

# Clinical Medical Policy

Biomarkers - #076

Last reviewed: 12/6/23

### Benefit Coverage

Covered Benefit for lines of business including:
RIte Care (MED), Substitute Care (SUB), Children with
Special Health Care Needs (CSN), Rhody Health Partners
(RHP), Medicare-Medicaid Plan (MMP) Integrity, Rhody
Health Expansion (RHE)
Excluded from Coverage:
Extended Family Planning (EFP)

# **Medicare Distinction**

For INTEGRITY 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.

# Description

Genetic variations can affect the efficacy of drug regimens due to subsequent variations in drug target protein expression. Identifying genetic variations can, in some cases, predict drug response, and serve as a useful tool in selecting treatment regimens and making clinical decisions.

# **Coverage Determination**

Requests for Evidence Based Services are covered ONLY when ALL of the following criteria are met:

- 1. The requested service or item is safe and effective,
- 2. The requested service or item is not experimental or investigational, and is supported by medical and scientific evidence,
- 3. The requested service or item is within accepted standards of medical practice,
- 4. The requested service or item is appropriate to the medical needs and condition of the member in the current clinical scenario,
- 5. The requested service or item is not specifically excluded by another Clinical Medical Policy or treatment guideline,



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- 6. Documentation has been provided showing a face-to-face visit with the ordering physician within the last 30 days OR there is confirmation that testing has been recommended by a Tumor Board or consulting specialist,
- The test will confirm or rule out a diagnosis, OR the results of the test are necessary to determine the correct treatment plan, OR the test is required to prevent, diagnose, monitor, or treat complications resulting from participation in a clinical trial AND
- 8. The requested service or item is ordered and furnished by qualified personnel.

Pharmacogenetic Multi-Gene Panels (5 or more genes) are considered proven and medically necessary for guiding treatment with antidepressants and/or antipsychotic medications when all of the following criteria are met:

- 1. The individual has a diagnosis of major depressive disorder or generalized anxiety disorder,
- 2. The individual has trialed and failed at least one prior medication to treat their condition,
- 3. The Multi-Gene Panel has no more than 15 relevant genes.

# Exclusions

Requests for biomarker testing that is the subject of a clinical trial or experimental protocol.

The use of pharmacogenetic Multi-Gene Panels (5 or more genes) for genetic polymorphisms for any other indication than guiding treatment with antidepressant and/or antipsychotic medication, including but not limited to pain management, ADHD, cardiovascular drugs, anthracyclines, or polypharmacy, is unproven and not medically necessary due to insufficient evidence. Examples of these panels include, but are not limited to, the following: GeneSight® ADHD, Pain Medication DNA Insights®, PharmacoDx, SureGene Test

The use of the PrismRA® molecular signature test is unproven and not medically necessary for evaluating likelihood of inadequate response to anti-TNF therapies for rheumatoid arthritis due to insufficient evidence of efficacy.

# **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.



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CMP Cross Reference:	
Created:	12/2023
Annual Review Month:	December
<b>Review Dates:</b>	12/6/23
<b>Revision Dates:</b>	
CMC Review Date:	12/6/23
Medical Director	12/6/23
Approval Dates:	
Effective Dates:	1/1/24

Neighborhood reviews clinical medical policies on an annual base.

#### **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:**