UnitedHealthcare®

Reimbursement Policy

Routine Costs in a Clinical Trial (NCD 310.1)

Policy Number	310.1	Approved By	UnitedHealthcare Medicare Reimbursement Policy Committee	Current Approval Date	12/18/2013

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies 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.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Summary

Overview

Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

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 medical review policies (LMRPs) or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare contractors' local policies.

For noncovered 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 noncovered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national noncoverage policy in Pub. 100-03, 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 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 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.

Effective September 19, 2000, 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;

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- 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 national coverage determination (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.

Reimbursement Guidelines

All Institutional Clinical Trial Claims

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is voluntary at this time.

****Effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1. Per the MLN Matter Article MM8401.**

Inpatient Clinical Trial Claims

Institutional providers billing clinical trial service(s) must report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer) and a condition code 30 regardless of whether all services are related to the clinical trial or not.

NOTE: HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., QV or Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

Outpatient Clinical Trial Claims

On all outpatient clinical trial claims, providers need to do the following:

1. Report condition code 30,
2. Report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer); and
3. Identify all lines that contain an investigational item/service with a HCPCS modifier of Q0 for dates of service on or after 01/01/2008.
4. Identify all lines that contain a routine service with a HCPCS modifier of Q1 for dates of service on or after 01/01/2008.

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.

Medicare regulations require Medicare+Choice (M+C) organizations to follow CMS's national coverage decisions. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of

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whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

CPT / HCPCS Codes

Code	Description
S9988	Services provided as part of a phase 1 clinical trial (Not covered by Medicare)
S9990	Services provided as part of a phase ii clinical trial (Not covered by Medicare)
S9991	Services provided as part of a phase iii clinical trial (Not covered by Medicare)
S9992	Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion (Not covered by Medicare)
S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion (Not covered by Medicare)
S9996	Meals for clinical trial participant and one caregiver/companion (Not covered by Medicare)

Modifiers

Code	Description
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study.
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study.

Condition Codes

Code	Description
30	Qualified clinical trial. When this condition code is reported on a claim, it generally means the service is part of a CMS related clinical trial, demonstration or study.

References Included (but not limited to):

CMS NCD

NCD 310.1 Routine Costs in a Clinical Trial

CMS Benefit Policy Manual

Chapter 15; § 50.4.5.C Use Supported by Clinical Research That Appears in Peer-Reviewed Medical Literature

CMS Claims Processing Manual

Chapter 13; § 60.15 Billing Requirements for CMS - Approved Clinical Trials and Coverage With Evidence Development Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified

Chapter 32; § 69-69.11 Requirements for Billing Routine Costs of Clinical Trials

CMS Transmittals

Transmittal 1657, Change Request 6320, Dated 12/31/2008 (January 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS))

Transmittal 107, Dated 06/22/2012 (Chapter 4, Benefits and Beneficiary Protections)

UnitedHealthcare Medicare Advantage Coverage Summaries

Experimental Procedures and Items, Investigational Devices and Clinical Trials

Infusion Pump Therapy

Neurophysiological Studies

Percutaneous Transluminal Angioplasty and Stenting

Transplants – Organ and Tissue Transplants

Ventricular Assist Device (VAD) and Artificial Heart

UnitedHealthcare Reimbursement Policies

Cochlear Implants (NCD 50.3)

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Islet Cell Transplantation in the Context of a Clinical Trial (NCD 260.3.1)

Percutaneous Transluminal Angioplasty (PTA) (NCD 20.7)

PET Scan

Transcatheter Aortic Valve Replacement (TAVR) (NCD 20.32)

Transcatheter Placement of Extra Cranial Vertebral or Intrathoracic Carotid Artery Stents

United Healthcare Coverage Determination Guidelines (CDGs)

Clinical Trials

MLN Matters

Article MM8401 Revised, Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims

Article MM5805, New Healthcare Common Procedure Coding System (HCPCS) Modifiers when Billing for Patient Care in Clinical Research Studies

Article MM5790, Use of an 8-Digit Registry Number on Clinical Trial Claims

Article SE0822 Revised, Clarification of Medicare Payment for Routine Costs in a Clinical Trial

History

Date	Revisions
09/17/2014	Removed all GA/GY modifier language from document
12/18/2013	Updated with the new clinical trial references and added references to the individual policies that address their clinical trials specifically