PRESBYTERIAN

Medical Policy

Subject: Clinical Trials, Routine Patient Care Costs for Commercial

Medical Policy #: 3.6 **Original Effective Date:** 08/26/2009

Status: Reviewed **Last Annual Review Date:** 12/11/2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans, or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

A clinical trial is a research study or protocol designed to test the safety and/or effectiveness of experimental drugs, devices or treatments in humans.
Routine care items and services refers to items and services that are otherwise generally available to beneficiaries that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

Other Related Medical Policy:
Clinical Trials Routine Patient Care Costs for Medicare, MPM 3.8
Cancer Clinical Trials, Routine Patient Care Costs for Medicaid, MPM 3.7

For purposes of this benefit, a "life-threatening disease or condition" is one from which the risk of death is most likely unless the course of the disease or condition is intervene.

Coverage Determination

Approved Clinical Trials is defined as:

Members may be eligible under the Plan for routine care and services costs* associated with interventional clinical trials, when the following criteria are met:

The term "approved clinical trial" means a Phase I, II, III or IV clinical trial that is conducted in relation to the prevention, detection or treatment of approved **cancer or other life-threatening illness** (any disease or condition from which there is a probable likelihood of death unless the course of the disease or condition is interrupted) that falls under one of the following categories:

A. Federally funded trials that is approved and funded (which may include funding through in-kind contributions) by one or more of the following:
   - National Institutes of Health (NIH) [includes National Cancer Institute (NCI)] (must also provide NCT number).
   - Centers for Disease Control and Prevention (CDC).
   - Agency for Healthcare Research and Quality (AHRQ).
   - Centers for Medicare and Medicaid Services (CMS).
   - A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the
   - the Veterans Administration (VA).
   - 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 as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following criteria:
     - Comparable to the system of peer review of studies and investigations used by the National Institutes of Health
     - Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

OR

B. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. FDA;

OR

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

Coverage Description:

Prior Authorization is required for routine medical care costs for cancer and life-threatening clinical trials. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

PHP follows §300gg–8 Coverage for individuals participating in approved clinical trials of the Patient Protection and Affordable Care Act (PPACA). Member 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.

A. Coverage of routine patient costs for items and services furnished in connection with participation in the trial. 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. 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.

C. For Approved clinical trial (see above Approved Clinical Trail definition).

1. Coverage for routine patient care costs in clinical trials will be allowed for out-of-network services (includes out-of-state) when the members health benefit plan allows coverage.
2. All utilization management rules and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials; *and*
3. Members must meet all applicable plan requirements for precertification, registration, and referrals; *and*
4. To qualify, a clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards (IRBs) before participants are enrolled. Providers will not routinely be required to submit documentation about the trial to PHP, but PHP can, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approval(s).

D. PHP covers costs of medically necessary treatments for conditions that result as unexpected consequences (complications) of clinical trials.

E. Travel, lodging and meals will only be covered if it is within the member's benefit.

F. Routine Patient Costs During Clinical Trials Include Covered Health Care Services.

- For which benefits are typically provided absent a clinical trial.
- Required solely for:
  - The provision of the Experimental or Investigational Service(s) or item (e.g., the infusion administration services to deliver an investigational drug); and/or
  - The clinically appropriate monitoring of the effects of the service or item (e.g., lab tests and imaging done at a frequency consistent with signs and symptoms and other standards of care for that diagnosis or treatment type); and/or
  - The prevention of complications
- Needed for reasonable and necessary care arising from the provision of an Experimental or Investigational Service(s) or item.

G. Limitations and Exclusions

- Routine patient costs do not include:
  - The investigational item, device, or service, itself.
  - Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the member.
    - Examples include, but are not limited to: Laboratory tests and imaging studies done at a frequency dictated by the study protocol and not consistent with signs and symptoms and other standards of care for that diagnosis or treatment type
  - A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.
  - Items and services provided by the research sponsors free of charge for any person enrolled in the trial.

- Routine patient costs obtained out-of-network when non-network benefits do not exist under the plan benefit.
- Clinical Trials that do not meet the requirements listed in the Indications for Coverage section above and
- Other items and services that, in our determination, that do not meet specified criteria in accordance with our medical and drug policies.

Other coverage and non-coverage (Intel HMO) information:

For additional information, see the member's plan handbook.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description
99199	Validated, statistically reliable, randomized, controlled, single-patient clinical investigation of FDA approved chronic care drugs, provided by a pharmacist, interpretation and report to the prescribing health care professional.
Other assigned codes, such as category III codes per CMS coverage approval letter per IDE reimbursement guidelines.	

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

ICD-10 Diagnosis Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program. (Includes: Examination of participant or control in clinical research program)
Other principal ICD-10-CM diagnosis code	

Modifier(s)	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

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Clinton White MD
Senior Medical Director: Jim Romero MD
Date Approved: 12-11-2024

References

1. U.S. Department of Health and Human Services, Health Care, Patient Protection and Affordable Care Act (PPACA), Public law 111-148, Mar. 23, 2010, 124 STAT. 119. ''SEC. 2709. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS. [Cited 10/08/2024]
2. CMS, The Center for Consumer Information & Insurance Oversight (CCIIO), Affordable Care Act FAQs, Coverage for Individuals Participating in Approved Clinical Trails, Page Last Modified: 09/06/2023 05:05 PM.

[Cited 10/08/2024]
3. Code of Federal Regulations, Title 21: Food and Drugs, Chapter 1, Subchapter H-Medical Devices, Part (812)-Investigational Device Exemptions (21 CFR 812), last amended: 09-30-2024, Subchapter. [Access 10/08/2024]
4. Federal Regulations, Title 42, Chapter IV, Subchapter B, Part 405, Subpart B-Medical Services Coverage Decisions That Relate to Health Care Technology (42 CFR 405),Last amended 10/02/2024. [Access 10/08/2024]

Publication History

08-26-09: Original Effective Date for Medical Policy

01-27-16: Annual Review. Removed ICD 9 codes. Removed SCI reference No other changes.

05-18-17: Annual Review. No changes.

07-31-19: Annual Review. Updated links to New Mexico Administrative Code. Experimental or Investigational Procedures, Technologies or Non-Drug Therapies. Accessed 06/11/2019. No change.

11-18-20 Annual Review on 10-19-20. Links are still active and have no change. Name change to policy from Cancer Clinical Trials, Routine Patient Care Costs –For group health coverage (including self-insured) to Centennial Care to Cancer Clinical Trials, Routine Patient Care Costs Coverage for Commercial and Medicaid. Codes S9988, S9990, S9991 will continue with PA.

11-17-21 Annual Review. Reviewed by Medical Policy Committee on 11/05/2021

- Continue to follow New Mexico Legislature Senate Bill 42 (SB 42) for requirement coverage of patient costs incurred in cancer clinical trial. Additional language was added to reflect the current language found in (SB 42-G). The updated language is in italic: For routine patient care costs are covered for only cancer clinical trials performed in New Mexico are eligible for coverage of routine patient care costs for members with group health coverage, including self-insured and Centennial Care. In no event shall the health plan be responsible for out-of-state or out-of-network costs unless the plan elected includes benefits for services rendered for out of state or out of network.
- Continue to follow the New Mexico Administrative Code (NMAC 8.310.2.12.P) for the “experimental or investigational services.” Additional language was added to policy from this NMAC.
- The CPT codes will continue PA requirement.

11-16-22 Annual Review. Reviewed by Medical Policy Committee on 09-21-2022.

- Continue to follow New Mexico Legislature Senate Bill 42 (SB 42) for requirement coverage of patient costs incurred in cancer clinical trial.
- Continue to follow the New Mexico Administrative Code (NMAC 8.310.2.12.P) for the “experimental or investigational services.”
- Continue PA requirement for S9988, S9990, S9991 and continue no PA for 99199.
- Coverage statement for “Routine patient care costs” in the Description section has been removed.
- Changed “Centennial Care” to “Medicaid”

Update May 24, 2023: Updated language to include Routine Cost to apply to outside of New Mexico. Annual review date will remain as 11/16/2022.

12-13-23 Annual Review. Reviewed by Medical Policy Committee on 11/15/2023. Changed: Clinical Trial coverage for Commercial was separated from Medicaid (MPM 3.7) since it was specific to cancer clinical trial only. Commercial members will now follow PPACA for approved cancer or other life-threatening illness clinical trials. Routine care cost will be approved at in-network benefits for approved studies. PA requirement will continue for both In-network and Out-of-Network.

12-11-24 **Annual Review. Reviewed by Medical Policy Committee on 10/09/2024. No change**. Continue to follow PPACA for approved cancer or other life-threatening illness clinical trials. Routine care costs will be approved at in-network benefits for approved studies. PA requirement will continue for both In-network and Out-of-Network.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

*For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: **Click here for Medical Policies***

Web links:
At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.