Neighborhood Health Plan OF RHODE ISLAND™

Clinical Medical Policy

Circulating Cell-free (ccfDNA) Aneuploidy Testing0-# 054

Last reviewed: 03/04/20

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. There is a broad range of sonographic and maternal serum-based options available 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. One type of screening involves testing that indicates whether the fetus is likely to have one of three types of aneuploidy: Trisomy 21 (Down Syndrome), Trisomy 13, and Trisomy18. This testing, cell-free DNA screening (cfDNA) for fetal aneuploidy, has been available since 2011. The circulating cell-free DNA test is a genetic test that extracts fetal cells from the maternal circulation and examines them for the trisomy abnormalities.

According to the American College of Obstetricians and Gynecologists (ACOG) and the Society of Maternal Fetal Medicine (SMFM) the optimal candidates for ccfDNA screening include:

- High risk for trisomy based on maternal age (> 35 years)
- Ultrasound findings suggesting Trisomy 13, 18 or 21
- History of prior pregnancy with Trisomy 13, 18 or 21
- Positive traditional screening test. (Initial screening for trisomy abnormalities is not considered necessary if a ccfDNA test is to be done.)
- Parental balanced Robertsonian translocation associated with risk for Trisomy 13 or 21.

Furthermore, ACOG and SMFM state:

- Cell free-DNA is a screening test and patients need thorough counseling
- Conventional screening methods (first trimester nuchal translucency with serum biomarkers and/or second trimester screening) are still the preferred first-line choice for the low-risk obstetric population
- Patients with cell-free DNA screening results suggesting aneuploidy should be offered diagnostic testing (amniocentesis or chorionic villus sampling) Detailed below

Neighborhood Health Plan of RI-910 Douglas Pike, Smithfield, RI 02917. www.nhpri.org. Authorization Line-401-459-6060. Authorization Fax- 401-459-6023

- 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 multiple gestations
- 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

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 when the following conditions are met:

☐ The member must be at high risk for fetal aneuploidy:
- ☐ The member has had an aneuploidy screening during the present pregnancy that would define her to be at high risk. These screening tests include first trimester, sequential, integrated, or quadruple screens, or a fetal ultrasound that indicates an increased risk, OR
- ☐ The member is of advanced maternal age (35 or greater) at delivery, OR
- ☐ History of a prior pregnancy with trisomy, OR
- ☐ There is a parental balanced Robertsonian translocation with risk of trisomy 13 or 21

☐ Genetic counseling must be performed prior to the ccfDNA testing.

Authorization Forms

Please access Prior Authorization forms by visiting Neighborhood's website at www.nhpri.org

1. Go to the section for Providers
2. Click on "Resources & FAQ's"
3. Click on "Medical Management Request Forms"- forms are listed alphabetically by program.

Prior Authorization Forms

For assistance with prior authorizations please contact Clinical Administrative Support at 401-459-6060.
Fax authorization forms to 401-459-6023.
Covered Codes: For information on Coding please reference the Authorization Quick Reference Guide

CMP Cross Reference: CMP-007 Genetic Testing

Created:	July 2012
Annual Review Month	March
Review Dates:	12/20/12, 1/21/14, 3/3/15, 2/18/16, 2/28/17, 3/20/18, 3/6/19, 3/4/20
Revision Dates:	1/15/13, 1/21/14, 3/3/15, 2/18/16, 6/30/16
CMC Review Dates	1/15/13, 1/21/14, 3/3/15, 3/1/16, 3/14/17, 3/20/18, 3/6/19, 3/4/20
Medical Director Approval Dates:	2/19/13, 1/28/14, 3/3/15, 3/1/16, 3/22/17, 4/30/18, 3/7/19, 3/4/20
Effective Dates:	1/28/14, 3/3/15, 3/28/16, 7/01/16, 3/23/17, 4/30/18, 3/7/19, 3/4/20

Neighborhood reviews clinical medical policies on an annual base.

Disclaimer:

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's coverage plan; a member's coverage plan will supersede the provisions of this medical policy. For information on member-specific benefits, call member services. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to review and revise this policy for any reason and at any time, with or without notice.

References:

American College of Obstetricians and Gynecologists: Committee Opinion No. 640: Cell-free DNA Screening for Fetal Aneuploidy. September 2015.

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