Overview
The purpose of this document is to describe the guidelines Neighborhood Health Plan (NHP) utilizes to determine treatments that are considered experimental and investigational.

Coverage Guidelines
NHP covers services, procedures, devices, biologic products, and drugs (collectively “treatment”) when there is sufficient scientific evidence to support their use or when the treatment is required by regulation.

The following guidelines are utilized to determine the extent to which scientific evidence is sufficient to support a treatment:

1. The treatment must have a final approval from the appropriate government regulatory bodies (for example, the Food and Drug Administration); and
2. The scientific evidence must demonstrate that conclusions pertaining to a treatment are based on sound scientific study methodology published in credible, peer-reviewed English-language journals. The following hierarchy of reliable evidence is used:
   a. Systematic reviews and/or high-quality Meta analyses of randomized controlled trials with definitive results
   b. Formal high-quality technology assessments
   c. Well-designed, randomized, controlled, double-blind studies
   d. Cohort studies
   e. Case-control studies
   f. Expert opinion from national professional medical societies or national medical policy organizations in the absence of definitive scientific data

Note: With respect to clinical studies, only those articles containing scientifically valid data and published in the credible, peer-reviewed medical and scientific literature shall be considered reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal professional opinions. Also not included in the meaning of reliable evidence is when a provider or a number of providers have elected to adopt a device, medical treatment, or procedure as their personal treatment or procedure of choice or standard of practice.

3. The treatment must be proven to be safe and effective:
   a. Beneficial effects on health outcomes must outweigh any harmful effects
   b. Health outcomes are superior or comparable to established alternatives
   c. Improvement in health outcomes have the potential to be realized outside the investigational setting
   d. It is as cost effective as established treatments that produce similar outcomes

Exclusions
No benefits or reimbursement are provided for health care charges that are received for, or related to, care that NHP considers experimental and investigational services or procedures.

Definitions
Experimental or Investigational: A treatment, service, procedure, supply, device, biologic product, or drug (collectively “treatment”) is experimental or investigational when scientific evidence to support its use is insufficient.

Relevant Regulations
Public Law 111 - 148 - Patient Protection and Affordable Care Act, Section 2709. Coverage for a Clinical Trial.

(a) COVERAGE.—
(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);
(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
(C) may not discriminate against the individual on the basis of the individual’s participation in such trial.

(2) ROUTINE PATIENT COSTS.—

(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—

i. the investigational item, device, or service, itself;
ii. items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or
iii. a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.

(2) Either—

(A) the referring health care professional is a participating health care provider and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or
(B) the participant or beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan’s (or coverage’s) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term ‘approved clinical trial’ means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

i. The National Institutes of Health.
ii. The Centers for Disease Control and Prevention.
iii. The Agency for Health Care Research and Quality.
iv. The Centers for Medicare & Medicaid Services.
v. cooperative group or center of any of the entities described in clauses (i) through (iv) or
the Department of Defense or the Department of Veterans Affairs.
vi. A qualified non-governmental research entity identified in the guidelines issued by the
National Institutes of Health for center support grants.
vii. Any of the following if the conditions described in paragraph (2) are met:
I. The Department of Veterans Affairs.
II. The Department of Defense.
III. The Department of Energy.
(B) The study or investigation is conducted under an investigational new drug application
reviewed by the Food and Drug Administration.
(C) The study or investigation is a drug trial that is exempt from having such an investigational
new drug application.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or
investigation conducted by a Department (“departments” as referenced above in vii.), are that the study
or investigation has been reviewed and approved through a system of peer review that the Secretary (of
the respective departments listed above in vii.) determines—
(A) to be comparable to the system of peer review of studies and investigations used by the
National Institutes of Health, and
(B) assures unbiased review of the highest scientific standards by qualified individuals who have
no interest in the outcome of the review.

(e) LIFE-THREATENING CONDITION DEFINED.—In this section, the term ‘life-threatening condition’ means any
disease or condition from which the likelihood of death is probable unless the course of the disease or condition
is interrupted.

General Laws of Massachusetts Part I, Title XXII Chapter 175: Section 47K –Off-label use drug use: cancer treatment
No individual policy of accident and sickness insurance issued pursuant to section one hundred and eight which provides
coverage for prescription drugs, nor any group blanket policy of accident and sickness insurance issued pursuant to
section one hundred and ten which provides coverage for prescription drugs, shall exclude coverage of any such drug
used for the treatment of cancer on the grounds that the off-label use of the drug has not been approved by the United
States Food and Drug Administration for that indication; provided, however, that such drug is recognized for treatment
of such indication in one of the standard reference compendia, or in the medical literature, or by the commissioner
under the provisions of section forty-seven L.

General Laws of Massachusetts Part I, Title XXII Chapter 175: Sections 47O –HIV/AIDS treatment; insurance coverage for
certain off-label use of prescription drugs
No individual policy of accident and sickness insurance issued or renewed pursuant to section one hundred and eight,
which provides coverage for prescription drugs, nor any group blanket policy of accident and sickness insurance issued
pursuant to section one hundred and ten which provides coverage for prescription drugs, shall exclude coverage of any such drug
for the treatment of HIV/AIDS on the grounds that the off-label use of the drug has not been approved by the
federal food and drug administration for that indication, if such drug is recognized for treatment of such indication in
one of the standard reference compendia, or in the medical literature, or by the commissioner under the provisions of
section forty-seven P of this chapter.

General Laws of Massachusetts Chapter 176G: Section 4G. Off-label use of prescription drugs for HIV/AIDS treatment
Any individual or group health insurance maintenance contract which provides coverage for prescription drugs shall
provide coverage for off-label uses of prescription drugs used in the treatment of HIV/AIDS as set forth in sections forty-
seven O and forty-seven P of chapter one hundred and seventy-five.

Effective
April 2017: Added language to include General laws.
February 2017: Annual update.
February 2016: Annual update.
February 2015: Effective date.

References
General Laws of Massachusetts Chapter 175: Section 47K. Off-label drug use; cancer treatment

General Laws of Massachusetts Chapter 175: Section 47O. HIV/AIDS treatment; insurance coverage for certain off-label use of prescription drugs

General Laws of Massachusetts Chapter 176G: Section 4F. Group health maintenance contracts; coverage for bone marrow transplants

General Laws of Massachusetts Chapter 176G: Section 4G. Off-label use of prescription drugs for HIV/AIDS treatment


Public Law 111 - 148 - Patient Protection and Affordable Care Act, Section 2709