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 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 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.

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

Description:

Genetic testing is defined by the National Human Genome Research Institute (NHGRI) as the use of a laboratory test to examine an individual's DNA for variations, typically performed in the context of medical care, ancestry studies or forensics. In a medical setting, the results of a genetic test can be used to confirm or rule out a suspected genetic disease. Results may also be used to determine the likelihood of parents passing on a genetic mutation to their offspring. Genetic testing may be performed prenatally or after birth. Genetic testing is also used to study the genomes of tumors in cancer cases. DNA is composed of four chemical building blocks, often referred to as the four "letters" of the genetic code. The sequence of these letters contains the instructions needed for growth, development, and normal body function. These long DNA sequences are organized into chromosomes, which package and store genetic information. An individual inherits approximately 3.2 billion DNA letters from each parent, resulting in a genome of about 6.4 billion DNA letters. The genome represents the complete set of genetic instructions for a person and serves as a biological blueprint that directs how cells grow, function, and maintain health. A copy of the

genome is present in nearly every cell of the body, and variations within the genetic code can influence physical traits and the development of certain diseases, collectively referred to as the phenotype.

Genetic testing evaluates a person's genotype, or the specific DNA sequence within a targeted portion of the genome. Genotyping compares an individual's genetic sequence to a reference sequence considered typical or expected, genetic testing can help diagnose inherited conditions, assess disease risk, and inform treatment decisions. Differences between an individual's genetic code and the reference sequence are known as genetic variants. Most variants are benign and do not affect health; however, some variants may disrupt normal biological function and contribute to disease. These disease-causing variants are referred to as pathogenic variants.

Genotyping can evaluate either germline cells or somatic cells. Germline cells contain the genetic information inherited from an individual's parents and are present in nearly all cells of the body. In contrast, somatic cells may acquire genetic changes after birth (i.e. cancer cells) and therefore may no longer reflect the original inherited genetic code. Analysis of germline DNA is commonly used to identify inherited genetic conditions, while analysis of somatic DNA is often used to detect acquired genetic changes associated with disease.

Germline variants are genetic changes in the DNA sequence that are inherited from a person's parents and are present at birth in nearly all cells of the body. In contrast, somatic variants are genetic changes that occur after birth. These acquired changes can result from environmental exposures, such as certain chemicals or ultraviolet (UV) radiation, or from natural DNA alterations that accumulate as cells divide and age. While germline variants can be passed to future generations, somatic variants are generally limited to the affected cells and are not inherited by offspring.

Genetic testing is a healthcare tool used to identify genetic variants associated with specific diseases or conditions. It may also be used for non-clinical purposes, such as paternity testing and forensic analysis. In clinical practice, genetic testing can help diagnose inherited disorders, confirm suspected diagnoses, assess the risk of developing certain diseases, identify the likelihood of passing genetic variants to future children, and predict an individual's response to specific treatments. They can be used to screen newborns and fetuses which may help diagnose and treat disease before symptoms develop. Genetic testing of embryos can also occur as part of the in vitro fertilization process.

There are many types of genetic tests, some examples include:

- **Whole genome sequence/Whole exome sequence:** These tests analyze the bulk of an individual's DNA to find genetic variations. Whole exome or whole genome sequencing is typically used when single gene or panel testing has not provided a diagnosis, or when the suspected condition or genetic cause is unclear. Whole exome or whole genome sequencing is often more cost- and time-effective than performing multiple single gene or panel tests.

- **Karyotype:** looks at the size, shape, and number of chromosomes in a sample of cells from your body.
- **Chromosomal microarray:** a test that looks at chromosomes in greater detail (multiple types of microarrays)
- **Panel:** look for variants in more than one gene. This type of test is often used to pinpoint a diagnosis when a person has symptoms that may fit a wide array of conditions, or when the suspected condition can be caused by variants in many genes. (For example, there are hundreds of genetic causes of epilepsy.)
- **Single gene test:** look for any genetic changes in one gene. These tests are typically used to confirm (or rule out) a specific diagnosis, particularly when there are many variants in the gene that can cause the suspected condition.
- **Targeted testing:** looks for a specific variant in a gene. The selected variant is known to cause a disorder (for example, the specific variant in the HBB gene that causes sickle cell disease).
- **Pharmacogenomic test:** a type of targeted testing looking at genes involved in drug metabolism
- **Tumor marker genotyping:** a panel test looking for genes that drive tumor growth and/or identify a tumor type

Genetic testing has important ethical, legal, and psychosocial considerations that should be addressed before and after testing. Potential issues include the emotional and psychological impact of test results, disclosure of genetic information to family members, testing of minors, discovery of previously unknown familial relationships, and concerns regarding privacy and the potential misuse of genetic information.

Genetic Counseling

The National Society of Genetic Counselors defines genetic counseling as the process of aiding individuals to understand and acclimate to the medical, psychological, and familial implications of genetic contributions to disease. Genetic counseling includes the compilation of a detailed family history; interpretation of the family history with the medical history to assess the chance of disease occurrence or recurrence; patient and family education about the inheritance, testing, management, risk reduction, resources, and research regarding the individual's specific condition; and counseling to help the individual make informed choices to provide appropriate interventions.

Definitions

Global Developmental Delay	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	Defined as a neurodevelopmental condition, originating before 18 years of age, that affects functioning in two areas: 1. Cognitive functioning, such as learning, problem solving and judgement. 2. Adaptive functioning, activities of daily life such as communication skills and social participation.

Coverage Determination:

Authorization **NOT** Required	Certain Genetic Services requested for the following 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 covers Genetic Testing, as a clinical option when determined medically necessary by the Medical Management Department. **Prior authorization is required**.

Neighborhood uses the most recent version of InterQual® CP: Molecular Diagnostics criteria to determine the medical necessity of genetic testing. Neighborhood makes InterQual® criteria available to the public through the InterQual® Transparency Tool on our website.

Important Prior Authorization Information

The ordering physician (or other qualified healthcare provider, i.e., nurse practitioner, clinical nurse specialist, physician assistant) is responsible for obtaining prior authorization. Labs cannot obtain prior authorization on behalf of the ordering provider.

Information for processing laboratories: When a specimen comes into your lab for genetic testing, before you analyze the specimen, please verify that there is an approved authorization for the test and the CPT and/or HCPCS codes approved as part of that authorization.

Information for Ordering Providers: Requests for prior authorization must include **ALL** of the following:

1. The gene(s) and/or gene variants to be tested.
2. The name of the test and the name and address of the lab performing the test.
3. All CPT and HCPCS codes and units of service for each (codes not authorized will not be reimbursed).
4. An explanation of how the results of the test will be clinically useful to the medical management of the member.
5. Previous testing performed (actual laboratory reports/results), and/or other alternatives available to obtain the information.
6. Clinical documentation from the treating provider's medical records that clearly supports the medical necessity of the test. Failure to provide this information will result in a denial of the request.

- **Prepopulated laboratory order forms, test requisitions, and Certificates of Medical Necessity do not constitute independent clinical documentation and are not acceptable for medical necessity review. Supporting clinical records from the treating provider must be submitted for consideration.**
- When multiple procedure codes are submitted on prior authorization request, the documentation supporting each code should be easily identifiable.
- When the documentation does not establish the medical necessity for the requested test(s), the test(s) will be denied as not medically necessary.
- In regard to panel testing, prior authorization is required for each component and/or gene/gene variant of a panel test when the panel is represented by multiple CPT codes. If any tests included in the panel do not meet criteria the entire panel will be denied. Unlisted codes should be used only if no other specific codes adequately describe the procedure or service. When requesting prior authorization for a laboratory test using an unlisted code, the documentation must clearly identify the name of unique genetic test performed and a short description of the test.

Criteria:

This policy serves as the baseline clinical policy for all requests when specific criteria are not available. When InterQual® criteria exist for the requested test or service, those criteria should be applied. Mandatory biomarker coverage requirements and applicable state or federal laws may supersede this policy.

Genetic testing is considered medically necessary and may be authorized 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.
- ☐ The genetic test is ordered by a practitioner within the scope of their practice.
- ☐ The results of the test must be clinically useful and have the potential to significantly alter the management or treatment of the member's condition. (e.g., initiate a new course of therapy, alter an existing therapy, or determine level of surveillance).
- ☐ The testing ordered is reasonable in scope, and the risks of testing do not outweigh its benefits. For example, it is not reasonable to order a whole exome sequence (looks at the coding sequences for approximately 20,000 genes) when looking for a single point mutation in one gene.
- ☐ Clinical documentation in the treating physician's medical records clearly supports the medical necessity of the test.
- ☐ 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.
- ☐ The testing is the only and/or most medically appropriate option available to obtain the necessary information to evaluate and treat the member.
- ☐ The test must be performed by a contracted laboratory unless none is available.

The criteria for Genetic Testing apply to all requests for genetic testing. This is in addition to InterQual Criteria, when InterQual Criteria are available.

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:

1. The member has developmental delay and/or intellectual disability, excluding isolated speech/language delay (see below), **OR**
2. The member has autism spectrum disorder, **OR**
3. The member has multiple congenital anomalies not specific to a well-delineated genetic syndrome, **OR**
4. 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.

Exclusions and Limitations:

- Testing will provide information for future generations of members' families.
- 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.
- Germline genetic testing is allowed once during the member's lifetime per disease for diagnostic purposes.
- Direct-to-consumer genetic testing, including, but not limited to, "home-test kits" or genetic tests ordered by the member over the telephone or Internet.
- Duplicate genetic testing for an inherited condition. Exceptions may be considered if there is uncertainty about the validity of the existing test result. The decision to retest a member will be considered based on the recommendation of a genetics professional who can best assess the incremental benefit of repeat testing.

References:

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- 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
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- 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.

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:

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, 4/8/26, 10/14/26
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, 4/8/26, 10/14/26
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, 4/8/26, 10/14/26
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, 4/8/26, 10/14/26
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, 4/8/26, 10/14/26

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.