

Cancer Clinical Trials, Routine Patient Care Costs -- For group health coverage (including self-insured), Salud and SCI MPM 3.7

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. As used in this Medical Policy, a cancer clinical trial means a course of treatment provided to a patient for the purpose of prevention, prevention of reoccurrence, early detection or treatment of cancer.

Routine patient care cost means:

- A medical service or treatment that is a benefit under a health plan that would be covered if the patient were receiving standard cancer treatment; or
- A drug provided to a patient during a cancer clinical trial if the drug is approved by the Food and Drug Administration (FDA), whether or not the FDA has approved the drug for use in treating the patient's particular condition, but only to the extent that the drug is not paid for by the manufacturer, distributor or provider of the drug.

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, Salud and State Coverage Insurance (SCI).

Related Medical Policy:

Clinical Trials for Members Enrolled in a Medicare Plan, MPM 3.8

**Coverage
Determination for
group health coverage
(including self-
insured), Salud and
SCI.**

Benefit Certification is required for cancer clinical trials. Medical services that are not investigational, such as lab and x-ray services, follow the guidelines in the Benefit Certification Guide. All claims are subject to retrospective review.

Routine patient care costs are covered for members in a cancer clinical trial in **New Mexico** when the following requirements are met:

Refer to member's specific benefit plan to determine coverage.

- The trial is undertaken for the purposes of prevention of cancer, prevention of reoccurrence of cancer, early detection or treatment of cancer for which no equally or more effective standard cancer treatment exists.
- The cancer clinical trial is not designed exclusively to test toxicity or disease pathophysiology, and it has a therapeutic intent.

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage.

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- The trial is being provided in New Mexico as part of a scientific study of a new therapy or intervention and is for the prevention, prevention of reoccurrence, early detection, treatment or palliation of cancer in humans, and in which the scientific study includes all of the following:
 - Specific goals;
 - Rationale and background for the study;
 - Criteria for patient selection;
 - Specific direction for administering the therapy or intervention and for monitoring patients;
 - Definition of quantitative measures for determining treatment response;
 - Methods for documenting and treating adverse reactions; and
 - Reasonable expectation that the treatment will be at least as efficacious as standard cancer treatment
- The cancer clinical trial is being conducted with the approval of at least one of the following:
 - One of the federal National Institutes of Health (NIH)
 - A federal NIH cooperative group or center
 - Department of Defense
 - FDA, in the form of an investigational new drug application
 - Department of Veterans Affairs
 - A qualified research entity that meets the criteria established by the NIH for grant eligibility
- The proposed cancer clinical trial has been reviewed and approved by an institutional review board that has an active federal-wide assurance of protection for human subjects.
- The personnel conducting the cancer clinical trial must agree to accept reimbursement as payment in full from PHP at established rates (e.g., PHP's normal reimbursement for similar services), and agree to provide written notification to PHP when a patient enters or leaves a clinical trial. ^{1,2,3}

Exclusions for group health coverage (including self-insured), Salud and SCI

Refer to member's specific benefit plan to determine coverage.

Routine patient care cost does not include:

- Costs of the cancer clinical trial that are customarily paid for by government, biotechnical, pharmaceutical or medical device industry sources
- The cost of an investigational drug, device or procedure
- The cost of a non-healthcare service that the patient is required to receive as a result of participation in the cancer clinical trial
- Costs associated with managing the research associated with the cancer clinical trial
- Costs that would not be covered by PHP if non-investigational

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treatments were provided

- Costs of extra tests that would not be performed except for participation in the cancer clinical trial
- Costs paid or not charged for by the cancer clinical trial providers^{1,2,3}

Coding

The coding listed in this Medical Policy is for reference only. Covered and non-covered codes are included in this list.

CPT Codes	Description
0130T	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.

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-9® Diagnosis Codes	Description
V70.7	Examination of participant in clinical trial

References:

1. New Mexico Legislature. Senate Bill 42, An Act Relating to Health Insurance; Amending, Repealing and Enacting Section of the NMSA 1978 that Relate to Coverage of Cancer Clinical Trials. 2009 Regular Session.
2. New Mexico Administrative Code (NMAC) 8.325.6. Experimental or Investigational Procedures, Technologies or Non-Drug Therapies.
3. New Mexico Administrative Code (NMAC) 8.306.7. State Coverage Insurance (SCI) Benefit Package.
4. Presbyterian Health Plan and Presbyterian Insurance Company, Inc. Commercial Plans Benefit Interpretation Manual. Cancer Clinical Trials. April 2006.
5. Presbyterian Health Plan and Presbyterian Insurance Company, Inc. State Coverage Insurance (SCI) Benefit Interpretation Manual. Cancer Clinical Trials. March 2006.

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- 09-24-01: Benefit Interpretation Manual, Commercial Plans, Cancer Clinical Trials. Revised 04-24-06. Merged into Medical Policy 08-26-09.
- 03-27-06: Benefit Interpretation Manual, State Coverage Insurance (SCI). Merged into Medical Policy 08-26-09.
- 08-26-09: Original Effective Date for Medical Policy.
- 02-24-10: Revised, Coverage for Medicare Members moved to separate Medical Policy.

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 on the Internet at:

<http://www.phs.org/phs/healthplans/providers/healthservices/Medical/index.htm>

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