MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

Policy Number: MP.126.MH
Last Review Date: 05/27/2021
Effective Date: 09/01/2021

MP.126.MH – Cell-Free DNA Test

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

Cell-free fetal DNA testing has been validated for screening for Trisomy 21, Trisomy 18 and Trisomy 13.

According to the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine, the test may be used for the following high-risk women:

Limitations
1. Patients whose cell-free DNA screening test results are not reported by the laboratory or are uninterpretable (a no-call test result) should be informed that test failure is associated with an increased risk of aneuploidy, receive further genetic counseling and be offered comprehensive ultrasound evaluation and diagnostic testing. Only one cell-free DNA testing will be covered per pregnancy. Only one screening modality will be covered per pregnancy.
2. In multifetal gestations (more than two), if a fetal demise, vanishing twin or anomaly is identified in one fetus, there is a significant risk of an inaccurate test result if serum-based aneuploidy screening or cell-free DNA is used.

Background
ACOG estimates that 6-11% of stillbirths and neonatal deaths result from aneuploidies (fetus with missing or extra chromosomes). Most aneuploidies involve the presence of an extra chromosome, also referred to as trisomy.

Down syndrome, which is most commonly caused by trisomy 21 (T21), is routinely evaluated as the standard of care for the majority of the 4 million women who give birth each year in the United States. Conventional screening tests typically involve measurement of blood serum markers in conjunction with ultrasound followed by recommendation for diagnostic invasive procedures for abnormal results from screening.

First trimester combined screening (FTS) and integrated screening (INT) have the best screening performance, yet still only have T21 detection rates of 82-87% and 88-95%, respectively, at false positive rates of 5%. Invasive testing with amniocentesis or CVS

is highly accurate but has up to a 3% risk of procedure related miscarriage. The reported complication rates have come down in the last 10 years, but there is still some procedure-related risk.

A prenatal test that evaluates cell-free DNA (cfDNA) in maternal blood has been shown to be highly accurate, with T21 detection rates >99%, 98% detection rate for fetal trisomy 18 and 99% detection rate for fetal trisomy 13 with a combined false positive rate of 0.13%.

cfDNA testing can detect more T21 cases and at the same time reduce unnecessary invasive procedures and in turn fewer procedure related fetal losses. cfDNA testing, when used as a follow-up test for an abnormal result from the FTS or INT screening test can spare the vast majority of the 5% of women with false positive results from undergoing invasive diagnostic testing. Any woman with an abnormal result from cfDNA test should undergo diagnostic testing by amniocentesis or chorionic villus sampling.

Currently, there are five cfDNA assays available in the United States: Harmony Prenatal Test, informaSeq, MateriT21 PLUS, Panorama Prenatal Test, and Verifi Prenatal Test (the assays are listed in order of market entrance date).

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
CPT Codes	
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
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
ICD-10 codes covered if selection criteria are met:	
O35.1XX0-O35.1XX9	Maternal care for (suspected) chromosomal abnormality in fetus
O35.8XX0-O35.8XX9	Maternal care for other (suspected) fetal abnormality and damage
O35.9XX0-O35.9XX9	Maternal care for (suspected) fetal abnormality and damage, unspecified

O09.511-O09.519	Supervision of elderly primigravida
O09.521-O09.529	Supervision of elderly multigravida
O28.0-O28.9	Abnormal findings on antenatal screening of mother

References

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