setting that is experiencing RhIg shortages. If cfDNA testing results confirm an Rh(D)-negative fetus, RhIg would not need to be routinely administered in the antepartum period (for bleeding, abortion, pregnancy loss, or at 28 weeks of gestation)."

Additionally, ACOG issued a clinical practice update in August 2024 providing new recommendations for noninvasive cfDNA in alloimmunized patients for fetal RhD genotyping. They state: "Because cfDNA testing possesses performance characteristics that appear comparable with those of molecular testing, while avoiding the rare complications and costs associated with diagnostic genetic testing, it is reasonable to use it as an alternative tool for fetal RHD testing among alloimmunized patients with potentially at-risk pregnancies who decline amniocentesis". (p. e.2)

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Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
Converted corporate to local policy.	09/23	11/27/23	
Semi-annual review. Updated title to reflect V1.2024 version. Overview, coding, reference-table, background and references updated. Throughout policy: replaced "coverage criteria" with "criteria. For Overview: added "via karyotype, FISH, or CMA"; added "Before testing, guidelines recommend…"; removed "recently". For Policy Reference Table: under Non-invasive Prenatal Screening (NIPS) for Chromosome 13, 18, 21, X and Y Aneuploidies added "with or without twin zygosity testing"; added "twin zygosity only"; added "Prenatal Test"; under Non-invasive Prenatal Screening (NIPS) for Microdeletions replaced "with microdeletion syndromes" with "Extended Panel"; removed "81420"; added "twin zygosity only"; under Non-invasive Prenatal Screening (NIPS) for Single-Gene Disorders added "81405". For Other Related Policies: added "and Molecular". For Criteria; Non-invasive Prenatal Screening (NIPS) for	11/23	2/27/24	

Chromosome 13, 18, 21, X and Y Aneuploidies: under I. removed "trisomy"; under I.B. removed "received appropriate counseling…"; added "NOT previously had cell-free DNA…"; under III. Added "B. For multiple gestation pregnancies…". For Notes and Definitions: removed "Clinical Considerations…". For Background and Rationale: added "American College of Medical Genetics (ACMG)…"; under Non-invasive Prenatal Screening (NIPS) for Single Gene Disorders: replaced "March 2020" with "October 2022"; under Maternal Serum Screening: removed "All women should be offered…"; added "The American College of Obstetricians…".			
Semi-annual review. Minor rewording for clarity throughout. Coding, reference-table, background and references updated.	06/24	9/17/24	10/17/24
Semi-annual review. Updated title to reflect V1.2025 version. Non-invasive Prenatal Screening (NIPS) for Microdeletions: Changed title of policy and criteria sets to include "Prenatal Cell-free DNA Testing" and eliminate Non-Invasive Prenatal Screening in line with ACMG guidance; See new policy and criteria sets within this document; Updated References in Policy Reference Table to reflect current references used. Non-invasive Prenatal Screening (NIPS) for Single-Gene Disorders: Changed title of policy and criteria sets to include "Prenatal Cell-free DNA Testing" and eliminate Non-Invasive Prenatal Screening in line with ACMG guidance; See new policy and criteria sets within this document; Update example test in Policy Reference Table. Non-invasive Prenatal Screening (NIPS) for Chromosome 13, 18, 21, X and Y Aneuploidies: Changed title of policy and criteria sets to include "Prenatal Cell-free DNA Testing" and eliminate Non-Invasive Prenatal Screening in line with ACMG guidance; See new policy and criteria sets within this document. Maternal Serum Screening (MSS): Changed title of policy and criteria sets to include "Prenatal Cell-free DNA Testing" and eliminate Non-Invasive Prenatal Screening in line with ACMG guidance; See new policy and criteria sets within this document. Non-invasive Prenatal Screening (NIPS) for Fetal RhD (Alternate): Alternate criteria with coverage for fetal RH genotyping; Changed title of policy and criteria sets to include "Prenatal Cell-free DNA Testing" and eliminate Non-Invasive Prenatal Screening in line with ACMG guidance; See new policy and criteria sets within this document.	01/25	3/31/25	5/1/25

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3. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Obstetrics; Committee on Genetics; Society for Maternal-Fetal Medicine. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin, Number 226. *Obstet Gynecol*. 2020;136(4):859-867. doi:10.1097/AOG.0000000000004084
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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