

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

Medical Policy #: 3.7

Status: Retired

Original Effective Date: 08/26/2009

Last Review Date: 12/13/2023

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 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

Clinical Trials, Routine Patient Care Costs for Commercial, MPM 3.6

Coverage Determination

Prior Authorization is required for routine medical care cost for cancer clinical trials. Logon to Pres Online to submit a request: <https://ds.phs.org/preslogin/index.jsp>

PHP follows NMAC 8.310.2.12(P)(1 thru 6). Experimental or investigational services: 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 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) 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.
- 4) 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.

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

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

Population Health & Clinical Quality Committee: [Gray Clarke MD](#)
VP Chief Medical Officer: [Clinton White MD](#)
Senior Medical Director: [Jim Romero MD](#)
Medical Director: [Ana Maria Rael MD](#)
Date Approved: 12-13-2023

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 09-19-2023].
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 09-19-2023].
3. 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].
4. CMS, The Center for Consumer Information & Insurance Oversight (CCIIO), Affordable Care Act FAQs, [Coverage for Individuals Participating in Approved Clinical Trials, Page Last Modified: 09/06/2023 05:05 PM](#). [Cited 09-19-2023]
5. 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 09-19-2023]
6. New Mexico, Medical Assistance Division, State Plan Amendments ([SPA](#)) [#22-0010](#) for Alternative Benefit Plan (ABP, Qualifying Clinical Trial-Alternative Benefit Plan (ABP), date approved by CMS: 06/13/2022. [Cited 09-19-2023]

Publication History

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

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 [MPMPPC051001].

- 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. Medicaid will continue to follow NMAC 8.310.2.12(P)(1-6). Removed criteria in section (P)(3)(a-c) -Experimental or investigational interventions of the NMAC from the policy. Removed coverage information for Commercial to MPM 3.6. PA requirement will continue for both In-network and Out-of-Network for Medicaid. The policy title changed to remove Commercial. The policy is specific to Medicaid only. See MPM 3.6 for Commercial.

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.