

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)

Except as otherwise required by law, Neighborhood Health Plan of Rhode Island (Neighborhood) does not cover experimental or investigative treatment or drugs. This policy applies to medications, procedures, devices, diagnostic modalities, supplies, services, facilities, and protocols. In this document, all such modalities will be referred to as “treatments.” Please note that there are other Clinical Medical Policies (CMPs) that may apply specifically to certain medications, procedures, devices, diagnostic modalities, supplies, services, facilities, and protocols.

Description and Definitions

Medical Management of many diseases is often a rapidly evolving process. As a result, there may exist ambiguities regarding the degree to which a treatment is experimental or investigational. Neighborhood has a formal mechanism to evaluate and review published scientific evidence detailing the clinical use, safety, efficacy and expected health outcomes of new technology and new applications of existing technology for inclusion in the benefit package to keep pace with advancements/developments and to meet the needs of our membership. Neighborhood will make a determination as to whether a medication, procedure, device, diagnostic modality, supply, service, facility, or protocol is not to be covered because the measure is experimental. A well-defined appeals process is in place to allow members, their representatives, or their providers to challenge these determinations if they so choose.

Treatment: In this document, the term “treatment” is used to apply to medications, procedures, devices, diagnostic modalities, supplies, services, facilities, and protocols.

Cancer: A disorder characterized by the proliferation of abnormal cells that generally grow in an uncontrolled and disorganized fashion and result in the invasion of and destruction of healthy organs and tissues.

Life-threatening Disease: A disease that is likely to cause death within one year of the request for treatment.

Experimental/Investigational: Experimental and/or investigational services are those that have not been recognized as proven effective in clinical medicine. Any treatment that does *not* meet at least one of the following definitions may be considered to be experimental or investigational and *may be subject to review or prior authorization by Neighborhood.*

- A. The treatment has been approved by the FDA or appropriate governmental body *for the intended use.*

- B. The treatment has been deemed as effective by a credible scientific evaluative organization such as Cochrane review, Up To Date, a medical textbook, or guidelines published or endorsed by a governmental agency.
- C. The treatment (for the indication being considered) is not presently being evaluated by means of a phase I or II or III clinical trial.

Coverage Determination

Experimental treatment for cancer or life-threatening disease:

In reference to all lines of business, Neighborhood Health Plan of Rhode Island will not restrict the ability of members with cancer or life-threatening diseases from participation in legitimate clinical trials provided that:

- the member is considered to be an appropriate candidate for the trial,
- the trial has been approved by the relevant Institutional Review Board,
- the organization administering the treatment by means of the trial is qualified to do so,
- and by a process of proper “informed consent,” the member has agreed to participate. *It is the responsibility of the organizations sponsoring the trial and the organization administering the trial, to ensure that the member’s participation in the trial meets ethical and professional standards in reference to protections of the rights of human subjects in clinical trials.*

Neighborhood Health Plan of Rhode Island will follow the current Medicare guidelines regarding coverage for trial-related items not already covered by the trial. Among the items excluded for coverage by Neighborhood are lodging, transportation, and any expenses that the clinical trial covers. Neighborhood will not provide duplicative coverage for services for which the investigator is already receiving payment or for drug/device costs borne by the trial. Reimbursements for visits with a clinician while the trial is ongoing are generally covered by the trial and providers should not duplicatively bill Neighborhood for such services.

Experimental treatment for all conditions other than cancer and life-threatening disease:

Requests for treatment, procedures, facilities, equipment, drugs, supplies, or services that have not been recognized as proven effective in clinical medicine and have not been previously evaluated by the Clinical Management Committee require prior authorization and a review for medical necessity.

The criteria outlined below are used to determine medical necessity. If multiple requests for a given experimental service are received, the service will be addressed by means of a new CMP or the modification of an existing CMP.

Treatments that do not meet the criteria A-C listed in the section above (definition of Experimental/investigational, page 1) are eligible for review. The possible outcomes for the review are summarized below:

1. *The treatment meets criteria for medical necessity* If upon review, it is determined that medical necessity warrants coverage of the requested treatment, procedure, facility, equipment, drug, supply or service, Neighborhood’s Medical Director (or physician designee) may issue a case-based decision.

2. *The treatment is deemed to be experimental* if, upon review, the treatment is deemed to be experimental/investigational, approval by Neighborhood will be granted only as described above.
3. *The treatment is deemed to be unsupported by scientific evidence* Neighborhood will not authorize treatment modalities that are not backed up by legitimate scientific evidence.

Criteria

The following criteria will be used in order to determine if a requested treatment is medically necessary:

- Where applicable, the treatment must have final approval from the appropriate governmental bodies
- Scientific evidence must include publication of results in peer-reviewed medical journals
- Scientific evidence must permit reliable conclusions to be drawn about the effect of the treatment on health outcomes
- The available evidence must support the conclusion that the treatment improves health outcomes
- The available evidence must support the conclusion that the treatment is:
 - As beneficial as any established alternative, or
 - More beneficial than existing alternatives for an identifiable subgroup of individuals
- The available evidence must support the conclusion that the treatment:
 - As safe as existing alternatives, or
 - If the treatment is less safe than existing alternatives but is efficacious for patients who are not adequately treated with existing alternatives, approval may be recommended provided that all other criteria, including #5 above are met.
- The available evidence must support the conclusion that the benefits outweigh the risks
- The available evidence must demonstrate that the benefits of the treatment are attainable outside controlled, investigational settings

Other

Any treatment that has not been identified as being a covered benefit (see page one-definition of experimental/investigational above) will not be covered.

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.

Covered Codes: For information on Coding please reference the [Authorization Quick Reference Guide](#)

CMP Cross Reference:

Created:	September 2007
Annual Review Month:	April
Review Dates:	12/29/09, 5/21/13, 1/21/14, 3/3/2015, 2/18/16, 2/28/17, 2/27/18, 3/6/19, 3/4/20, 3/10/21, 03/16/22, 3/8/23, 4/10/24
Revision Dates:	1/21/14, 2/18/16, 6/30/16, 2/27/18, 3/6/19
CMC Review Date:	2/12/08, 1/12/10, 1/11/11, 1/10/12, 5/21/13, 1/21/14, 3/3/15, 3/01/16, 3/14/17, 3/20/18, 3/6/19, 3/4/20, 3/10/21, 03/16/22, 3/8/23, 4/10/24
Medical Director Approval Dates:	2/12/08, 1/12/10, 2/14/11, 2/23/11, 6/04/13, 1/28/14, 3/3/15, 3/01/16, 3/22/17, 4/12/18, 3/7/19, 3/4/20, 3/10/21, 03/16/22, 3/8/23, 4/10/24
Effective Date:	1/28/2014, 3/3/2015, 3/14/16, 7/1/16, 3/23/17, 4/12/18, 3/7/19, 3/4/20, 3/10/21, 03/16/22, 3/8/23, 4/10/24

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:

Contract between State of RI and Providence Plantations Department of Human Services and Neighborhood Health Plan of Rhode Island, Inc for the Provision of Health Plan Services

Medicare coverage for trials

<http://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/downloads/finalnationalcoverage.pdf>

