Benefit Coverage:

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

Medicare Distinction

For Medicare Advantage Product 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 payment policies, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other available CMS published guidance.

In the absence of an applicable or incomplete NCD, LCD, or other CMS published guidance 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 peer-reviewed scientific evidence, such as InterQual® and/or internal Clinical Medical Policies as a means of secondary coverage through the members' Medicaid benefit.

Approval is based on review of the medical necessity documentation.

For aneuploidy testing (MaterniT21 and other names – refer to CMP Circulating Cell-free (ccfDNA) Aneuploidy Testing for additional information.

For Hematological and Oncological Genetic testing, please reference the "Genomic/Genetic/Biomarker/Tumor Marker Tests" Clinical Medical Policy

Description:

Tests done for clinical genetic purposes including the diagnosis of genetic disease in children and adults, the identification of future disease risks, the prediction of drug responses, and the detection of risks of disease to future children.

Coverage Determination:

Authorization NOT	Pregnancy Diagnosis Codes listed below **DO NOT Require Authorization**: ICD-10 Diagnosis Code: O01.0 to O01.9, O02.0, O02.89, O02.9, O31.00X0 to O31.03X9, O26.20 to O26.23, O99.411, O99.419, O99.43, O35.0XX0 to O35.2XX9, O36.4XX0 to O36.4XX9, O30.029 O30.021 to O30.023
Requires Authorizati	Neighborhood Health Plan of Rhode Island (Neighborhood) covers Genetic Testing, as a clinical option when determined medically necessary by the Medical Management Department. **Prior authorization is required**.

Definitions

Global developmental delay is defined as a significant delay in two or more developmental domains, including gross or fine motor, speech/language, cognitive, social/personal and activities of daily living in children less than 5 years of age.

Intellectual disability is defined as a disability originating before 18 years of age characterized by significant limitations in both intellectual functioning and in adaptive behavior.

Documentation:

Medical Necessity documentation sent to Neighborhood for review MUST be submitted by a participating practitioner and **MUST** include the following documentation:

- ☐ Previous testing performed (actual laboratory reports/results), and/or other alternatives available to obtain the information.
- ☐ What the treating practitioners will do differently - diagnostically, therapeutically, or preventively, based on the results of this test (relevant consult notes must be submitted).
- ☐ Where the testing will be done and who will interpret the results.

Requests for genetic testing that do not include the above requested documentation will be considered incomplete.

Criteria:

Genetic testing is considered a clinical option for patients when **ALL** the following criteria are met:

- ☐ Signs and symptoms are present that may be genetically linked to an inheritable disease, or documentation of a direct risk factor for a heritable disease, **AND**

- ☐ The testing is the only and/or most medically appropriate option available to obtain the necessary information to evaluate and treat the member. **AND**
- ☐ Testing will impact the management of the member's treatment plan and result in a clinical difference for the member. **AND**
- ☐ The testing method is considered a proven method for the identification of a genetically linked heritable disease; the sensitivity and specificity of the test are known, and there is evidence that the test is considered reproducible and accurate.

Exclusions:

Genetic testing is **NOT** considered a clinical option for any of the following indications:

- Testing will provide information for future generations of member's family.
- Testing is being conducted to benefit the care and treatment of members of the patient's family who are not covered by Neighborhood.
- Experimental testing.
- Testing of parent(s) for the diagnosis of a child.

Criteria for Specific Tests

Fragile X Syndrome

Genetic testing for Fragile X Syndrome meets the definition of medical necessity for children with **ONE** of the following:

1. Individuals with global developmental delay, intellectual disability or autism, **OR**
2. Family history of Fragile X Syndrome, **OR**
3. Family history of undiagnosed global developmental delay, intellectual disability, or autism.

Microarray Testing

Chromosomal microarray analysis for developmental delay, intellectual disability, autism spectrum disorder, or congenital anomalies (81228, 81229, S3870, 0209U) is considered medically necessary when:

A. The member has developmental delay and/or intellectual disability, excluding isolated speech/language delay (see below), **OR**

B. The member has autism spectrum disorder, **OR**

C. The member has multiple congenital anomalies not specific to a well-delineated genetic syndrome, **OR**

D. The member has short stature.

Chromosomal microarray analysis for developmental delay, intellectual disability, autism spectrum disorder, or congenital anomalies (81228, 81229, S3870, 0209U) are considered investigational for all other conditions of delayed development, including:

A. Isolated speech/language delay*.

For genetic testing subsequent to Fragile X and microarray testing, the results of prior testing must be submitted with the clinical information. The results must not just be referenced in the clinical notes.

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-054 Circulating Cell-free (ccfDNA) Aneuploidy Testing

Created:	11/03
Annual Review Month	April
Review Dates:	4/08, 3/09/10, 3/02/11, 8/28/12, 5/02/13, 1/21/14, 5/20/14, 5/19/15, 6/27/16, 2/28/17, 3/20/18, 3/6/19, 3/4/20, 10/01/20, 3/10/21. 3/16/22, 3/8/23, 4/10/24, 10/9/24, 04/9/25
Revision Dates:	8/28/12, 5/02/13, 1/21/14, 5/19/15, 6/27/16, 2/28/17, 1/10/20, 03/04/20, 10/01/20, 3/16/22, 3/8/23, 10/9/24, 04/9/25
CMC Review Dates	3/09/10, 3/08/11, 9/13/11, 9/11/12, 5/21/13, 1/21/14, 5/20/14, 5/19/15, 7/12/16, 3/14/17, 3/20/18, 3/6/19, 03/04/20, 3/10/21, 3/16/22, 3/8/23, 4/10/24, 10/9/24, 04/9/25
Medical Director Approval Dates:	11/03, 7/12/07, 5/13/08, 3/09/10, 3/15/11, 12/05/11, 1/22/13, 6/04/13, 1/28/14, 6/20/14, 6/8/15, 7/12/16, 3/22/17, 4/12/18, 3/7/19, 1/10/20, 03/04/20, 10/01/20, 3/10/21, 3/16/22, 3/8/23, 4/10/24, 10/9/24, 04/9/25
Effective Dates:	1/28/14, 6/20/14, 6/8/15, 7/13/16, 3/23/17, 4/12/18, 3/7/19, 2/1/20, 3/4/20, 10/01/20, 3/10/21, 3/16/22, 3/8/23, 4/10/24, 10/9/24, 04/9/25

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:

Medicine.Net (MedicineNet® is a network of U.S. Board Certified Physicians and Allied Health Professionals)

Trompeter, E.- Editor. Mass, A.- Managing Editor. (n.d.). Genetic Testing and Diagnostic Tools in the Pharmacy Benefit. www.AISHealth.com. Specialty Pharmacy News. Neal Learner, Managing Editor, Drug Benefit News, Susan Namovicz-Peat, Managing Editor. Atlantic Information Services, Inc.

National Guideline Clearinghouse. (02/18/2014). Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility. www.guideline.gov. From US Preventive Services Task Force

Genetic Cancer risk assessment and counseling: recommendations of the National Society of Genetic Counselors

Clinical genetic evaluation of the child with mental retardation or developmental delays. circ.ahajournals.org/ Pediatrics. 2006 Jun;117(6):2304-16.

National Institute for Health and Clinical Excellence in the United Kingdom. (n.d.). Autism in children and young people. Section 8.3 Evidence Statements

American Academy of Neurology (AAN). Model Coverage Policy. Chromosomal microarray analysis for intellectual disabilities. March 2015. Available at: https://www.aan.com/siteassets/home-page/tools-and-resources/practicing-neurologist-- administrators/billing-and-coding/model-coverage-policies/15microarrayanalysismodel_tr.pdf

NCCN BRCA Testing Guidelines.

Moeschler John et al. (2014). Comprehensive Evaluation of the Child with Intellectual Disability or Global Developmental Delays. Pediatrics. DOI: 10.1542/peds.2014-183

UpToDate: Autism spectrum disorder in children and adolescents: Evaluation and diagnosis, May 2022.

Mintz CS, Seaver LH, Irons M, Grimberg A, Lozano R, ACMG Professional Practice and Guidelines Committee. Focused Revision: ACMG practice resource: Genetic evaluation of short stature. Genet Med. 2021;23(5):813-815.

CMS. (March 2018) National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2) https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372&ncdver=1&DocID=90.2&bc=gAAAABAAAAAA&