

Routine Costs in Clinical Trials (NCD 310.1)

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Policy Summary

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Overview

In accordance with applicable Medicare fee-for-service rules, Medicare Administrative Contractors (MACs) will directly pay providers for covered clinical trial services furnished to a UnitedHealthcare Medicare member. (Medicare Managed Care Manual Chapter 8, section 40.4.3)

Original Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in Medicare Advantage (MA) plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials. All other original Medicare rules apply. (Medicare Managed Care Manual Chapter 4, section 10.7)

The Centers for Medicare & Medicaid Services (CMS) will make payments for MA enrollees on a fee-for-service basis for covered clinical trial costs under the September 2000 National Coverage Determination (NCD). This policy is in effect until further notice. In CY 2000, CMS determined that the cost of covering these new benefits was not included in the 2001 MA capitated payment rates, and since this cost met the threshold for "significant cost" under 42 CFR 422.109(a), Medicare paid for covered clinical trial services outside of the capitated payment rate. CMS continues the policy of making payments on a fee-for-service basis for covered clinical trial items and services provided MA enrollees until further notification, because the capitation rates have not been appropriately adjusted to account for costs of this NCD, as required under §1853(c)(7) of the Social Security Act (the Act). (Medicare Managed Care Manual Chapter 8, section 40.4.3)

Medicare Advantage is responsible for payment of claims related to enrollees' participation in both Category A and B Investigational Device Exemption (IDE) studies that are covered by the MAC with jurisdiction over the MA plan's service area. Medicare Advantage is responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. Medicare Advantage is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage. (Medicare Managed Care Manual Chapter 4, section 10.7.2)

Medicare Advantage is responsible for payment of items and services in CMS-approved Coverage with Evidence Development (CED) studies unless CMS determines that the significant cost threshold is exceeded for that item or service. (Medicare Managed Care Manual Chapter 4, section 10.7.3)

Routine Costs

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions found in 42 CFR 405.201-405.215, 411.15, and 411.406.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited; Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100-03, National Coverage Determination (NCD) Manual, and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the noncovered item or service, itself, will not.

Requirements for Medicare Coverage of Routine Costs

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

- The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
- The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
- The trial does not unjustifiably duplicate existing studies;
- The trial design is appropriate to answer the research question being asked in the trial;
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
- The trial is in compliance with Federal regulations relating to the protection of human subjects; and
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Qualification Process for Clinical Trials

Using the authority found in §1142 of the Social Security Act (the Act) (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA)

to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to the Centers for Medicare & Medicaid Services (CMS).

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

Clinical trials that are deemed to be automatically qualified are:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;
- Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b) (1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

The CMS, through the NCD process, through an individualized assessment of benefits, risks, and research potential, may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

Guidelines

It is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under coverage with evidence development (CED). (Medicare Claims Processing Manual Chapter 32, section 69.6).

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Should CMS find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §1879, 1842(l), or 1834(j)(4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

To access the list of CMS approved clinical trials/clinical research studies, go to [Medicare Approved Facilities/Trials/Registries](#). Select the applicable Facility/Trial/Registry from the list on the left column to view the current approved clinical trials/clinical research studies. To access the list of NCD's requiring Coverage with Evidence Development (CED), go to [Coverage with Evidence Development](#). The NCDs requiring CED are listed to the left- clicking on an NCD will lead to a listing of approved clinical studies for that specific NCD.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Modifier	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

Diagnosis Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

References

CMS National Coverage Determinations (NCDs)

[NCD 310.1 Routine Costs in Clinical Trials](#)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A52430 Clinical Trials - Medical Policy Article	CGS	KY, OH	KY, OH
N/A	A52840 Clinical Trials - Medical Policy Article	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
N/A	A53784 Billing and Coding: The Routine Costs of Investigational Chemotherapy Drugs Studied In a Qualifying Clinical Trial	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

CMS Benefit Policy Manual

[Chapter 14 Medical Devices](#)

CMS Claims Processing Manual

[Chapter 4; § 240.6 Submitting Provider-Liable “No-Pay” Part A Claims and Beneficiary Liability](#)

[Chapter 32; § 68 - 68.4 Investigational Device Exemption \(IDE\) Studies, § 69 - 69.11 Qualifying Clinical Trials](#)

CMS Transmittal(s)

[Transmittal 3105, Change Request 8921, Dated 11/06/2014 \(Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption \(IDE\) Studies\)](#)

[Transmittal 3181, Change Request 8961, Dated 01/30/2015 \(Implementation of New NUBC Condition Code “53” “Initial placement of a medical device provided as part of a clinical trial or a free sample”\)](#)

MLN Matters

[Article MM8921, Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption \(IDE\) Studies](#)
[Article MM8961, Implementation of New National Uniform Billing Committee \(NUBC\) Condition Code “53” - “Initial placement of a medical device provided as part of a clinical trial or a free sample”](#)

Related Medicare Advantage Policy Guidelines

[Artificial Hearts and Related Devices \(Formerly NCD 20.9\)](#)

[Avastin® \(Bevacizumab\)](#)

[Blood-Derived Products for Chronic Non-Healing Wounds \(NCD 270.3\)](#)

[Cochlear Implantation \(NCD 50.3\)](#)

[Continuous Positive Airway Pressure \(CPAP\) Therapy for Obstructive Sleep Apnea \(OSA\) \(NCD 240.4\) and Other Respiratory Assist Devices \(RAD\)](#)

[Extracorporeal Photopheresis \(NCD 110.4\)](#)

[Home Oxygen Use to Treat Cluster Headache \(CH\) \(NCD 240.2.2\)](#)

[Home Use of Oxygen in Approved Clinical Trials \(NCD 240.2.1\)](#)

[Infusion Pumps \(NCD 280.14\)](#)

[Islet Cell Transplantation in the Context of a Clinical Trial \(NCD 260.3.1\)](#)

[Magnetic Resonance Imaging \(NCD 220.2\)](#)

[Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis \(NCD 150.13\)](#)

[Percutaneous Transluminal Angioplasty \(PTA\) \(NCD 20.7\)](#)

[Pharmacogenomic Testing for Warfarin Response \(NCD 90.1\)](#)

[Positron Emission Tomography \(PET\) Scan \(Including NCDs 220.6-220.6.20\)](#)

[Transcatheter Aortic Valve Replacement \(TAVR\) \(NCD 20.32\)](#)

[Transcatheter Mitral Valve Repair \(TMVR\) \(NCD 20.33\)](#)

[Transcutaneous Electrical Nerve Stimulation \(TENS\) for Chronic Low Back Pain \(CLBP\) \(NCD 160.27\)](#)

[Vagus Nerve Stimulation \(VNS\) \(NCD 160.18\)](#)

Related Medicare Advantage Coverage Summaries

[Cardiac Procedures: Pacemakers, Defibrillators and Pulmonary Artery Pressure Measurements](#)

[Chemotherapy, and Associated Drugs and Treatments](#)

[Deep Brain Stimulation for Essential Tremor and Parkinson's Disease](#)

[Experimental Procedures and Items, Investigational Devices and Clinical Trials](#)

[Extracorporeal Photopheresis](#)

[Hearing Aids, Auditory Implants and Related Procedures](#)

[Infusion Pump Therapy](#)

[Oxygen for Home Use](#)

[Pain Management and Pain Rehabilitation](#)

[Percutaneous Transluminal Angioplasty and Stenting](#)

[Positron Emission Tomography \(PET\)/Combined PET-CT \(Computed Tomography\)](#)

[Stimulators: Electrical and Spinal Cord Stimulators](#)

[Transcatheter Heart Valve Procedures](#)

[Transplants: Organ and Tissue Transplants](#)

[Ventricular Assist Device \(VAD\) and Artificial Heart](#)

Other(s)

[Clinical Trials Registry and Database](#)

[CMS Instructions: Medicare Coverage Related to Investigational Device Exemption \(IDE\) Studies](#)

[CMS Mandatory Reporting of National Clinical Trial \(NCT\) Identifier](#)

[Coverage with Evidence Development](#)

[Medicare Approved Facilities/Trials/Registries](#)

[Medicare Clinical Trial Policies](#)

[Medicare Managed Care Manual Chapter 4 § 10.7 Clinical Trials](#)

[Medicare Managed Care Manual Chapter 8 § 40.4.3 Special Rules for the September 2000 NCD on Clinical Trials](#)

[2019 Advanced Call Letter \(Advanced Notice Part 2\), Attachment II, Section E](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
11/11/2020	Applicable Codes <ul style="list-style-type: none">Removed HCPCS codes S9988, S9990, S9991, S9992, S9994, and S9996 Supporting Information <ul style="list-style-type: none">Updated <i>References</i> section to reflect the most current informationArchived previous policy version MPG268.06

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).