

Clinical Trial Coverage for Members Enrolled in a Medicare Plan

MPM 3.8

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.

Related Medical Policy:

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

Coverage Determination

Benefit Certification is required. Log on to Pres Online to submit a request: <https://ds.phs.org/preslogin/index.jsp>

Clinical trials must meet qualifying criteria in order to receive Medicare coverage of routine cost.² See CMS NCD 310.1 for information on the qualifying process for clinical trials.

For Medicare beneficiaries enrolled in a managed care plan: Your managed care plan will not be responsible for payment of a clinical trial. Original Medicare will be the payer for clinical trial services. Medicare will cover routine health care costs for people with Medicare involved in a clinical trial. Medicare will also pay for standard costs including hospital and physician visits, routine lab tests, as well as those costs that are due to medical problems as a result of being part of a clinical trial. In most cases, Medicare doesn't pay for the experimental item being investigated.¹

For Medicare beneficiaries enrolled in a Medigap plan: If you have a Medigap policy, and your routine costs are covered by Original Medicare while in a clinical trial, then your Medigap policy must pay the coinsurance amounts for those costs.¹

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For providers: Clinical trial services are to be processed as though the services were rendered to a Medicare Fee-For-Service (FFS) patient. Medicare guidelines must be followed.^{3,4,5}

Providers requiring information on this CMS policy should refer to the following documents:

- Change Request 6455 of CMS Manual System, Pub 100-04 Medicare Claims Processing. "Ensuring Only Clinical Trial Services Receive Fee-For-Service Payment on Claims Billed for Managed Care Beneficiaries." Effective date: October 1, 2009.
- MLN Matters® Number: MM6455 Revised. "Ensuring Only Clinical Trial Services Receive Fee-For-Service (FFS) Payment on Claims Billed for Managed Care Beneficiaries". Effective date: October 1, 2009.
- Provider Inquiry Assistance, JA6455. "Ensuring Only Clinical Trial Services Receive Fee-For-Service Payment on Claims Billed for Managed Care Beneficiaries." Effective date: October 1, 2009.

Coding

The coding listed in this Medical Policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description
0130T	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-9® Diagnosis Codes	Description
V70.7	Examination of participant in clinical trial

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.

[MPMPPC021004]

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- References:**
1. Medicare. The Official US Government Site for People with Medicare. Information about Clinical Trials (Inpatient). Answer ID 2189. Date Created 08-31-09. Accessed 02-4-10 on the Internet at: http://questions.medicare.gov/cgi-bin/medicare.cfg/php/enduser/std_adp.php?p_faqid=2189&p_created=1251732111
 2. Centers for Medicare and Medicaid Services. National Coverage Determination for Routine Costs in Clinical Trials (310.1). Publication 100-3. Implementation date: 10-09-07.
 3. CMS Manual System. Publication 100-04 Medicare Claims Processing. Transmittal 1723. Change Request 6455. Subject: Ensuring Only Clinical Trial Services Receive Fee-For-Service Payment on Claims Billed for Managed Care Beneficiaries. Implementation date: 10-05-09.
 4. CMS MLN Matters®. Number MM6455 Revised. Ensuring Only Clinical Trial Services Receive Fee-For-Service (FFS) Payment on Claims Billed for Managed Care Beneficiaries. Implementation date: 10-05-09.
 5. CMS Provider Inquiry Assistance. Ensuring Only Clinical Trial Services Receive Fee-For-Service (FFS) Payment on Claims Billed for Managed Care Beneficiaries – JA6455. Implementation date: 10-05-09.

Approval Signatures: **Clinical Quality Committee:** Charles Baumgart, MD

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Publication History: 08-26-09: Original effective date for Cancer Clinical Trials, MPM 3.7
02-24-10: Medicare portion of Cancer Clinical Trials moved into new Medical Policy. Original effective date.

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 on the Internet at: <http://www.phs.org/phs/healthplans/providers/healthservices/Medical/index.htm>

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