

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

**Medical Policy #:** 3.7

**Status:** Reviewed

**Original Effective Date:** 08-26-2009

**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

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

## Coverage Determination

**Prior Authorization is NOT required for routine medical care cost for clinical trials.**

PHP follows New Mexico Administrative NMAC [Letter of Direction \(LOD\) #46](#), which covers routine patient care costs incurred as a result of the Medicaid eligible recipient's participation in an approved Qualified Clinical Trial, (QCT).

**Covered Services:**

- Routine patient care services and other medical services that **are** included as part of the QCT are covered when billed as part of the clinical trial, and indicated with the primary or secondary diagnoses, in addition to an appropriate modifier.
- Routine patient care service and other medical services that are **not** included as part of the QCT are reimbursed at the current fee schedule published at <https://www.hsd.state.nm.us/providers/fee-schedules/>

**Coverage Criteria:**

**All** of the following must be met:

- Provider Requirements: Providers must ensure that billed services adhere to one or more criteria as described in CMS letter, #SMD-21-005, at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf>
- The Clinical Trial has been approved by the state as a Qualified Clinical Trial as supported by the provided National Clinic Trial (NCT) identifier number.

**Non-Covered Services:**

- Experimental or investigational services: PHP does not cover procedures, technologies or therapies that are considered experimental or investigational.
- Data Collection and Analysis Services: PHP does not cover any routine patient cost item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the QTC that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project.

## 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

Modifier(s)*	Description
Q0	Investigational clinical service provided in 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

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)

\* Modifier Q0 or Q1 required

\*\* Z00.6 required as primary or secondary diagnosis code

## 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. 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 10-09-2024].
2. New Mexico Administrative Code (NMAC) [8.310.2.12.P NMAC General Benefits, SERVICES, Experimental or investigational services](#), effective date:04/05/2022. [Accessed 10-09-2024].
3. 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 10-09-2024]
4. 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 10-09-2024]
5. 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 10-09-2024]

6. New Mexico Administrative NMAC Letter of Direction (LOD) #46 , [Final-LOD-46-Qualified-Clinical-Trials.pdf \(nm.gov\)](#) Posted 1/6/2025, [Cited 1-16-2025]
7. CMS letter, #SMD-21-005, posted 4/13/2022, [Cited 1-16-2025]

## 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. 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.
- 12-11-24: **Annual Review.** Reviewed by Medical Policy Committee on 10/09/2024 and 1/17/2025. This policy has been updated to follow the Health Care Authority (HCA) Letter of Direction (LOD), #46, Qualified Clinical Trials. Continue to not include Experimental information stated in LOD #46. Remove the PA requirement for routine medical care cost for all clinical trials for Medicaid line of business. Removed previous instruction following NMAC 5.310.2.12(P)(1-6), which has been redacted.
- 3-26-25 Ad Hoc:** Reviewed by Medical Policy Committee on 01/17/2025 to adopt Qualified Clinical Trials (QCT) Information, provided by Health Care Authority, Letter of Direction (LOD) #46-effective Jan 06, 2025. LOD-46 is a directive enforced by Centers for Medicare & Medicaid Services (CMS) related to Qualifying Clinical Trial (QCT) for services furnished to Medicaid beneficiaries, including beneficiaries enrolled in Alternative Benefit Plans (ABPs). Update to policy includes removal of PA requirement; removal of coverage determination guideline language and reformatted to only include weblinks to see CMS letter SMD-21-005 for criteria. The new guidance includes removal of restrictions (and title) for cancer trials only to allow for all approved trials with guidance as outlined in the LOD (Dx, QCT code approval). Removed PA for HCPCS codes: S9988, S9990, S9991.

*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.*