



Coverage of Treatments Provided in a Clinical Trial

Effective: February 1, 2025

Next Review: November 2025

Last Review: December 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Effective January 1, 2014, the Affordable Care Act (ACA) requires group health plans or a health insurance issuer offering group or individual health insurance coverage to provide coverage for routine patient costs associated with participating in an approved clinical trial. This policy is written to assist in applying Sec. 2709 of the ACA, Coverage for Individuals Participating in Approved Clinical Trials.

MEDICAL POLICY CRITERIA

Routine patient costs associated with approved clinical trials may be considered **medically necessary** for qualified individuals with respect to treatment of cancer or other life threatening disease or condition, when the Affordable Care Act definitions for clinical trial participation are met.

- See Background for definitions.
- See Policy Guidelines for clinical trial registry resource.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

[ClinicalTrials.gov](https://clinicaltrials.gov) includes a registry of publicly and privately supported clinical studies.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

1. Pertinent History and Physical, including specific diagnosis and treatment history
2. Clinical trial name and the NCT number
3. Phase of the trial
4. Currently planned, requested interventions
5. Anticipated possible interventions

CROSS REFERENCES

1. [COVID-19 Testing](#), Laboratory, Policy No. 74

BACKGROUND

DEFINITIONS^[1]

- Routine patient costs
 - 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.
 - Routine patient costs *do not include* the investigational item, device, or service, itself; 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 a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

- Approved clinical trial

An approved clinical trial is defined as 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 that is described by any of the following:

- The study or investigation is approved or funded by one or more of the following:
 - The National Institutes of Health
 - The Centers for Disease Control and Prevention
 - The Agency for Health Care Research and Quality
 - The Centers for Medicare & Medicaid Services
 - A cooperative group or center of any of the above four entities or the Department of Defense or the Department of Veterans Affairs
 - A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants

- The Department of Veterans Affairs, the Department of Defense or the Department of Energy if the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review; OR
 - The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration; OR
 - The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

- Life-threatening condition

A life-threatening condition is defined as any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

- Qualified individual

A participant who is a beneficiary in a health plan who is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or another life-threatening disease or condition and either:

- 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 clinical trial eligibility requirements; or
- 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 clinical trial eligibility requirements.

REFERENCES

1. Affordable Care Act, Section 2709. [cited 11/24/2024]. 'Available from:' <http://www.hhs.gov/sites/default/files/ppacacon.pdf>.

CODES

Codes	Number	Description
HCPCS	S9988	Services provided as part of a phase I clinical trial
	S9990	Services provided as part of a phase II clinical trial
	S9991	Services provided as part of a phase III clinical trial

Date of Origin: November 2013