Application

Application of this Medical Policy applies to:
RIte Care (MED), Rhody Health Partners (RHP), Rhody Health Expansion (RHE), Children with Special Health Care Needs (CSN), Substitute Care (SUB), Commercial (HBE), INTEGRITY for Duals (FIDE), Duals CONNECT (CO-DSNP)
Application Excluded for:
Extended Family Planning (EFP)

Medicare Distinction

For INTEGRITY for Duals (FIDE) and Duals CONNECT (CO-DSNP) members: Neighborhood Health Plan of Rhode Island (Neighborhood) uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations, including medical necessity. Coverage determinations are based on applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other Medicare guidelines.

For FIDE Members: In the absence of an applicable or incomplete NCD, LCD, or other Medicare guidelines OR if available Medicare coverage guidance is not met, then Neighborhood will apply coverage guidance from the Rhode Island Executive Office of Health & Human Services (EOHHS), or other widely used treatment guidelines with peer-reviewed scientific evidence, such as InterQual® and/or internal Clinical Medical Policies as a means of secondary coverage through the member's Medicaid benefit.

For CO-DSNP Members: In the absence of an applicable or incomplete NCD, LCD, or other Medicare guidelines, then Neighborhood will apply coverage guidance from other widely used treatment guidelines with peer-reviewed scientific evidence, such as InterQual® and/or internal Clinical Medical Policies.

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

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

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

Authorization Request Forms

Access prior authorization request forms by visiting Neighborhood's website at www.nhpri.org.

1. Click on Providers
2. Click on Provider Resources
3. Click on Forms
4. Click on "Click here for a list of prior authorization request forms" – forms are listed alphabetically.

A phone messaging system is in place for requests/inquiries both during and outside of business hours. Providers can call 1-800-963-1001 for assistance.

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	February
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, 3/10/21, 3/16/22, 6/1/22, 3/8/23, 2/14/24, 2/12/25
Revision Dates:	1/15/13, 1/21/14, 3/3/15, 2/18/16, 6/30/16, 3/16/22, 6/1/22
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, 3/10/21, 3/16/22, 3/8/23, 2/14/24, 2/12/25
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 3/10/21, 3/16/22, 6/1/22, 3/8/23, 2/14/24, 2/12/25
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, 3/10/21, 3/16/22, 6/1/22, 3/8/23, 2/14/24, 2/12/25

Neighborhood reviews clinical medical policies on an annual basis.

Disclaimer:

Neighborhood has developed medical policies to assist us in administering health benefits. This medical policy is made available to you for informational purposes only and does not constitute medical advice. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Members should always consult their physician before making any decisions about medical care. Treating providers are solely responsible for medical advice and treatment of members. 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.