Clinical Trials Payment Policy

Policy Statement

Clinical trials are a type of research that evaluates new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.

Scope

This policy applies to:

☒**Medicaid**
☒**INTEGRITY**
☒**Commercial**

Prerequisites

All services must be medically necessary to qualify for reimbursement. Neighborhood may use the following criteria to determine medical necessity:

- National Coverage Determination (NCD)
- Local Coverage Determination (LCD)
- Industry accepted criteria such as InterQual
- Rhode Island Executive Office of Health and Human Services (EOHHS) recommendations
- Clinical Medical Policies (CMP)

It is the provider's responsibility to verify eligibility, coverage and authorization criteria prior to rendering services.

For more information please refer to:

- Neighborhood's plan specific Prior Authorization Reference page.
- Neighborhood's Clinical Medical Policies.

Please contact Provider Services at 1-800-963-1001 for questions related to this policy.

Reimbursement Requirements

Clinical trials generally proceed through four phases:

Phase I clinical trials – the study drug or treatment is given to a small group of people for the first time to evaluate its safety, determine a safe dosage range, and to identify side effects;

Phase II clinical trials – the study drug or treatment is given to a large group of people to see if it is effective and to further evaluate its safety;
Phase III clinical trials – the study drug or treatment is given usually to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely;
Phase IV clinical trials – studies performed after the drug or treatment has been marketed to collect information about its effects in various populations and any side effects associated with long-term use.

RIGL § 27-20-60 Coverage for individuals participating in approved clinical trials. [1]

(a) As used in this section,

(1) "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 a life- threatening disease or condition and is described in any of the following:

(A) 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 federal National Institutes of Health;

(ii) The federal Centers for Disease Control and Prevention;

(iii) The federal Agency for Health Care Research and Quality;

(iv) The federal Centers for Medicare & Medicaid Services;

(v) A cooperative group or center of any of the entities described in items (i) through (iv) or the U.S. Department of Defense or the U.S. Department of Veteran Affairs;

(vi) A qualified non-governmental research entity identified in the guidelines issued by the federal National Institutes of Health for center support grants; or

(vii) A study or investigation conducted by the U.S. Department of Veteran Affairs, the U.S. Department of Defense, or the U.S. Department of Energy, if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of U.S. Department of Health and Human Services determines:

(I) Is comparable to the system of peer review of studies and investigations used by the federal National Institutes of Health; and

[1] http://webserver.rilin.state.ri.us/Statutes/title27/27-20/27-20-60.HTM

(II) Assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration; or

(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

(2) "Participant" has the meaning stated in section 3(7) [29 U.S.C. § 1002] of federal ERISA.

(3) "Participating provider" means a health care provider that, under a contract with the health carrier or with its contractor or subcontractor, has agreed to provide health care services to covered persons with an expectation of receiving payment, other than coinsurance, copayments or deductibles, directly or indirectly from the health carrier.

(4) "Qualified individual" means a participant or beneficiary who meets the following conditions:

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

(B)(i) The referring health care professional is a participating provider and has concluded that the individual's participation in such trial would be appropriate based on the individual meeting the conditions described in subdivision (A) of this subdivision (3); or

(ii) The participant or beneficiary provides medical and scientific information establishing the individual's participation in such trial would be appropriate based on the individual meeting the conditions described in subdivision (A) of this subdivision (3).

(5) "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.

(b)(1) If a health insurance carrier offering group or individual health insurance coverage provides coverage to a qualified individual, the health insurance carrier:

(A) Shall not deny the individual participation in an approved clinical trial.

(B) Subject to subdivision (3) of this subsection, shall 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 approved clinical trial; and

(C) Shall not discriminate against the individual on the basis of the individual's participation in the approved clinical trial.

(2)(A) Subject to subdivision (B) of this subdivision (2), routine patient costs include all items and services consistent with the coverage typically covered for a qualified individual who is not enrolled in an approved clinical trial.

(B) For purposes of subdivision (B) of this subdivision (2), routine patient costs do 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) If one or more participating providers are participating in a clinical trial, nothing in subdivision (1) of this subsection shall be construed as preventing a health carrier 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) Notwithstanding subdivision (3) of this subsection, subdivision (1) of this subsection shall apply to a qualified individual participating in an approved clinical trial that is conducted outside this state.

(5) This section shall not be construed to require a health insurance carrier offering group or individual health insurance coverage to provide benefits for routine patient care services provided outside of the coverage's health care provider network unless out-of-network benefits are otherwise provided under the coverage.

(6) Nothing in this section shall be construed to limit a health insurance carrier's coverage with respect to clinical trials.

(c) The requirements of this section shall be in addition to the requirements of Rhode Island general laws §§ 27-18-36 - 27-18-36.3.

(d) This section shall not apply to grandfathered health plans. This section shall not apply to insurance coverage providing benefits for: (1) hospital confinement indemnity; (2) disability income; (3) accident only; (4) long term care; (5) Medicare supplement; (6) limited benefit health; (7) specified disease indemnity; (8) sickness or bodily injury or death by accident or both; and (9) other limited benefit policies.

(e) This section shall be effective for plan years beginning on or after January 1, 2014.

History of Section.
(P.L. 2012, ch. 256, § 2; P.L. 2012, ch. 262, § 2.)

Routine Costs associated with a Clinical Trial[2]

Neighborhood Health Plan covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Neighborhood members that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

The following modifiers are used for clinical trial services:

- **Q0** Investigational clinical service provided in a clinical research study that is in an approved clinical study.
- **Q1** Routine clinical service provided in a clinical research study that is in an approved clinical research study.

Note: In instances where the item, drug or service is reimbursed by the clinical trial sponsor and payment is not expected, append modifier Q0 to the claim line. Services filed with Q0 modifier will not be reimbursed.

[2] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1

Per CMS mandate, clinical trial claims should include the clinical trial number

- Professional claims
  - CMS 1500 form – box 19
  - 837P Loop 2300
- Institutional claims
  - UB 04 – value code 'D4'
  - 837I – Loop 2300

Inpatient Institutional claims should also include condition code 30

Exclusions

Coverage does not include:

- The investigational item, device or service itself
- Items and services provided solely to satisfy data collection and analysis needs and not used in the direct clinical management of the member
- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
- Lodging and transportation
- Any expenses that the approved trial covers
- Non covered items or services
- Any service billed with a Q0 modifier

Claim Submission

Original Medicare pays for the costs of routine services provided to an INTEGRITY member who joins a qualifying clinical trial. Neighborhood Health Plan pays the original Medicare cost-sharing incurred for qualifying clinical trial items and services.[3]

Billable services are subject to contractual agreements, when applicable. Providers are required to submit complete claims for payment within contractually determined timely filing guidelines.

Coding must meet standards defined by the American Medical Association's Current Procedural Terminology Editorial Panel's (CPT®) codebook, the International Statistical Classification of Diseases and Related Health Problems, 10th revision, Clinical Modification (ICD-10-CM), and the Healthcare Common Procedure Coding System (HCPCS) Level II.

[3] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

Documentation Requirements

Neighborhood reserves the right to request medical records for any service billed. Documentation in the medical record must support the service(s) billed as well as the medical necessity of the service(s). Neighborhood follows CMS standards for proper documentation requirements.

Member Responsibility

Commercial plans include cost sharing provisions for coinsurance, copays, and deductibles. Members may have out of pocket expenses based on individual plan selection and utilization. Please review cost sharing obligations or contact Member Services prior to finalizing member charges.

Disclaimer

This payment policy is informational only and is not intended to address every situation related to reimbursement for healthcare services; therefore, it is not a guarantee of reimbursement.

Claim payments are subject to the following, which include but are not limited to: Neighborhood Health Plan of Rhode Island benefit coverage, member eligibility, claims payment edit rules, coding and documentation guidelines, authorization policies, provider contract agreements, and state and federal regulations. References to CPT or other sources are for definitional purposes only.

This policy may not be implemented exactly the same way on the different electronic claims processing systems used by Neighborhood due to programming or other constraints; however, Neighborhood strives to minimize these variations.

The information in this policy is accurate and current as of the date of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to update this payment policy at any time. All services billed to Neighborhood for reimbursement are subject to audit.

Coding

Table 1 contains the following modifiers for clinical trial services:

Note: Use for professional and facility outpatient claims.

Modifier Codes	Description
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study

Table 2 contains the primary diagnosis code required for all clinical trial claims submitted to Neighborhood Health Plan.

Note: Use for professional and facility outpatient claims.

Diagnosis Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Document History

Date	Action
09/18/2024	Annual Review; no content changes
09/05/2023	Annual Review; added language around clinical trial number
11/15/2022	Policy Reviewed and Revised to align with CMS requirements
6/10/2022	Policy Created