

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.

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: <u>ICD-10 Diagnosis Code:</u> 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 Authorization	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 TestsFragile 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.

Oncotype DX: Gene Expression Profiling Tests for Breast Cancer CPT 81519Or ENDOPREDICT: Breast Cancer Prognostic CPT 81599

Gene expression profiling can be used to sub-classify breast cancer, predict disease prognosis, and determine likely response to specific therapy. It may be used to estimate the risk of breast cancer recurrence in women with early stage disease and may be used to identify those patients who would benefit from chemotherapy in addition to surgical treatment. Prior authorization is required.

- ☐ The breast tumor is hormone receptor positive, **AND**
- ☐ The breast tumor is HER2 receptor negative, **AND**

- ☐ The tumor size is greater than 0.5 cm, **AND**
- ☐ The tumor is stage pT1, pT2 or pT3; is non-metastatic or has axillary lymph node micro metastases less than or equal to 2 mm.
- ☐ Gene expression testing is being used to appropriateness of using chemotherapy; and
- ☐ The ordering clinician attests that the results are needed to determine the potential benefit of chemotherapy as a drug class.

Coverage will not be approved when test is requested in order to:

1. Predict response to specific chemotherapy regimens.
2. Repeat testing or testing of multiple tumor sites in the same patient.

Required clinical documentation:

1. Completed and signed request must include;
 - a. Primary diagnosis and proper code.
 - b. Date of diagnosis.
 - c. Most recent clinical notes.
 - d. Tumor pathology report.
 - e. Results of hormone and receptor testing.

Next Generation Sequencing (Codes 0036U and 0037U)

Description: Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. In addition, in vitro companion diagnostic laboratory tests provide a report of test results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product. Next Generation Sequencing (NGS) is one technique that can measure one or more genetic variations as a laboratory diagnostic test, such as when used as a companion in vitro diagnostic test. Patients with cancer can have recurrent, relapsed, refractory, metastatic, and/or advanced stages III or IV of cancer. Clinical studies show that genetic variations in a patient's cancer can, in concert with clinical factors, predict how each individual responds to specific treatments. In application, a report of results of a diagnostic laboratory test using NGS (i.e. information on the cancer's genetic variations) can contribute to predicting a patient's response to a given drug: good, bad, or none at all. Applications of NGS to predict a patient's response to treatment occurs ideally prior to initiation of such treatment.

National Coverage Indications

Effective for services performed on or after March 16, 2018, the Centers for Medicare & Medicaid Services (CMS) has determined that Next Generation Sequencing (NGS) as a diagnostic laboratory test is reasonable and necessary and covered nationally, when performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, when ordered by a treating physician, and when all of the following requirements are met:

- ☐ Patient has:
 - ☐ Either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; and,

- ☐ Either not been previously tested using the same NGS test for the same primary diagnosis of cancer, or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by treating physician; and,
- ☐ Decided to seek further cancer treatment (e.g., therapeutic chemotherapy)
- ☐ The diagnostic laboratory test using NGS must have:
 - ☐ Food & Drug Administration (FDA) approval or clearance as a companion in vitro diagnostic; and,
 - ☐ And FDA-approved or –cleared indication for use in that patient’s cancer; and,
 - ☐ Results provided to the treating physician for management of the patient using a report template to specify treatment options.

BRCA Testing Criteria

Note: National Comprehensive Cancer Network (NCCN) guidelines state that meeting one or more of these criteria warrants further personalized risk assessment, genetic counseling and consideration of genetic testing.

Comprehensive BRCA1/BRCA2 genetic testing includes sequencing of both BRCA1 and BRCA2 genes and analysis for large genomic rearrangements, either concurrently or sequentially. NCCN guidelines emphasize the need for comprehensive testing for individuals who meet the testing criteria for BRCA1/BRCA2 and have no known familial BRCA1/BRCA2 mutations who have undergone accurate risk assessment and genetic counseling.

I. BRCA1 and BRCA2 testing is proven and medically necessary for women with a personal history of breast cancer in the following situations and where gene testing results will impact medical management:

- ☐ **A. Breast cancer diagnosed at age 45 or younger with or without family history; OR**
- ☐ **B. Breast cancer diagnosed at age 50 or younger with:**
 - ☐ An additional primary breast cancer, **OR**
 - ☐ At least one close blood relative with breast cancer at any age, **OR**
 - ☐ At least one close blood relative with pancreatic cancer, **OR**
 - ☐ At least one close blood relative with prostate cancer (Gleason score ≥ 7), **OR**
 - ☐ An unknown or limited family history (see Definitions section for further clarification of limited family history)
- ☐ **C. Breast cancer diagnosed at any age with:**
 - ☐ At least one close blood relative with breast cancer diagnosed at age 50 or younger, **OR**
 - ☐ At least two close blood relatives on the same side of the family with breast cancer at any age, **OR**
 - ☐ At least one close blood relative with ovarian cancer at any age, **OR**
 - ☐ At least two close blood relatives on the same side of the family with pancreatic and /or prostate cancer (Gleason score ≥ 7) at any age, **OR**
 - ☐ Close male blood relative with breast cancer, **OR**
 - ☐ At least one close blood relative who has a BRCA1 or BRCA2 mutation (Testing should be targeted to the known BRCA1/BRCA2 mutation in the family. Further BRCA1/BRCA2 testing

should only be pursued if the results are negative and the patient otherwise meets testing criteria),

OR

- ❑ Ashkenazi Jewish or ethnic groups associated with founder mutations. Testing for Ashkenazi Jewish founder-specific mutations should be performed first. Further BRCA1/BRCA2 testing should only be pursued if the results are negative and the patient otherwise meets testing criteria without considering Ashkenazi Jewish ancestry.

❑ **D. Triple-negative breast cancer diagnosed at age 60 or younger.**

II. BRCA1 and BRCA2 testing is proven and medically necessary for women with a personal history of ovarian cancer.

III. BRCA1 and BRCA2 testing is proven and medically necessary for women and men with a personal history of pancreatic cancer at any age and at least one close blood relative on the same side of the family with breast (\leq age 50 years), ovarian, pancreatic and/or prostate cancer (Gleason score ≥ 7) at any age.

IV. BRCA1 and BRCA2 testing for Ashkenazi Jewish founder-specific mutations is proven and medically necessary for women and men with a personal history of pancreatic cancer and Ashkenazi Jewish ancestry.

V. BRCA1 and BRCA2 testing is proven and medically necessary for men with a personal history of prostate cancer (Gleason score ≥ 7) at any age and at least one close blood relative on the same side of the family with breast (\leq age 50 years), ovarian, pancreatic and/or prostate cancer (Gleason score ≥ 7) at any age.

VI. BRCA1 and BRCA2 testing is proven and medically necessary for men with a personal history of breast cancer.

VII. BRCA1 and BRCA2 screening tests are proven and medically necessary for men and women without a personal history of breast or ovarian cancer with at least one of the following familial risk factors only when there are no family members affected with a BRCA associated cancer available for testing (**see Note below**):

- ❑ At least one first- or second-degree blood relative meeting any of the above criteria (I-VI),

OR

- ❑ At least one third-degree blood relative with breast cancer and/or ovarian cancer who has at least 2 close blood relatives with breast cancer (at least one with breast cancer at age 50 or younger) and/or ovarian cancer, **OR**

- ❑ A known BRCA1/BRCA2 mutation in a blood relative (defined as first-, second- or third-degree relative). Testing should be targeted to the known BRCA1/BRCA2 mutation in the family. Further BRCA1/BRCA2 testing should only be pursued if the results are negative and the patient otherwise meets testing criteria.

► **Note:** NCCN guidelines state that significant limitations of interpreting test results for an unaffected individual should be discussed. If there are no living family members with breast or ovarian cancer available for testing, consider testing family members affected with other cancers associated with BRCA1/BRCA2, such as prostate cancer (Gleason score ≥ 7), pancreatic cancer or melanoma.

Testing of unaffected individuals should only be considered when there is no affected family member available for testing (NCCN, 2015).

VIII. BRCA1 and/or BRCA2 testing is unproven and not medically necessary for all other indications including: 1) screening for breast or ovarian cancer risk for individuals not listed in the proven indications above or 2) for risk assessment of other cancers.

Further evidence is needed to establish the clinical utility of testing in other populations.

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

Created:	11/03
Annual Review Month	March
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
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
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
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
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

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. Retrieved from: <http://www.cms.hhs.gov/mcd/cptlicense.asp?page=overview.asp&type=lcd&from=basket&lmpid=23664&lmpversion=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.AISHHealth.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 Health 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. Pediatrics. 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=gAAAABAAAA&>