Subject: Clinical Trial, Routine Patient Care Costs for Medicare

Medical Policy #: 3.8 **Original Effective Date:** 08/26/2009

Status: Reviewed **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. This Medical Policy only applies to members enrolled in a Medicare plan.

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:
Cancer Clinical Trials, Routine Patient Care Costs for Medicaid, MPM 3.7
Clinical Trials, Routine Patient Care Costs for Commercial, MPM 3.6

Coverage Determination

Prior Authorization is not required for participation in a Medicare-qualified clinical trial. However, prior authorization is required for non-qualified clinical trial.[14] **Logon to Pres Online to submit a request:**
https://ds.phs.org/preslogin/index.jsp

The following applies to Medicare members enrolled in ANY Medicare approved clinical trial.

A. Clinical Trial

PHP follows Centers for Medicare & Medicaid Services (CMS) Clinical Trials, (NCD 310.1). For clinical trials covered under the Clinical Trials 310.1 (NCD), Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials.

- A National Coverage Determination (NCD) that allows payment of routine items/services, and payment of investigational item/service if it is normally covered outside of trial and meets medical necessity requirements, in clinical trials that qualify for coverage.

B. Investigational Device Exemption (IDE) Studies:[6]

CMS allows coverage only for routine care items and services related to Category A IDE device studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website. The devices involved in Category A IDE device studies are not eligible for payment under Medicare.

Providers participating in and seeking reimbursement for items and services for CMS approved Category A and B IDE studies must notify PHP, prior to submitting claims. Interested parties must submit the following information:

- Study title;
- NCT or IDE number that corresponds to each device granted an IDE, Category B;
- CMS approval date; and
- Supporting materials which may include applicable CPT, Category III codes, HCPCS codes and ICD-10 codes.

An Investigational Device Exemption (IDE) allows an investigational device to be used in a clinical study setting to collect **safety** and effectiveness data required to support submission for approval for use to the FDA. The FDA will place all approved IDE devices into two categories:

A. Category **A** IDE Studies:

- (Experimental) device, which refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.
- Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met.

B. Category **B** IDE Studies:
- (Non-experimental/investigational) device, which refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.
- Medicare may make payment for a Category B IDE device **and** routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria are met.

C. Coverage with Evidence Development (CED):
- Medicare allows items and services, if they are furnished in the context of approved clinical studies or with the collection of additional clinical data, to assess their appropriateness. Medicare may issue an NCD that requires participation in certain clinical trials, longitudinal studies, or registries for coverage of an item/service and routine and related items/services. Some examples of CEDs include, but may not be limited to, artificial hearts, cochlear implantation and leadless pacemakers, Monoclonal Antibodies for Treatment of Alzheimer's Disease.
- NCDs that include CED criteria can be found on the CMS web page for Coverage with Evidence Development.

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

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. Novitas, Clinical Trials & Devices, Clinical Trials Background, Last modified: 05/24/2016. [Cited 09-19-2023]
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 09-19-2023]
3. CMS Manual System, Pub 100-03 Medicare National Coverage Determination, Change Request 5719, Transmittal 74, Date: September 07, 2007. [Cited 09-19-2023]
4. CMS, Pub. 100-04 Medicare Claims Processing Manual Chapter 32 – Billing Requirements for Special Services, (Rev. 10891, 07-20-21). [Cited 09-19-2023]
5. CMS, The Center for Consumer Information & Insurance Oversight (CCIIO), Affordable Care Act FAQs, Coverage for Individuals Participating in Approved Clinical Trails. [Cited 09-19-2023]
6. CMS, Medicare Benefit Policy Manual, Chapter 14, Medical Devices, (Rev. 198, 11-06-14). 20-FDA, Approved Investigational Device Exemption (IDE) Studies, (Rev. 198, 11-06-14). [Accessed 09-19-2023]
7. Code of Federal Regulations, Title 21: Food and Drugs, Chapter 1, Subchapter H-Medical Devices, Part (812)-Investigational Device Exemptions (21 CFR 812), last amended: Aug 31, 2023, Subchapter. [Access 09-19-2023]
8. Federal Regulations, Title 42, Chapter IV, Subchapter B, Part 405, Subpart B-Medical Services Coverage Decisions That Relate to Health Care Technology (42 CFR 405), amended at 78 FR 74810, Dec. 10, 2013. [Access 09-19-2023]
9. Federal Regulations, Title 42, Chapter IV, Subchapter B, Part 422, Subpart C, § 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials, [88 FR 22329, Apr. 12, 2023]. [Accessed 10-24-2023]
10. CMS, Medicare Coverage Related to Investigational Device Exemption (IDE) Studies, Page Last Modified: 09/06/2023 04:57 PM. [Access 09-19-2023]
11. U.S. Department of Health and Human Services, Health Care, Patient Protection and Affordable Care Act, Public law 111-148, Mar. 23, 2010, 124 STAT. 119. ‘‘SEC. 2709. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS. [Cited 11/03/2023]
12. CMS, NCD for Home Use of Oxygen in Approved Clinical Trials (240.2.1), Version #1, effective date: 03-20-2006. [Cited 10/03/2023]
13. CFR, Title 42, Chapter IV, Subchapter B, Part § 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials.
14. CMS, 100-16-Medicare Managed Care Manual, Ch 4, Benefits and Beneficiary Protections, 10.7-Clinical Trials, (Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15) [Cited 11/09/2023]

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.
12-13-23	Annual Review. Reviewed by Medical Policy Committee on 11/15/2023. Continue to follow NCD 310.0. Added IDE and CED criteria to policy. Prior Authorization requirement has been lifted for Medicare, (which includes MA) for participation in a Medicare-qualified clinical trial. However, prior authorization is required for non-qualified clinical trial. Removed Presbyterian Senior Care Plan 2 with Rx (HMO) 2023 Evidence of Coverage (phs.org).

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.