

Subject: Clinical Trial Coverage for Members Enrolled in a Medicare Plan

Medical Policy #: 3.8

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. This Medical Policy only applies to members enrolled in a Medicare plan.

Other Related Medical Policy:

Cancer Clinical Trials, Routine Patient Care Costs – Commercial and Medicaid, MPM 3.7. (This policy is applicable for group health coverage, including self-insured, and State Coverage Insurance)

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: <https://ds.phs.org/preslogin/index.jsp>

The CMS has issued a National Coverage Determination (NCD) which allows Medicare coverage for the routine costs of qualifying clinical trial services as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. Clinical trials must meet qualifying criteria in order to receive Medicare coverage of routine cost. See CMS Routine Costs in Clinical Trials, ([NCD 310.1](#)) for information on the qualifying process for clinical trials.

See also Medicare, [Pub 100-04, Ch.32](#) Medicare Claims Processing.

For additional information, see [2023 Senior Care Plan 2 with Rx \(HMO\) Evidence of Coverage \(EOC\)](#), Your Medicare Health Benefits and Services and Prescription Drug Coverage as a Member of Presbyterian Senior Care Plan 2 with Rx (HMO) booklet.

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 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)

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

Clinical Quality & Utilization Mgmt. Committee: David Yu MD

Medical Director: Ana Maria Rael MD

Date Approved: 11-16-2022

References

1. Novitas, Clinical Trials & Devices, [Clinical Trials Background](#), Last modified: 05/24/2016. [Cited 09-06-2022]
2. CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials ([310.1](#)), Version 2, Effective Date: 07/09/2007, Implementation Date 10/09/2007. [Cited 09-06-2022]
3. CMS Manual System, Pub 100-03 Medicare National Coverage Determination, [Change Request 5719, Transmittal 74](#), Date: September 07, 2007. [Cited 09-06-2022]
4. CMS, [Pub. 100-04 Medicare Claims Processing Manual Chapter 32](#) – Billing Requirements for Special Services, (Rev. 10891, 07-20-21). [Cited 09-06-2022]
5. CMS, The Center for Consumer Information & Insurance Oversight (CCIIO), Affordable Care Act FAQs, [Coverage for Individuals Participating in Approved Clinical Trials](#). [Cited 09-06-2022]
6. US Food & Drug Administration (FDA). FDA's role: ClinicalTrials.gov information. [U.S. Food and Drug Administration](#). Published April 28, 2021. [Cited 09-06-2022]
7. CMS, [Medicare Claims Processing Manual Chapter 32](#) – Billing Requirements for Special Services, Table of Contents, (Rev. 10891, 07-20-21) 68.1- Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE. [Cited 09-06-2022]
8. CMS, Medicare Benefit Policy Manual, [Chapter 14, Medical Devices](#), (Rev. 198, 11-06-14).
9. Presbyterian Health Plan, Inc., [2023 Senior Care Plan 2 with Rx \(HMO\) Evidence of Coverage \(EOC\)](#). [Cited 09-06-2022]

Publication History

- 08-26-09: Original effective date for Cancer Clinical Trials, PM 3.7
- 03-23-16: Annual Review. NCD 310.1 last reviewed July 2007.
- 05-18-17: Annual Review. Accessed NCD 310.1. No change.
- 07-31-19: Annual Review: Updated References.
- 11-18-20: Annual Review on 10-19-20. No change, links are still active. Codes S9988, S9990, S9991 will continue with PA.
- 11-17-21: Annual Review. Reviewed by Medical Policy Committee on 10/08/2021 and 11/05/2021. PHP will continue to follow Medicare (NCD 310.1) coverage statement for the routine costs of qualifying clinical trial services. The CPT codes will continue PA requirement. Reference changes were made which involved the removal of language and replacing it with the appropriate current citations for the following:
- “Medicare beneficiaries enrolled in a managed care plan” was replaced with Medicare Pub 100-04, Ch.32, section 69.9 Medicare Claims Processing.
 - “For Medicare beneficiaries enrolled in Medigap” was replaced to see 2022 Senior Care Plan 2 with Rx (HMO) Evidence of Coverage (EOC) instead.
- 11-16-22: Annual Review. Reviewed by Medical Policy Committee on 09-21-2022. Continue to follow NCD 310.0. Continue PA requirement for S9988, S9990, S9991 and continue no PA for 99199.

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.