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)

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** Required	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 Authorizatio	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).
- ☐ Genetic counseling received by the member and/or plans for this.
- ☐ 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** of 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**
- ☐ Pre and post genetic counseling must be provided by a qualified and appropriately trained practitioner. **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 care and treatment of member of the patient's family who is 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

Microarray testing is covered for children when **ALL** the following conditions are met:

- ☐ Biochemical tests for metabolic disease have been performed and the results are non-diagnostic, **AND**
- ☐ In the case of speech/language delay, audiometry has been performed and the results are available, **AND**
- ☐ The results for the genetic testing have the potential to impact the clinical management of the patient, **AND**
- ☐ Testing is requested after the parent(s) have been engaged in face-to face genetic counseling with a health care professional who has appropriate genetics training and experience
- ☐ **AND** in individuals with **ONE** of the following:
  - ☐ Multiple anomalies not specific to a well-delineated genetic syndrome, **OR**
  - ☐ Apparently non-syndromic global developmental delay/intellectual disability, **OR**
  - ☐ Autism spectrum disorders

Microarray is considered investigational in individuals with growth retardation, speech delay, and other indications. (Per ACMG)

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

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.
For More information on Coding, please reference the Authorization Quick Reference Guide

CMP Cross Reference: CMP-054 Circulating Cell-free (ccfDNA) Aneuploidy Testing

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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)

CMS. (2007). Excerpts from LCD for Genetic Testing L23664. CMS.gov. Retreived from: http://www.cms.hhs.gov/mcd/cptlicense.asp?page=overview.asp&type=lcd&from=basket&lmrpid=23664&lmrpversion=4&viewAMA=N&basket=lcd%3A23664%3A4%3AGenetic+Testing%3ACarrier%3ANoridian+Administrative+Services%7C%7C+LLC+%2800820%29%3A

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/

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

NCCN BRCA Testing Guidelines.

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

Uptodate: Autism spectrum disorder: Diagnosis May 2014

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&

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