

POLICY ON CLINICAL RESEARCH BILLING
March 2006

Purpose:

Patients who participate in a clinical trial or clinical research may be provided services in a variety of departments within EVMS and EVMS Health Services. In order to meet Federal and State requirements, it is essential that clinical care costs are charged appropriately to third party payers and that EVMS and EVMS Health Services jointly develop mechanisms to track billing related to clinical research studies. To assist investigators in meeting compliance requirements for research billing in clinical trials, EVMS and EVMS Health Services has developed the following guidance and procedures for the development of clinical trial research budgets. These requirements are necessary for the final approval of clinical research contracts by the Office of Research, for the authorization of patient and insurance billing by EVMS Health Services and for internal auditing by EVMS and EVMS Health Services. They are intended to facilitate the accurate and timely billing of charges in clinical studies conducted by EVMS and EVMS Health Services researchers. It is applicable to all Eastern Virginia Medical School departments, practice groups, and centers.

Background

The protocol for a clinical research study may include standard, conventional treatment for a patient's medical condition. Often, costs of standard care (SOC) provided to a patient enrolled in a clinical study may be billed to third party insurers. However, when the sponsor of the trial provides funding for services/procedures customarily designated as SOC, these costs cannot be billed to Medicare, Medicaid, other third party insurers or the research subject. There may also be services, items or tests that are purely experimental – not known to be effective, or, are required for investigational purposes only. As a general rule, costs for items and services that are experimental – not considered medically necessary, safe and effective – may not be billed to Medicare, Medicaid, other third party insurers, or the research subject.

Costs for services, drugs, devices and tests that are experimental are the responsibility of the sponsor or other entity funding the research (i.e., industry, government agency, non-profit, hospital providers, or departmental funds of the School of Medicine). Under certain limited circumstances, as provided in law and regulation, costs for experimental services or items required as part of a clinical trial may be billed to a third party or to the subject so long as these elements of costs are not reimbursed by the sponsor. It is essential that the principal investigator determine early in the process which cost elements of a trial are SOC and which are investigational and/or research specific. For each clinical study, the principal investigator must document which costs can be billed to third

parties, and must be certain that safeguards are in place to ensure that all services and items are billed appropriately.

BILLING REQUIREMENTS FOR CLINICAL RESEARCH STUDIES

1. Completion of the **Research Billing Template** and **Sponsored Project/Research Information Worksheet**. These forms are required with submissions of all clinical trial contracts to the Office of Research. The budget template can be adapted to fit the particular needs (visits, procedures, etc) of research studies and will not be submitted to sponsors. Note: A separate study budget will still be required for the sponsor. EVMS Health Services can assist EVMS Health Services physicians and staff with questions regarding CPT codes and billing categories. An **internal review process** that helps to identify “Non-Covered” versus “Covered” care should occur prior to submittal of the budget template to the Office of Research. The documented billing plan should cover not only patient care services but drugs, devices, procedures and tests.
2. For EVMS Health Services physicians, register all clinical trial subjects in IDX in a way that identifies the IRB protocol #, the duration of the study and the department engaged in the study.
3. 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.
4. Include a completed budget template for the study with the IRB application materials. The subject informed consent form should not state that sponsor will pay for costs not covered by insurance. No statements should be made that subjects will not incur any costs if insurance is billed during any aspect of the study (including adverse events).

GUIDANCE ON CLINICAL SERVICES BILLING

Billing occurs during a research study when participants are enrolled in clinical trials that involve items or services that are billed to patients, third party payers, study sponsors and/or the research participant. Oftentimes, the study sponsor will not cover all of the participant’s care costs – in this case, the study budget should specifically document those items/services that the sponsor will not cover. The final, approved study budget should identify the sponsors, third party insurance and the subject/patient’s financial obligation.

Steps to Budget Development:

- 1- Review the clinical trial protocol to develop a research participant schedule. (i.e. How often do participants receive the item/services?)
- 2- Identify all of the costs associated with items/services provided during the course of the clinical trial including patient care services, drugs, devices, procedures and tests. (i.e. What type of items/services will be provided to participants each visit?)
- 3- Determine what costs the Research Sponsor will pay for in the study.
- 4- Determine what costs are considered “standard of care” [or routine care] (for example, items/services that are typically provided absent the clinical trial. This is defined as the Centers for Medicare and Medicaid and their website can be visited as a reference at <http://www.cms.hhs.gov/>)
- 5- Determine if the standard of care item/service is covered by Medicare – if so list as “Standard of Care” in the budget. If not, list in the budget as “Non-Covered Standard of Care.” (See Form, “Research Trial Budget Worksheet”)

NOTE: If all expenses are not covered for the research activity, the Principal Investigator may need to re-negotiate the Study reimbursement. (It is recommended that a procedure be put into place whereby the Departmental Chairs must sign off on all Research Trial Budgets when expenses are greater than Sponsor reimbursement)

A few principles apply to all circumstances and all payers:

It is never acceptable to receive reimbursement for a specific clinical research activity from more than one revenue source (i.e. you can't seek insurance reimbursement for a specific activity if you are being reimbursed for the activity by a sponsor).

It is never acceptable to misrepresent clinical research activities as being medically appropriate and/or indicated clinical care. As such, appropriate procedure and diagnosis codes must be used when conveying clinical research interventions, items or services, to any third party payer in an effort to recover research related patient care costs not covered by a research sponsor.

Medicare Policy:

Medicare covers the routine costs of qualifying clinical trials as well as reasonable and necessary items and services used to diagnose and treat

complications arising from participation in all clinical trials. Routine costs include items or services that are generally available to Medicare beneficiaries.

ROUTINE COSTS OF COVERED SERVICES

Includes:

- Items or services that are typically provided absent of a clinical trial.(e.g. conventional care);
- Items or services required solely for the provision of the investigational items or service (e.g. administration of non-covered chemotherapeutic agent) clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or service 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.

Excludes:

- Investigational items or services, itself
- Items or services provided solely to satisfy data collection and analysis needs 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 or services provided by the research sponsor free of charge for any enrollee in the trial.

REQUIREMENTS FOR COVERAGE OF ROUTINE COSTS

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified or have certified that they meet the qualifying criteria unless CMS subsequently finds that the clinical trial does not qualify or jeopardizes the safety and welfare of Medicare beneficiaries.

A. A clinical trial may be eligible for Medicare coverage of routine costs as follows:

- The purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g. physician's service, durable medical equipment, diagnostic tests) and is not statutorily excluded (e.g. cosmetic surgery, hearing aids)
- There must be a therapeutic intent. The trial must not be designed to exclusively test for toxicity or disease pathophysiology.
- 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

1- In addition to the three requirements above, clinical trials should have the following **desirable characteristics**:

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

B. Qualification Process (see: CMS website MCR Coverage- Clinical Trials Final National Coverage Decision <http://www.cms.hhs.gov/ClinicalTrialPolicies/Downloads/finalnationalcoverage.pdf>)

1- Enrollment in Medicare Clinical Trials Registry

Clinical trials that meet the qualifying criteria above will receive Medicare coverage after the trial's lead principal investigator certifies that the trial meets the criteria. The principle investigator, or agent, will enroll the trial in the Medicare clinical trials registry. The Office of Research will register EVMS in the Medicare clinical trial registry. Principal investigators should contact the Office of Research for information on enrolling a clinical trial.

2- Automatically Qualified

Some clinical trials are automatically qualified to receive Medicare coverage for routine costs because they have been deemed by the AHRQ (Agency for Healthcare Research and Quality) to be highly likely to have the above listed desirable characteristics. Clinical trials considered deemed to be automatically qualified are:

- a. Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA;
- b. Trials supported by centers or cooperative groups that are funded by the above agents;
- c. Trials conducted under the investigational new drug (IND) application reviewed by the FDA; and

d. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until qualifying criteria are developed and the certification process is in place. At that time the principal investigator 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.

For additional guidance on Medicare research billing, please review the attached tables and algorithms.