



## **Clinical Medical Policy Experimental, or Investigational Services**

### **Benefit Coverage:**

Except as otherwise required by law, Neighborhood Health Plan of Rhode Island (Neighborhood) does not cover experimental or investigative treatment or drugs. In compliance with Rhode Island General Law (RIGL) 27-18-36.2, New Cancer Therapies, Neighborhood covers new cancer therapies still under investigation.

### **Description:**

Experimental and/or investigational services are those that have **not been recognized as proven effective in clinical medicine**. Neighborhood Health Plan of Rhode Island (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.

### **Coverage Determination:**

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 upon review, it is determined that medical necessity warrants coverage of the requested treatment, procedure, facility, equipment, drug, supply or service, Neighborhood's Associate Medical Director may issue a case-based decision. The request will be reviewed at the next scheduled Clinical Management Committee for a final determination regarding coverage for Neighborhood's entire member population.

Neighborhood provides coverage for new cancer therapies, in accordance with Rhode Island General Laws 27-18-36, 27-20-27, 27-41-41.

### **Criteria:**

If all of the following criteria are NOT met, the requested service is considered to be experimental or investigational, and therefore not eligible for coverage by Neighborhood:

- 1) Where applicable, the technology must have final approval from the appropriate governmental bodies
- 2) Scientific evidence must include publication of results in peer-reviewed medical journals
- 3) Scientific evidence must permit reliable conclusions to be drawn about the effect of the technology on health outcomes.
- 4) The available evidence must support the conclusion that the technology improves net health outcomes.
- 5) The available evidence must support the conclusion that the technology is:



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- a. As beneficial as any established alternative, or
  - b. More beneficial than existing alternatives for an identifiable subgroup of individuals
- 6) The available evidence must support the conclusion that the technology is:
- a. As safe as existing alternatives, or
  - b. If the technology 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.
- 7) The available evidence must support the conclusion that the benefits outweigh the risks.
- 8) The available evidence must demonstrate that the benefits of the technology are attainable outside controlled, investigational settings.

### Covered Procedures:

N/A

### Exclusions:

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***CMP Number:*** CMP-026

***CMP Cross Reference:***

### ***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

U.S. Food and Drug Administration – General Information

<http://www.fda.gov/cdrh/pmapage.html>

Rhode Island Laws - Chapter 9 Health Care and Insurance

[http://www.gcd.state.ri.us/RI\\_Laws/chapt\\_9.htm#\\_Toc506619179](http://www.gcd.state.ri.us/RI_Laws/chapt_9.htm#_Toc506619179)

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