Clinical Policy: Cell-free Fetal DNA Testing

Reference Number: CP.MP.84
Last Review Date: 03/20

Coding Implications
Revision Log

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

Description

Cell-free fetal DNA testing is a screening test of the woman's blood taken after 10 weeks of pregnancy. It measures the relative amount of free fetal DNA and indicates if the fetus is at increased risk of having Down syndrome (trisomy 21), Edwards syndrome (trisomy 18) and Patau syndrome (trisomy 13).

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that cell-free fetal DNA testing is **medically necessary** for members meeting all of the following criteria:
- **A.** Underwent pretest counseling;
- **B.** A cell-free fetal DNA test has not been performed yet in this pregnancy;
- **C.** Current pregnancy not a multiple gestation;
- **D.** Current pregnancy ≥ 10 weeks and < 23 weeks at the time the blood was drawn;
- **E.** High risk for fetal aneuploidy as evidenced by one of the following:
  1. Maternal age ≥ 35 years at delivery;
  2. Maternal history of a child affected with trisomy;
  3. Abnormal ultrasound findings;
  4. Positive test result for aneuploidy, including first trimester, sequential, or integrated screen, or quadruple screen;
  5. A parent carrying a balanced Robertsonian translocation with increased risk of trisomy 13 or trisomy 21.

II. It is the policy that cell-free fetal DNA testing for any indication not listed above is considered **not medically necessary**.

III. Cell-free fetal DNA testing for additional chromosomal abnormalities other than trisomy 21, 18 or 13 are considered **not medically necessary**, including, but not limited to, other trisomies, aneuploidies, or microdeletions.

Authorization Protocols

Requests for prior authorization will be accepted up to 10 business days after specimen collection and reviewed for medical necessity based on the above stated criteria.

Background

Cell-free fetal DNA testing offers a new screening tool for fetal aneuploidy. Fragments of fetal DNA, known as cell-free fetal DNA, comprise approximately 3-13% of the total cell free maternal DNA. Since its discovery in 1997, techniques for identification and analysis of cell-free fetal DNA have rapidly advanced and the range of genetic traits identifiable using these process will continue to grow.

There are limitations of cell-free fetal DNA testing and they should be discussed during pre-test counseling. The decision for testing should be an active and informed choice of the mother. Patients should be counseled that cell-free DNA screening does not replace the precision obtained with diagnostic tests, such as chorionic villus sampling or amniocentesis and, therefore, is limited in its ability to identify all chromosome abnormalities. Cell-free DNA screening does not assess risk of fetal anomalies such as neural tube defects or ventral wall defects. Pre-test counseling should also include review of the family history and possible baseline ultrasound to confirm viability, single gestation, gestational dating and review for anomalies. If a fetal structural anomaly is identified on ultrasound exam, diagnostic testing or cell-free DNA screening should be offered. Also, the mother needs to be aware that a negative cell-free fetal DNA test result does not assure an unaffected pregnancy. Invasive prenatal testing and genetic counseling should be offered for any patient with a positive test result.

Conventional screening methods remain the most appropriate choice for most women in the general obstetric population. While the sensitivity and specificity in the general obstetrics population is similar to the high-risk population, the positive predictive value is lower given the low prevalence of aneuploidy in the general population. Conventional screening methods allow for higher detection rates of chromosome abnormalities that occur at a higher rate in the general population as well as other adverse pregnancy outcomes. There is still limited data on the cost-effectiveness of cell-free fetal DNA testing in the general obstetric population.

Coding Implications

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Codes that support medical necessity

CPT® Codes	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.
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.

Codes that do not support medical necessity

CPT® Codes	Description
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.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed, specialist reviewed	07/13	08/13
Added to criteria current pregnancy between 10 and 20 weeks gestation and only one per pregnancy	06/14	07/14
Updated coding implications	01/15	
Changed criteria to allow testing up to 22 weeks of pregnancy	03/15	03/15
Removed high-risk indication of ultrasound findings, updated background	07/15	07/15
Added CPT codes 81420 and 81479 as these are codes billed by providers for cell free fetal DNA testing	10/15	
Policy converted to new template. References reviewed and updated.	07/16	07/16
Added the statement that cell-free fetal DNA testing for any indication not listed above is considered **not medically necessary**.	03/17	
Added abnormal ultrasound findings as an indication. References reviewed and updated. Updated CPT codes.	05/17	06/17
Added III. "Cell-free fetal DNA testing for additional chromosomal abnormalities other than trisomy 21, 18 or 13 are considered not medically necessary, including, but not limited to, other trisomies, aneuploidies, or microdeletions. Background information updated.	04/18	04/18
References reviewed and updated.	03/19	03/19
Changed period in which authorizations can be requested from 5 days post-service to 10 days.	05/19	
Moved 81422 and 81479 to a table for codes that do not support medical necessity. Clarified that between "10 and 22 weeks gestation" is ≥ 10 weeks and < 23 weeks gestation.	08/19	
References reviewed and updated. Removed CPT-0009M as code deleted as of 1/1/2020. Specialist review.	02/20	03/20

References

1. The American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Obstetrics, Committee on Genetics, and Society for Maternal-Fetal Medicine. Practice Bulletin: Screening for Fetal Aneuploidy. Number 163, May 2016. (Reaffirmed 2018)
2. The American College of Obstetricians and Gynecologists Committee on Genetics and Society for Maternal-Fetal Medicine Publications Committee. Committee Opinion: Cell-free DNA screening for fetal aneuploidy. Number 640, September 2015. (Reaffirmed 2017)

3. Sayres L, et al. Cell-free fetal DNA testing: A pilot study of obstetric healthcare provider attitudes towards clinical implementation. Prenat Diagn. 2011 November; 31(11): 1070–1076. Doi:10.1002/pd.2835.
4. Palomaki GE, Messerlian GM, Halliday JV. Prenatal screening for common aneuploidies using cell-free DNA. In: UpToDate, Wilkins-Haug L (Ed), UpToDate, Waltham, MA. Accessed February 26, 2020.
5. The American College of Obstetricians and Gynecologists. Practice Advisory: Cell-free DNA to Screen for Single-Gene Disorders. Practice Advisory, February 21, 2019.
6. Hayes Clinical Utility Evaluation. Cell-Free DNA (CfDNA) [Formerly NIPS, NIPT] Screening For Fetal Trisomy 21, 18, And 13 In High-Risk Women. Feb 16,2018/ Last review Feb 3, 2020

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 members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, 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 members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, 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.