Subject: Cancer Clinical Trials, Routine Patient Care Costs, Coverage for Commercial and Medicaid

Medical Policy #: 3.7 **Original Effective Date:** 08/26/2009

Status: Reviewed **Last Review Date:** 11/16/2022

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.

***Definition as defined by (2009 Senate Bill 42):**

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; and
- does not include those items listed in the Exclusion section below.

Health plan means:

- 1) a health insurer; 2) a nonprofit health service provider; 3) a health maintenance organization; 4) a managed care organization; 5) a provider service organization; or 6) the state's medical assistance program, whether providing services on a managed care or fee-for-service basis; **and**
- does not include individual policies intended to supplement major medical group-type coverages such as Medicare supplement, long-term care, disability income, specified disease, accident only, hospital indemnity or other limited-benefit health insurance policies.

Other Related Medical Policy:
Clinical Trials for Members Enrolled in a **Medicare Plan**, MPM 3.8

Coverage Determination

Prior Authorization is required for cancer clinical trials. Medical services that are not investigational, such as lab and x-ray services, follow the guidelines in the Prior Authorization Guide. All claims are subject to retrospective review. **Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp**

REQUIRED COVERAGE OF PATIENT COSTS INCURRED IN CANCER CLINICAL TRIALS:

According to New Mexico Legislature, 2009 Regular Session – SB 42, Cancer Clinical Trial Insurance Coverage: Group health coverage, including any form of self-insurance, offered, issued or renewed under the Health Care Purchasing Act shall provide coverage pursuant to Section 59A-22-43 NMSA 1978 for **routine patient care costs* incurred as a result of the patient's participation in cancer clinical trials**." Section 2. Section 59A-22-43 NMSA 1978 (being Laws 2001, Chapter 27, Section 1, as amended) is amended to read: "59A-22-43. REQUIRED COVERAGE OF PATIENT COSTS INCURRED IN CANCER CLINICAL TRIALS.

Routine patient care costs are covered for: Cancer clinical trials performed in New Mexico or out of New Mexico are covered for routine patient care costs could include otherwise covered physician services or laboratory or medical imaging services that assist with prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation for group health coverage, including self-insured and Medicaid.

A health plan* shall provide coverage for routine patient care costs incurred as a result of the patient's participation in a cancer clinical trial if:

1) The clinical 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;

2) The cancer clinical trial is not designed exclusively to test toxicity or disease pathophysiology, and it has a therapeutic intent;

3) The clinical trial is being provided in New Mexico or out of 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:

   a. Specific goals;
   b. Rationale and background for the study;
   c. Criteria for patient selection;
   d. Specific direction for administering the therapy or intervention and for monitoring patients;
   e. Definition of quantitative measures for determining treatment response;
   f. Methods for documenting and treating adverse reactions; and
   g. Reasonable expectation that the treatment will be at least as efficacious as standard cancer treatment.

Exclusions for group health coverage (including self-insured) and Medicaid

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 treatments were provided;
- Costs of extra tests that would not be performed except for participation in the cancer clinical trial; **and**
- Costs paid or not charged for by the cancer clinical trial providers.

Experimental or investigational services:

According to NMAC (8.310.2.12.P): MAD covers medically necessary services which are not considered unproven, investigational or experimental for the condition for which they are intended or used as determined by MAD. MAD does will not cover experimental or investigational medical, surgical or health care procedures or treatments, including the use of drugs biological products, other products or devices, except the following:

1) Phase I, II, III or IV: May approve coverage for routine patient care costs incurred as a result of the eligible recipient's participation in the phase I, II, III, or IV cancer trial that meets the following criteria. The cancer clinical trial is being conducted with the approval of at least one of the following:

   a) One of the federal National Institutes of Health (NIH);
   b) A federal NIH cooperative group or center;
   c) The federal Department of Defense;
   d) FDA, in the form of an investigational new drug application;
   e) The federal Department of Veterans Affairs; **or**
   f) A qualified research entity that meets the criteria established by the NIH for grant eligibility.

2) Review and approval: The proposed cancer clinical trial has been reviewed and approved by an institutional review board that has multiple project assurance contract approved by the office of protection from research risks of the federal national institutes of health.

3) Experimental or investigational interventions: Any medical, surgical, or other healthcare procedure or treatment, including the use of a drug, a biological product, another product or device, is considered experimental or investigational if it meets any of the following conditions:

   a) current, authoritative medical and scientific evidence regarding the medical, surgical, or other health care procedure or treatment, including the use of a drug, a biological product, another product or device for a specific condition shows that further studies or clinical trials are necessary to determine benefits, safety, efficacy and risks, especially as compared with standard or established methods or alternatives for diagnosis or treatment or both outside an investigational setting;

   b) the drug, biological product, other product, device, procedure or treatment (the "technology") lacks final approval from the FDA or any other governmental body having authority to regulate the technology;

   c) the medical, surgical, other health care procedure or treatment, including the use of a drug, a biological product, another product or device is the subject of ongoing phase I, II, or III clinical trials or under study to determine safety, efficacy, maximum tolerated dose or toxicity, especially as compared with standard or established methods or alternatives for diagnosis or treatment or both outside an investigational setting.

4) Review of conditions: On request of MAD or its designee, a provider of a particular service can be required to present current, authoritative medical and scientific evidence that the proposed technology is not considered experimental or investigational. HEALTH CARE PROFESSIONAL SERVICES EFF: 8/10/2021 GENERAL BENEFIT DESCRIPTION 8.310.2 NMAC 17

5) Reimbursement: MAD does not reimburse for medical, surgical, other health care procedures or treatments, including the use of drugs, biological products, other products or devices that are considered experimental or investigational, except as specified as follows. MAD will reimburse a provider for routine patient care services, which are those medically necessary services that would be covered if the MAP eligible recipient were receiving standard cancer treatment, rendered during the MAP eligible recipient's participation in phase I, II, III, or IV cancer clinical trials.

6) Experimental or investigational services: MAD does not cover procedures, technologies or therapies that are considered experimental or investigational.

7) 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

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.

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 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)

Reviewed by / Approval Signatures

Clinical Quality & Utilization Mgmt. Committee: David Yu MD
Medical Director: Ana Maria Rael MD
Date Approved: 11/16/2022

References

1. New Mexico Legislature Senate Bill 42, Cancer Clinical Trial Insurance An Act Relating to Health Insurance; Repealing and Enacting Section of the NMSA 1978, Sponsor: Dede Feldman , 2009 Regular Session [Cited 08-30-2022].
2. New Mexico Administrative Code (NMAC) 8.310.2.12.P NMAC General Benefits, SERVICES, Experimental or investigational services, effective date: August 10, 2021. [Accessed 08-30-2022].
3. Presbyterian Health Plan and Presbyterian Insurance Company, Inc. Commercial Plans Benefit Interpretation Manual, Evidence of Coverage, Cancer Clinical Trials [Cited 08-30-2022]
4. New Mexico Administrative Code (NMAC) 8.325.6, Experimental or Investigational Procedures, Technologies or Non-Drug Therapies, Repealed effective 1/1/2014]. [Accessed 08-30-2022].
5. CMS, The Center for Consumer Information & Insurance Oversight (CCIIO), Affordable Care Act FAQs, Coverage for Individuals Participating in Approved Clinical Trails. [Cited 08-30-2022]
6. See 42 USC Chapter 6a, Subchapter XXV, Part A, Subpart I: General Reform, From Title 42—The Public Health and Welfare, Chapter 6a—Public Health Service, Subchapter XXV—Requirements Relating to Health Insurance Coverage, Part A—Individual and Group Market Reforms, Subpart I General Reform, Section 300gg-8, Coverage for individuals participating in approved clinical trials. [Cited 09-06-2022]

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.

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.