Payment Policy | Clinical Trials Mandate Commercial

EFFECTIVE DATE: 11|15|2016
POLICY LAST UPDATED: 11|05|2025

OVERVIEW
This documents Rhode Island General Law (RIGL§ 27-20-60), the federal Patient Protection and Affordable Care Act (PPACA) Sec. 2709 applicable to Commercial products.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Commercial Products
The State of Rhode Island mandate and the federal Patient Protection and Affordable Care Act require coverage for qualified individuals participating in approved clinical trials as detailed below. Coverage includes routine patient costs for covered health services furnished in connection with participation in the trial. These include covered healthcare services that are typically covered for a patient who is not enrolled in a clinical trial.

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. Items, drugs or services filed with **Q0** modifier will not be reimbursed.

In instances where the item, drug or service is not covered by the trial sponsor and payment is expected, append modifier **Q1** to the claim line. These items, drugs, or services may also require prior authorization; providers must confirm and obtain authorization when applicable to ensure proper reimbursement.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet or Subscriber Agreement for the applicable experimental/investigational services.

Rhode Island-mandated benefits do not apply to Medicare Advantage Pans. Self-funded groups may or may not choose to follow state mandates.

BACKGROUND
Clinical trials (or clinical research studies) are scientific investigations of treatment alternatives designed to help compare the safety and efficacy of new, untested, or non-standard treatments to standard currently accepted treatments. Clinical trials are intended to improve clinicians' knowledge about a treatment and to

improve clinical outcomes for future members. Improvement of health outcomes for members enrolled in clinical trials is a desirable but secondary consideration.

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.

The state and federal mandates are similar in coverage and the federal law supersedes the state law.

RIGL § 27-20-60 Coverage for individuals participating in approved clinical trials. – (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

(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) of federal ERISA.

(3) "Participating provider" means a healthcare provider that, under a contract with the health carrier or with its contractor or subcontractor, has agreed to provide healthcare 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) The referring healthcare 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) If a health insurance carrier offering group or individual health insurance coverage provides coverage to a qualified individual, the health 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) 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 nonprofit medical service corporation 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.

In general, Public Health Service (PHS) Act section 2709(a) as added by the PPACA, states that if a group health plan or health insurance issuer in the group and individual health insurance market provides coverage to a qualified individual (as defined under PHS Act section 2709(b)), then such plan or issuer: (1) may not deny the qualified individual participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (2) 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 (3) may not discriminate against the individual on the basis of the individual's participation in the trial.

A qualified individual under PHS Act section 2709(b) is generally a participant or beneficiary who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the treatment of cancer or another life-threatening disease or condition; and either: (1) the referring healthcare professional is a participating provider and has concluded that the individual's participation in such trial would be appropriate; or (2) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate.

CODING

See Policy Statement

RELATED POLICIES

Clinical Trials Medicare Advantage Plans
Coding and Payment Guidelines- Modifiers
Prior Authorization of Drugs

PUBLISHED

Provider Update, November 2025
Provider Update, December 2021
Provider Update, October 2020
Provider Update, November 2019
Provider Update, Nov. /Dec. 2018
Provider Update, June 2017

REFERENCES

1. Rhode Island General Law (RIGL) 27-20-60 Coverage for individuals participating in approved clinical trials. http://webserver.rilin.state.ri.us/Statutes/title27/27-20/27-20-60.HTM
2. Patient Protection and Affordable Care Act
http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf
3. The Center for Consumer Information & Insurance Oversight Affordable Care Act Implementation FAQs - Set 15 http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html

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