Clinical Policy: Clinical Trials

Reference Number: PA.CP.MP.94
Effective Date: 01/2018
Date of Last Revision: 06/2023 Revision Log

Description
Medical necessity guidelines for routine costs of clinical trials in accordance with Centers for Medicare & Medicaid (CMS) and the Patient Protection and Affordable Care Act (PPACA) requirements.

Note: For experimental technologies, refer to PA.*CP.MP.36 Experimental Technologies.*

Policy/Criteria

I. It is the policy of Pennsylvania Health and Wellness® that routine costs of a qualifying clinical trial and services used to diagnose and treat complications arising from participating in a qualifying clinical trial are **medically necessary** based upon the following guidelines and limitations.[1,2]

A. Routine costs in a clinical trial include all items and services generally considered medically necessary and a covered benefit to Plan members/enrollees that are provided in either the experimental or control arms and include:
   1. Items or services that are typically provided absent a clinical trial;
   2. Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapy agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications;
   3. 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.

B. Excluded costs/services:
   1. The investigational item or service itself;
   2. 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);
   3. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

C. Administrative limitations:
   1. All applicable Plan limitations for coverage of out-of-network care applies to routine costs in a clinical trial;
   2. All existing utilization management guidelines apply to routine care for members/enrollees in clinical trials, including prior-authorization and notification requirements.

D. Qualifying clinical trials must meet the following:
   1. The clinical trial must have a written protocol that describes a scientifically sound study and be approved by all relevant institutional review boards (IRBs);

2. The subject or purpose of the trial must be the evaluation of an item or service that falls within a covered benefit category (i.e., physician's service, durable medical equipment, diagnostic test, etc.);
3. The trial must have therapeutic intent and not solely designed to test toxicity or disease pathophysiology;
4. Trials of therapeutic interventions must enroll patients with the diagnosed disease (trials of diagnostic interventions may enroll healthy patients in order to have a proper control group);
5. Trials must be federally-funded or approved by one of the following groups:
   a. Agency for Healthcare Research and Quality (AHRQ);
   b. Centers for Disease Control and Prevention (CDC);
   c. Centers for Medicare and Medicaid Services (CMS);
   d. National Institutes of Health (NIH);
   e. A cooperative group or center of any of the above listed entities or the Department of Defense (DoD) or Department of Veterans Affairs (VA);
   f. A qualified nongovernmental research entity identified in the guidelines issued by the NIH for center support grants;
   g. The Departments of VA, DoD, or Department of Energy (DoE) if the trial has been reviewed and approved through a system of peer review comparable to the system used by the NIH and that ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review;
   h. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration (FDA);
   i. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

Background

This policy was adapted from Medicare Coverage ~ Clinical Trials, Final National Coverage Decision policy.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual Review. References Updated.	10/18	
Added reference to PA.CP.MP.36 Experimental Technologies. References reviewed and updated.	12/2020	1/28/2021
References reviewed, updated and reformatted. Replaced all instances of "member" with "member/enrollee." Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date."	10/2021	
Annual review. Criteria I., II., III., IV. updated to remove "and" after semi-colons. Criteria IV.B. "et al" changed to "etc." Criteria IV.E. #7 abbreviation updated for Department of Energy (DoE). References reviewed and updated.	2/23/2023	
Annual review completed; policy reformatted. Minor rewording with no clinical significance. References reviewed and updated.	06/2023	

References

1. National coverage determination: routine costs in clinical trials (301.1). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published October 09, 2007. Accessed May 9, 2023.
2. Office of the Legislative Counsel for the use of the U.S. House of Representatives. Compilation of Patient Protection and Affordable Care Act. https://www.hhs.gov/sites/default/files/ppacacon.pdf?language=es. Published June 09, 2010. Accessed May 9, 2023.
3. National Institutes of Health U.S. National Library of Medicine. ClinicalTrials.gov. https://clinicaltrials.gov/. Accessed May 9, 2023.