

Clinical Trials Billing Administration

Managing Patient Care Costs
In Clinical Trials

What Are Patient Care Costs Associated with Clinical Trials?

- Lab, radiology, pathology and other tests required under the sponsor's protocol.
- Routine treatment provided to patients while they are participating in a qualifying clinical trial.
- Costs associated with complications arising out of participation in a clinical trial (occurring either during or after the trial)

Who Generally Pays These Costs?

- Trial Sponsors (when their protocols require specific tests)
- Medicare and other Third Party Payers (when the patient receives routine inpatient or outpatient care while participating in a clinical trial or as the result of complications from participation in the trial)

Who Else May Pay These Costs?

- The institution (when controls are not in place to establish the appropriate payer, the institution may absorb the cost, without reimbursement)
- The trial subject (when a complication occurs and there is no other payer)
- Some combination of the above

The Trial Sponsor

Trial sponsor protocols often require laboratory, radiology and other tests to establish eligibility for participation in the trial as well as periodic updates to determine the efficacy of the drug or device under review.

In these cases, the sponsor should provide sufficient funds to pay for these tests.

Medicare (and Other Third Party Payers)

To encourage participation in clinical trials by senior citizens, Medicare now covers many routine care costs of a *qualifying* trial and all reasonable and necessary items and services to diagnose and treat complications arising out of participation in *all* clinical trials (Medicare - National Coverage Decision - 2000)

What is Billable to Medicare

- Items or services typically provided absent a clinical trial
- Items or services required for the provision of the investigational item or service
- Items or services required for clinically monitoring the effects of the trial drug or device or to prevent complications
- Items or services that are medically necessary for the diagnosis or treatment of complications

What's Not Billable to Medicare

- The investigational item itself
- Items or services not directly needed for the management of the patient
- Items or services specifically outlined in the protocol
- Items provided free of charge (by sponsor or other provider)
- Items to determine trial eligibility
- Non covered services (e.g., cosmetic surgery)
- Experimental items (Category A)

The Healthcare Institution

When neither of the two previous options are exercised, the hospital may find itself an unintended partner in the clinical trial. For example, the cost of providing a lab test or an MRI, may be absorbed by the hospital without reimbursement, often without hospital administration even being aware.

Who Makes the Payment Determination?

- In many cases it is the Principal Investigator
- The PI's decision may be effected by several factors including:
 - How the sponsor pays for the trial (e.g., a set amount per patient, one amount for the entire trial, etc.)
 - Whether or not there will be funds remaining at close of trial
 - Lack of knowledge of how the institution captures and bills for patient services

The Research Billing Program

- The players in this process are the Grants Office, Patient Accounts and Fund Accounting
- Ensures proper charge back to the clinical trial sponsor and/or appropriate 3rd party billing
- Establishment of Research Billing Gatekeeper

First Steps

- Meet with Management of Grants Office, Patient Accounts and Fund Accounting to discuss billing program controls
- Establish policies and procedures to cover all billing contingencies, including a mechanism to charge back clinical trials and consideration of a research CDM

First Steps (continued)

- Establish third party billing standards including coding, use of appropriate modifiers and denial management procedures
- Establish documentation standards for clinical trial information in the patient's inpatient and outpatient medical records
- Develop a “gatekeeper” job description and determine where this position will reside in the institution

Functions of the Research Billing Gatekeeper

- Review all clinical trial budgets
- Identify tests and other patient care costs required by protocol to ensure they are captured in the budget
- Ensure sufficient funds are made available by the sponsor to cover these costs
- Ensure the informed consent is clear as to how costs will be covered and who will be responsible for costs

Functions of Research Gatekeeper (continued)

- During discussions with the PI, determine if any services are billable to the third party payer
- Act as liaison between Grants Office, Patient Accounts and Fund Accounting
- Manage the fund charge back process to ensure costs are allocated back to the appropriate trial sponsor
- The trial may not go forward without clarification of costs