

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

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| Chapter 7 | Research and Sponsored Programs | Effective: | April 2003 |
| Section 7.7 | Clinical Research | Revised: | February 2009 |
| 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

Each Principal Investigator (PI) is responsible for ensuring there is proper oversight and monitoring procedures in place for the budgeting and billing of clinical services provided under a clinical trial. PIs must comply with the budgeting and billing requirements of the studies, and the applicable laws and regulations.

This policy applies to any human subject research in which medical items or services are provided as part of a clinical research study, regardless of funding source (industry sponsor, federal grant, foundation grant, or other source). It applies to any study that involves a non-FDA approved drug, device, or off-label use of an FDA-approved drug; a study involving FDA approved drugs; a study which involves a clinical intervention, such as a laboratory test or procedure; and, to any Health Science Center research where any intervention tests or procedures are performed in a Health Science Center clinic or an affiliate organization. For purposes of this policy, the terms “clinical trial” and “clinical research” are intended to include all research to which this policy is applicable.

This policy does not apply to a study that does not have human subjects, or those studies consisting of only surveys, chart reviews, or limited data sets.

Definitions

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

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.

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

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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).

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.

STANDARD OF CARE (SOC): Refers to those medical items or services which the clinical trial participant would have received even if he/she were not enrolled in the trial. This does not include any items or services that are performed more often than would otherwise be the case.

**Industry
Sponsor
Agreements**

CTAs should explicitly detail the charges for the study and the extent to which the sponsor is funding patient clinical services, including payment for research-related injuries. If the CTA (including any attachments) does not specifically identify what services the sponsor is funding, the PI must have another document which clearly identifies what clinical services the sponsor is funding. All rates charged to sponsors in a study budget for medical items or services must be fair market value,

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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.

Office of Clinical Research Responsibilities

The Office of Clinical Research (OCR) is responsible for developing standardized institutional policy and processes, training, oversight and monitoring of issues pertaining to budgeting and billing for medical services provided as part of a clinical trial.

The OCR 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 services are standard of care, which items/services the patient is financially responsible for, and which items are provided by the sponsor;
 - 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);
 - documenting in the clinical trial files what clinical services a participant would have received if not enrolled in the trial (i.e., which services are standard of care as defined by this policy);
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- ensuring there is proper oversight and monitoring procedures in place within the research team for the billing of medical services provided under the clinical trial;
 - registering trials at clinicaltrials.gov if the sponsor has not already done so; and,
 - obtaining the permission from the fiscal intermediary/carrier to bill Medicare for device trials.
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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 standard of 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 for free in the ICF.

Communication to Billing Entities for Services Provided Outside of the Health Science Center

For services rendered by health care providers/entities other than the Health Science Center, PIs 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.

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**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 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 standard of care services and any reasonable and necessary items and services used to diagnose and treat complications arising from participation in the study. Even if the only items/services in a trial which are not funded by the sponsor are standard of 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 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). Trials that are conducted exclusively to test toxicity or disease pathophysiology are not covered under Medicare’s policy. The Health Science Center will not bill Medicare for services provided in a Phase I clinical trial which would be considered “routine costs”, other than standard of care treatment for that patient.
- Enrolls Diagnosed Beneficiaries. 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.

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- 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:
 - 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;
- 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.

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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 “standard of care” work-up to determine appropriate clinical management of the patient.

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. For trials involving a device with an IDE from the FDA, however, it is required that the PI submits a request to the local Medicare fiscal intermediary/carrier requesting coverage prior to billing for anything related to the trial. If the PI does not submit a request, then the Health Science Center (including UT Medicine and the CTTC) cannot bill for any items or services required by the protocol.

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

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“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.

Medicare Managed Care Plans

Payment for standard of care clinical trial services furnished as part of a “qualified” 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 standard of 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. Consult the OCR Web site (<http://research.uthscsa.edu/ocr/clinical.shtml>) for additional information and guidance.

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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 standard of 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 policies pertaining to waivers for indigent patients.
