Neighborhood Health Plan OF RHODE ISLAND™

Clinical Medical Policy

Circulating Cell-free (ccfDNA) Aneuploidy Testing-# 054

Last reviewed: 03/08/23

Benefit Coverage:

Covered Benefit for lines of business including:
RiteCare (MED), Substitute Care (SUB), Children with Special Needs (CSN), Rhody Health Partners (RHP), Medicare-Medicaid Plan (MMP) Integrity, Rhody Health Expansion (RHE), Health Benefit Exchange (HBE)
Excluded from Coverage:
Extended Family Planning (EFP)

Description:

Prenatal screening is currently recommended in pregnancy for a number of genetic disorders, chromosomal aneuploidy, and structural defects in the fetus regardless of maternal age or family history. A broad range of sonographic and maternal serum-based options exist for carrying out aneuploidy risk assessment in the first and/or second trimester. Many pregnant Neighborhood Health Plan of Rhode Island (Neighborhood) members are screened in the first and second trimester for congenital abnormalities. Circulating cell free DNA (ccfDNA) testing, obtains fetal cells from maternal circulation, and screens for the following aneuploidies: Trisomy 21 (Down Syndrome), Trisomy 13, and Trisomy 18.

According to the American College of Obstetricians and Gynecologists (ACOG) and the Society of Maternal Fetal Medicine (SMFM) circulating cell free DNA screening for Fetal Chromosomal Abnormalities should be offered in all singleton or twin pregnancies, in concordance with appropriate pre and post-test genetic counseling.

- Patients with cell-free DNA screening results suggesting aneuploidy should be offered diagnostic testing (amniocentesis or chorionic villus sampling) Detailed below
- Patients with fetal anomalies should be offered diagnostic testing
- Patients with “indeterminate,” “inadequate” or “not reported” results should be offered diagnostic testing
- Cell-free DNA screening is not currently recommended for gestations of greater than two fetuses
- Routine screening for microdeletions with cell-free DNA is not recommended
- Negative cell-free DNA results do not guarantee an unaffected pregnancy
- Cell-free DNA does not screen for all anomalies or genetic abnormalities
- Cell-free DNA testing of single gene disorders is not covered

Studies done, primarily in women who have screened positive or at high risk of trisomy because of advanced maternal age, have shown that this test has an extremely high sensitivity and specificity for the trisomy abnormalities. If the screen is positive, then a definitive test can be done. The definitive tests are a chorionic villous sample that can be done in the first trimester, or an amniocentesis, that can be done in the second trimester. A small number of the women who screen positive actually are found to have affected fetuses. Also, those definitive procedures have a risk of fetal damage or related pregnancy loss.

Generally, if the ccfDNA test is negative, the amniocentesis or chorionic membrane sample is not needed to confirm the negative status.

Coverage Determination/Criteria:

Prior authorization is required.

Neighborhood will support the use of the ccfDNA test only in singleton or twin pregnancies; gestations of greater than two fetuses are not covered for testing

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CMP Cross Reference: CMP-007 Genetic Testing

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Neighborhood reviews clinical medical policies on an annual base.

Disclaimer:

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References:

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 Oct;136(4):e48-e69. doi: 10.1097/AOG.0000000000004084. PMID: 32804883.

Society for Maternal-Fetal Medicine Statement: Clarification of Recommendations Regarding cell-free DNA Aneuploidy Screening. Am J Obstet Gynecol. 2015; 213 (6): 753-754

Norton ME: Cell-free DNA screening for women at low risk for fetal aneuploidy. OBG Manag.2016; 28(1):34-40, 42

Cell-free DNA screening for fetal aneuploidy: Strengths and limitations. OBG Manag.2016; 28 (1):24,33

The American College of Obstetricians and Gynecologists: Practice Advisory: Cell-free DNA to Screen for Single-Gene Disorder, February 21, 2019
Available at: https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Advisories/Cell-free-DNA-to-Screen-for-Single-Gene-Disorders