Clinical Policy: Cell-free Fetal DNA Testing

Reference Number: PA.CP.MP.84
Effective Date: 06/18
Last Review Date: 12/18

Coding Implications
Revision Log

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 PA Health & Wellness® (PHW) that all pregnant women should be offered prenatal assessment for aneuploidy by screening or diagnostic test regardless of maternal age or other risk factors.

II. It is the policy of Pennsylvania Health and Wellness® (PHW) that one cell-free fetal DNA test per pregnancy is **medically necessary** for members meeting all of the following criteria:
- **A.** Underwent pretest counseling, *and*
- **B.** Current pregnancy not a multiple gestation, *and*
  1. Current pregnancy between 10 and 22 weeks gestation at the time the blood was drawn.

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

IV. 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 or microdeletions.

Authorization Protocols
Requests for prior authorization will be accepted up to 5 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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CPT® Codes	Description
81420	Fetal chromosomal aneuploidy (eg, 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 (eg, 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.
81479	Unlisted molecular pathology procedure
0009M	Fetal aneuploidy (trisomy 21, and 18) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy

Reviews, Revisions, and Approvals	Date	Approval Date
Added III. "Cell-free fetal DNA testing for additional chromosomal abnormalities other than trisomy 21, 18 or 13 are considered not medically	05/18	

Reviews, Revisions, and Approvals	Date	Approval Date
necessary, including, but not limited to, other trisomies or microdeletions. Background information updated.		
Language updated in Policy/Criteria I. to reflect ACOG recommendation that all pregnant women be offered pre-natal screening for aneuploidy.	12/18	

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.
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 (Ed), UpToDate, Waltham, MA. Accessed 04/04/18.