Revision log
Coding Implications

CONCERT GENETIC TESTING: PRENATAL SCREENING

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

OVERVIEW

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

This policy addresses the use of tests for fetal screening of genetic disorders during pregnancy. These include prenatal cell-free DNA testing for chromosome 13, 18, 21, X, and Y aneuploidies, microdeletions, and single-gene disorders, as well as maternal serum screening (MSS).

Before testing, guidelines recommend that pregnant people be counseled about the risk of a false-positive result. Pre-test and post-test genetic counseling that facilitates informed decision-making, addresses the possibility of secondary or incidental findings, and a plan for returning results before testing occurs is strongly advised.

For additional information see the Rationale section.

POLICY REFERENCE TABLE

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. 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. 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.

The tests, CPT codes, and ICD codes referenced in this policy are not comprehensive, and their inclusion does not represent a guarantee of coverage or non-coverage. Please see the Concert Platform for additional registered tests.

CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	REF
Prenatal Cell-Free DNA Testing			
Prenatal Cell-free DNA Testing for Chromosome 13, 18, 21, X and Y Aneuploidies	Panorama Prenatal Panel (with or without twin zygosity testing - 0060U) (Natera)	81420, 81507, 0060U, 0327U, O09, O28, O30, O35, Q90-Q99, Z34, Z36.0	1, 2, 3, 5, 6
	Harmony Prenatal Test - 81507 (ACL Laboratories)		
	Vasistera - 0327U (Natera)		
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, 0489U, O09, O28, O30, O35, Q90-Q99, Z34, Z36.04	4
	PreSeek Non-invasive Prenatal Gene Sequencing Screen (Baylor Genetics, LLC)		

	UNITY Fetal Risk Screen - 0489U (Billion to One)		
	UNITY Fetal Risk Screen - 0489U (Billion to One)		
Prenatal Cell-free DNA Testing for Fetal RhD Genotyping	Fetal RhD NIPT (add-On) - 0494U (Natera)	0488U, 0494U, 81403	7, 8, 9
	UNITY Fetal RhD NIPT (add on) (Billion to One)		
	UNITY Fetal Antigen NIPT (add on) - 0488U (Billion to One)		
Maternal Serum Screening			
Maternal Serum Screening (MSS)	First Trimester Maternal Screen, Serum (Mayo Clinic Laboratories)	81508, 81509, 81510, 81511, 81512, O09, O28, O30, O35, Q90-Q99, Z34, Z36.0	3
	Quad Screen (Quest Diagnostics)		
	Serum Integrated Screen, Part 2 (Quest Diagnostics)		

RELATED POLICIES

This policy document provides criteria for cell-free prenatal screening. Please refer to:

- ***Oncology Testing: Solid Tumor Molecular Diagnostics*** for criteria related to molecular profiling of a known or suspected cancer (e.g. broad molecular profiling, including Minimal Residual Disease (MRD) Testing, Tumor Mutational Burden (TMB), and cytogenetic / fusion testing).
- ***Reproductive Testing: Carrier Screening*** for criteria related to parental carrier screening for genetic disorders before or during pregnancy.

- ***Reproductive Testing: Fertility*** for criteria related to preimplantation diagnosis.
- ***Reproductive Testing: Prenatal Diagnosis*** for criteria related to fetal diagnostic testing for genetic disorders during pregnancy and following a pregnancy loss.
- ***Specialty Testing: Multisystem Genetic Conditions*** for criteria related to diagnostic tests for genetic disorders that affect multiple organ systems (e.g. whole exome and genome sequencing, chromosomal microarray, and multigene panels for broad phenotypes).
- ***General Approach to Laboratory Testing*** for criteria related to reproductive testing, including known familial variant testing, that is not specifically discussed in this or another non-general policy.

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CRITERIA

It is the policy of health plans affiliated with Centene Corporation® that the specific genetic testing noted below is **medically necessary** when meeting the related criteria:

PRENATAL CELL-FREE DNA TESTING

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 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. Current evidence does not support prenatal cell-free DNA testing to predict twin zygosity.

III. Current evidence does not support prenatal cell-free DNA testing for all other indications, including the following:

A. For all other aneuploidies (other than trisomy 13, 18, 21, X, and Y)

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. Current evidence does not support prenatal cell-free DNA testing for microdeletions for all indications.

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Prenatal Cell-free DNA Testing for Single-gene Disorders

I. Current evidence does not support prenatal cell-free DNA testing for mutations associated with single gene disorders for all indications.

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Prenatal Cell-free DNA Testing for Fetal RhD Genotyping

I. Prenatal cell-free DNA testing for fetal RhD genotyping is considered **medically necessary** when:

A. The member/enrollee is pregnant, **AND**

B. The member/enrollee is confirmed to be RhD negative, **AND**

C. The member/enrollee is not planning to undergo amniocentesis, **AND**

D. One of the following:

1. The member/enrollee's practice setting is experiencing Rho(D) immune globulin (RhIG) shortages, **OR**
2. There is documentation of an unknown or heterozygous RhD genotype in the biological father of the fetus.

II. Current evidence does not support prenatal cell-free DNA testing for fetal RhD genotyping for all other indications.

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MATERNAL SERUM SCREENING

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)

B. Second trimester screening (hCG, msAFP, uE3, and DIA)

C. Integrated, stepwise sequential, or contingent sequential screening

D. Penta screen (hCG, msAFP, uE3, DIA, ITA).

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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, reaffirmed 2024) 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 (also called prenatal cell-free screening) for fetal aneuploidy.

ACMG recommends:

- Informing all pregnant women that prenatal cell-free screening 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 prenatal cell-free screening (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 prenatal cell-free screening over traditional screening for all pregnant patients with singleton and twin gestations for fetal trisomies 21, 18, and 13 and strongly recommends prenatal cell-free screening 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)."

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).

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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, reaffirmed 2024) 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 evidence-based clinical practice guideline (2022) on prenatal cell-free DNA screening 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 prenatal cell-free DNA screening 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 prenatal cell-free DNA screening have 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.

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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). In the advisory, they include various skeletal dysplasias, sickle cell disease, and cystic fibrosis as examples of single-gene disorders, and state that at this time, there is insufficient evidence regarding the accuracy of cell-free testing for these and other single gene conditions during pregnancy.

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Prenatal Cell-free DNA Testing for Fetal RhD Genotyping

American College of Obstetrics and Gynecology (ACOG)

ACOG issued a practice advisory in March 2024 due to an FDA announcement regarding a shortage of Rho(D) immune globulin (Rhld) shortages. The advisory acknowledges that ACOG guidelines currently do not recommend routine use of prenatal cell-free DNA testing for Rh(D) status due to "cost-effectiveness analyses". However, the committee states that the use of cfDNA testing "is a reasonable consideration" in a practice that is experiencing shortages, and that if a cfDNA test confirms an Rh(D)-negative fetus, they do not recommend further Rhlg treatments.

Additionally, ACOG issued a clinical practice update in August 2024 providing new recommendations for noninvasive cfDNA in alloimmunized patients for fetal RhD genotyping. Their updated clinical recommendation includes fetal antigen genotyping in the setting of heterozygous or unknown paternal Rh(D) genotype. They recommend consideration of fetal cell-free RHD testing as an alternative test in alloimmunized individuals who have declined invasive diagnostic procedures (p. e.1 and e.2).

Rego, et al.

A 2024 prospective, multisite, blinded study titled "Cell-Free DNA Analysis for the Determination of Fetal Red Blood Cell Antigen Genotype in Individuals With Alloimmunized Pregnancies" demonstrated that cf-DNA testing for fetal antigen genotype, including Rh(D), was highly sensitive and specific as early as 10 weeks gestation (p. 437). Per the discussion, "Concordance between fetal antigen genotype as determined by cell-free DNA analysis and neonatal antigen genotype as determined by an outside laboratory was 100% for all 190 calls on antigens to which the pregnant person was alloimmunized. Concordance was also 100% when the antigen calls were expanded to include all 465 antigens for which the pregnant person was genotype negative, resulting in a calculated assay sensitivity and specificity of 100%" (p. 439).

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Maternal Serum Screening (MSS)

The American College of Obstetricians and Gynecologists (ACOG)

ACOG provided an updated position statement (number 226) (2020, reaffirmed 2024) 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).

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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. **Singleton pregnancy** is a pregnancy with one fetus.
3. **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).
4. **Rho(D) immune globulin (RhIG)** is a medication that is used to help manage and treat Rh-negative pregnancies

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	03/23	03/23
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".	10/23	10/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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 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. Updated title to reflect V2.2024 version. Minor rewording for clarity throughout. Coding, reference-table, background and references updated.	04/24	04/24
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	11/24	11/24

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Cell-free DNA Testing" and eliminate Non-Invasive Prenatal Screening in line with ACMG guidance; See new policy and criteria sets within this document.		
Annual review. Policy name changed from Concert Genetic Testing: Non-Invasive Prenatal Screening (NIPS) to Concert Genetic Testing: Prenatal Screening. Minor wording updates without clinical significance. Changed all "investigational" policy statements to note that "current evidence does not support…" Prenatal Cell-free DNA Testing for Chromosome 13, 18, 21, X and Y Aneuploidies: Criterion III.A. corrected to include chromosomes X and Y in the list of aneuploidies. Prenatal Cell-free DNA Testing for Single-gene Disorders: noted that the test is not supported by current evidence "for all indications." New criteria section created for Prenatal Cell-free DNA Testing for Fetal RhD Genotyping. Coding table updates. Rationale and references updated.	11/25	12/25

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8. "Paternal and Fetal Genotyping in the Management of Alloimmunization in Pregnancy". Clinical Practice Update from The American College of Obstetricians and Gynecologists (ACOG). https://journals.lww.com/greenjournal/abstract/2024/08000/acog_clinical_practice_update__paternal_and_fetal.34.aspx. Published August 2024.
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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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid member/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.