

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	April 2003
Section 7.7	Clinical Research	Revised:	May 2015
Policy 7.7.1	Budgeting and Billing for Clinical Services Provided as Part of Research Involving Human Subjects	Responsibility:	Vice President for Research

BUDGETING AND BILLING FOR CLINICAL SERVICES PROVIDED AS PART OF RESEARCH INVOLVING HUMAN SUBJECTS

Policy

Clinical researchers routinely depend on the clinical services provided by healthcare organizations to perform conventional care or research care/procedures that are dictated by the research protocol. This policy applies to research whenever clinical items or services are provided as part of the protocol, regardless of finding source (industry sponsor, federal grant, foundation grant, or other source).

It is the Principal Investigator's (PI) responsibility to ensure that budgeting and billing of clinical services that are required by the study plan are performed according to applicable regulations and policies. The Vice President for Research Clinical Trials Office (VPR CTO) provides the institutional review and approval of clinical trial budgets and billing plans to ensure compliance to the business and regulatory requirements of this policy.

Definitions

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS): A federal agency responsible for key federal health care programs.

CLINICAL SERVICES: Clinical services include clinical care, clinical tests or clinical procedures that are delivered as part of healthcare (i.e. delivered by professional and technical staff in a clinic, hospital, laboratory, research center, etc.). Examples of clinical services include: a blood test performed by a healthcare laboratory, an x-ray performed by an affiliated hospital's radiology department, investigational drug administered by inpatient nursing staff. In general, all research involving a drug or medical device include some form of clinical service. Clinical services that are stipulated in the study plan are either conventional care or research care/procedures.

CLINICAL TRIAL AGREEMENT (CTA): An agreement between the Health Science Center and the financial sponsor.

CONVENTIONAL CARE: This includes clinical items and services typically provided, absent the research, by professional and technical staff in a clinic, hospital, laboratory, research center, etc. This does not

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include any items or services that are performed more often than would otherwise be considered acceptable practice. A bill or claim is typically generated for these items and services.

COVERAGE WITH EVIDENCE DEVELOPMENT (CED): A National Coverage Decision (NCD) which first requires development and capture of additional patient data to supplement standard claims data in order to obtain Medicare coverage of the item or service.

FISCAL INTERMEDIARY: An entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

FOOD AND DRUG ADMINISTRATION (FDA): A federal agency responsible for protecting public health by regulating drugs, devices, and biologics.

INFORMED CONSENT FORM (ICF): The consent document which a participant signs prior to being enrolled in a clinical trial.

INVESTIGATIONAL DEVICE EXEMPTION (IDE): Issued by the Food and Drug Administration (FDA), it allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval application or a Premarket Notification (510(k)) submission to FDA.

Category A device: These are experimental investigational devices for which the initial questions of safety and effectiveness of the device have not been proven (FDA Class III).

Category B device: Non-experimental investigational devices for which the initial questions of safety and effectiveness have already been proven even though the device may not yet be approved by the FDA (FDA Class I and II).

LOCAL COVERAGE DECISION (LCD): A decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis (i.e., a determination as to whether the service is reasonable and necessary).

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NATIONAL COVERAGE DECISION (NCD): A national policy statement granting, limiting, or excluding Medicare coverage for a specific medical item or service. The NCD may be issued as a manual instruction or other document such as a program memorandum, ruling, or Federal Register notice.

RESEARCH PROCEDURES/CARE: This includes clinical items and services required only for research purposes by professional and technical staff in a clinic, hospital, laboratory, research center, etc. This includes items or services needed for the diagnosis or treatment of complications arising from the study intervention being tested or evaluated. A bill or claim is typically generated for these items and services.

Funding Agreements

Documentation of the agreement with the financial sponsor (industry sponsor, federal grant, foundation grant, or other source), should explicitly detail the costs of any clinical services and the extent to which the financial sponsor is paying for these costs. If the CTA or grant does not include this, the PI must have other documentation, such as an itemized budget, which clearly identifies which clinical services the sponsor is funding.

For grants all charges for clinical items or services must be the actual cost. For industry sponsors, all rates charged to sponsors in a study budget for clinical items or services must be fair market value, although the rate can also reflect research personnel time in addition to the charge for the actual item/service, if their time is not also a separate budget entry.

Where there is potential for a research-related injury, the CTA must indicate who will provide care and who is responsible to pay for it. The Health Science Center requires that industry sponsors be responsible for paying for care for research-related injury (exceptions are considered on a case-by-case basis).

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Clinical Trials Office Responsibilities

The VPR Clinical Trials Office (VPR CTO) is responsible for developing institutional policy and processes, training, oversight and monitoring of issues pertaining to budgeting and billing for clinical services provided as part of a research study. These operations must support applicable regulatory requirements (e.g. FDA and CMS) as well as University of Texas System policy and guidance. (Note: the Cancer Therapy and Research Center has offices with equivalent responsibilities that are required to comply with the same regulations and UT System policy; the VPR CTO verifies conformance of the CTRC policy and process)

As part of an institutional review and approval prior to study activation, the VPR CTO will review billing plans for studies with clinical services, regardless of payor for the services – e.g. the sponsor, participant or insurance. This review and approval will be initiated prior to or at the time of IRB study submittal. The VPR CTO will also advise research teams on the applicability of this policy and institutional budgeting and billing processes in the event of a discrepancy between this policy and a government or private foundation grant policy, or conflicts with industry sponsors regarding interpretation and application of budgeting and billing rules.

Investigator Responsibilities

Principal Investigators (PIs) are responsible for:

- ensuring appropriate billing according to payor coverage limitations and rules;
- ensuring that the clinical trial agreement, or a detailed cost assignment/budget grid, clearly articulates which medical items/services required by the protocol are funded by the sponsor or grant;
- ensuring the ICF correctly reflects which items/services the patient is financially responsible for, and which items are provided by the sponsor (as applicable);
- ensuring consistency between the ICF and CTA/budget with regards to sponsor funding and patient financial responsibility (including responsibility for treatment for research-related injuries);

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- documenting in the research files which clinical services a participant would have received if not enrolled in the study (i.e. conventional care).
 - ensuring there is proper oversight and monitoring/reconciliation procedures in place within the research team for the billing of medical services provided in accordance with the protocol;
 - registering the study with clinicaltrials.gov if not already registered by the sponsor; and,
 - obtaining the permission from the fiscal intermediary/carrier to bill Medicare for device trials, if not previously obtained by Sponsor. <http://www.cms.gov/Medicare/Coverage/IDE/>

PIs and their research teams will comply with the standardized VPR CTO processes and procedures that facilitate and support performance of these responsibilities. <http://research.uthscsa.edu/CTO/clinical.shtml>

General Billing Rules

Once a participant enrolls in a study, his/her insurance may limit coverage for their medical care, even if that care would otherwise be considered conventional care. Third-party payors, such as Medicare, Medicaid, other governmental programs, and commercial insurance plans have differing coverage limitations and billing requirements. The research team and billing personnel must be aware of these limitations and requirements and take them into consideration when negotiating funding with sponsors and when ensuring compliant billing.

The Health Science Center cannot bill a third-party payor or patient for the following:

- Items/services for which the sponsor has agreed to pay;
- Items provided free of charge by the sponsor to the Health Science Center; and,
- Any items which are promised free of charge in the ICF.

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Communication to Billing Entities for Services Provided

For services rendered by health care providers/entities other than by the PI or research team, PI's will ensure the service provider is aware that the patient is a research study participant and communicate to the appropriate personnel/departments whether the Health Science Center research study or the patient (or patient's insurer) is to be billed for the service. This applies to providers within the Health Science Center, e.g. UTMEd Clinics, and outside, e.g. University Health System.

Medicare Reimbursement for Research (Other Than IDE Device Trials)

This section applies to all research studies other than device trials with a Category A or B IDE. Medicare coverage rules for devices with an IDE are explained in the following section.

The Medicare program, under a NCD 310.1 and other regulations issued by the CMS, covers the "routine costs" of "qualifying clinical trials". Even if a trial does not "qualify," Medicare will still pay for conventional care services and any reasonable and necessary items and services used to diagnose and treat complications arising from participation in the study, unless the item or service is covered by a national non-coverage policy. Even if the only items/services in a trial which are not funded by the sponsor are conventional care services, PIs must still analyze whether the trial "qualifies" for coverage due to special coding requirements. In addition to determining whether the trial qualifies, each PI is also responsible for determining which medical services fall within CMS's definition of "routine costs."

In order to be considered a qualifying trial, it must first meet all of the following criteria:

- Evaluates a Medicare Benefit. 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., physician's services, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- Has a Therapeutic Intent. The trial must have a therapeutic intent (i.e., the trial must, to some extent, assess the effect of the intervention on patient outcome and not test exclusively for toxicity or disease pathophysiology).

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- Enrolls Diagnosed Beneficiaries. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than only healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
 - Deemed Trials. Under the NCD, trials must have certain desirable characteristics. At present, trials which fall under one of the following are “deemed” to have these characteristics, and as such, are automatically qualified:
 - Funded or supported by centers of cooperative groups that are funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), Department of Defense (DOD), and Department of Veterans Affairs (VA);
 - Conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration (FDA); or,
 - Drug trials that are exempt from having an IND under 21 CFR 312.2 (b)(1) (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.2>)

If the trial “qualifies”, then the Health Science Center may bill for the “routine costs” of that trial and which includes:

- Items and services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);
- Items and services required solely for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications;

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- Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service; and,
 - Standard of care items/services. (i.e. conventional care)

The following are specifically excluded from the definition of “routine cost” and are not billable to Medicare:

- The investigational item or service itself, unless it is otherwise specifically covered by an NCD, a LCD, or CED;
- 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 computed tomography scans for a condition usually requiring only a single scan);
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial; and,
- Items and services provided solely to determine whether a potential participant meets the trial inclusion or exclusion criteria. The Health Science Center may, however, bill for the “conventional care” work-up to determine appropriate clinical management of the patient.

The claims for Qualifying Clinical Trials must include applicable codes and modifiers as per the CMS Clinical Trial Policy. The national clinical trial number (NCT#) must also be submitted on claims for items and services provided in a Qualifying Clinical Trial. The NCT# is assigned by the National Library of Medicine (NLM) at the National Institutes of Health (NIH) when a new study is registered in the NLM Clinical Trials database at <http://clinicaltrials.gov/>

**Medicare
Reimbursement
for IDE-Device
Trials**

The extent to which Medicare covers items, services, or the investigational device involved in a device trial depends on the category of the device. Effective January 1, 2015, trials involving a device with an IDE from the FDA, must be submitted for CMS’ central review by the

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Study Sponsor following the instructions provided by CMS:
<http://www.cms.gov/Medicare/Coverage/IDE>

Studies approved for coverage may be found on the CMS website under “Approved IDE Studies”:
<http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html>

Device studies prior to January 1, 2015 will continue to be administered by the local Medicare fiscal intermediary/carrier (Novitas) as previously submitted by the local PI. Approval for coverage is required prior to any items or services required by the protocol being billed by the Health Science Center (including UT Medicine and the CTRC)

For Category A Devices: These are experimental investigational devices for which the initial questions of safety and effectiveness of the device have not been proven (FDA Class III). For these trials, the Health Science Center cannot bill Medicare for the device itself, but may be able to bill for services related to the use of the device if the device is used to diagnose, monitor or treat an “immediately life threatening disease or condition”, The types of services which may be billed are the same as “routine costs” discussed above for drug trials. CMS defines “immediately life threatening disease or condition” as “a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment”.

For Category B Devices: Non-experimental investigational devices for which the initial questions of safety and effectiveness have already been proven even though the device may not yet be approved by the FDA (FDA Class I and II). In these cases, the device itself may be billable, in addition to services incident to its use, taking into consideration factors such as medical necessity, frequency, acceptable medical standards, and, appropriate setting.

**Medicare
Documentation
Requirements**

The trial name, name of sponsor, and the sponsor-assigned protocol number must be documented in the patient’s medical record and must be provided if requested for a medical review. A copy of the participant’s ICF must also be made available if requested for medical review.

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Medicare Managed Care Plans

Payment for conventional care services furnished as part of a Qualifying Clinical Trial to beneficiaries enrolled in Medicare managed care plans (Medicare Advantage plans) will be made on a fee-for-service basis by the Medicare contractors that process fee-for-service claims. The same coverage rules apply to these plans. The payment amounts will be based on the applicable Medicare fee schedules for such services.

Claims related to IDE trials (Category A and Category B) and claims for conventional care services related to “non-qualifying” clinical trials are to be submitted to the Medicare Advantage Plan for prior approval to determine if they are covered.

Other Third Party Payors

Commercial health insurance plans and other government programs (such as Medicaid, etc.) also may have coverage limitations for clinical trial participants.

Medicaid

Coverage limitations for Medicaid are determined by each state and are not established by the CMS. For Texas, Medicaid does not pay for any item, service, drug or device which is considered investigational, but will pay for the conventional care medical services provided as part of the research study.

Waiving of Co-Payments, Co-Insurance, and Deductibles

All applicable deductible, co-payment, and co-insurance rules apply to services which are billable to a patient’s insurance. These deductibles, co-payments, and co-insurance must be paid by the patient and cannot be waived, except in accordance with applicable [UT Medicine Charity Care Policy](#). In the event a sponsor contracts to pay a “standard of care” service, it must be applied equally to all patients.
