UNIVERSITY OF ROCHESTER
CLINICAL RESEARCH BILLING POLICY

PURPOSE/SCOPE STATEMENT

The purpose of this document is to establish a uniform policy for billing of procedures, items or tests provided to subjects who participate in **clinical research** studies.

This policy supplements existing policies related to the conduct of **clinical research** studies (refer to web sites of University of Rochester (University) departments noted in the "Internal Contacts and Resources" section of this policy).

This policy is applicable to medical items or services (1) provided as part of a **clinical research** study; however, it does not apply to studies that do not involve human subjects (as defined in University policies and/or federal regulations) or studies that do not involve a test article or clinical procedure (e.g. studies that only include survey and chart review).

This policy must be followed regardless of the funding source of the **clinical research** study.

1 Includes both FDA approved and FDA non-approved drugs or devices; off-label use of a FDA approved drug or device outside of the practice of medicine; and other studies involving clinical interventions (lab tests and procedures)

INTRODUCTION/RATIONALE

A **clinical trial** is a type of clinical research study. Billing for procedures, items or tests furnished to clinical research subjects is a complex task because of the need to determine whether a **clinical trial** might qualify for insurance reimbursement and, if so, which costs are reimbursable by insurance and what approvals/documentation/other requirements might be prerequisites to such billing. Fines and penalties for noncompliance may be substantial.

POLICY STATEMENT

General Principles

Clinical research teams (including, but not limited to Principal Investigators, co-investigators, sub-investigators, study coordinators and department administrators) have a responsibility to ensure that: billing for procedures, items or tests furnished to participants in **clinical trials** is appropriate (type and fee amount); is consistent with the informed consent document, the budget, and contract; and is allowable by applicable laws, regulations, manuals/instructions and payer policies.

All faculty and staff involved in **clinical research** are individually responsible for understanding this policy, participating in any required training, fulfilling recordkeeping requirements, seeking clarification when questions arise and responding in a timely manner to requests for information associated with internal audits and investigations.

In accordance with the University's Code of Conduct for Business Activities, any employee who becomes aware of noncompliance with this policy has a responsibility to report such noncompliance to his or her supervisor (who shall then inform University administration). Employees also have the option to report noncompliance anonymously to the University's Integrity Hot Line (585-756-8888).

Determination of Party Responsible for Payment of Procedures, Items or Tests

A. General Rules

1. Clinical procedures, items or tests that are purely experimental (i.e., not considered medically necessary, safe or effective) cannot be billed to insurance or to the patient; rather, they are to be paid by the sponsor of the trial.

2 Clinical trial agreements should identify or describe the procedures, items or tests of the study which are to be reimbursed by the sponsor.

3. Neither the patient nor the third party payer may be billed for procedures, items or tests

    a. that the sponsor has indicated it will pay for,
    b. that are promised as free of charge in the patient's informed consent document,
    c. or that are drugs/devices provided free of charge by the sponsor.

4. Procedures, items or tests furnished to participants in a **clinical trial** that represent **standard of care** treatment are generally billable to third party insurers if the sponsor does not agree to reimburse the University for those procedures, items or tests. (1) (2) (3)

5. The clinical trial agreement should address payment for research-related injuries.

(1) Third party insurers may have specific limits and requirements which must be understood. Patient deductibles and co-payments cannot be waived when procedures, items or tests are billable to insurance (except with regards to indigent patients).

(2) The cost of procedures and tests—whether paid by the sponsor, patient, or third party insurance—must be based on fair market value.

(3) Patients and insurers can be billed for **investigational drugs, investigational devices (see Medicare exception in section C below) and investigational biologics** not yet approved for marketing only if the FDA provides prior written approval.

B. Medicare (Other than Device Trials)

1. Medicare may only be billed for costs permitted under the **National Coverage Determination (NCD)** which is found in section 310 of the Medicare National Coverage Determination Manual (http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf.). The requirements for submitting these claims are explained in Chapter 32 of the Medicare Claims Processing Manual, beginning at Section 69 (http://www.cms.gov/manuals/downloads/clm104c32.pdf).

2. When a research subject is enrolled in a **Medicare Advantage** plan such as MVP Gold or Medicare Blue Choice, the outpatient services that are related to the **clinical trial** should be submitted to the Medicare Part A/Part B **Medicare Administrative Contractor ("MAC")**, National Government Services (NGS). Outpatient services that are unrelated to the **clinical trial** should be submitted to the **Medicare Advantage** plan. See the Medicare Claims Processing Manual, Chapter 32, Section 69.9 for more information about how to submit these claims (http://www.cms.gov/manuals/downloads/clm104c32.pdf).

3. Claims submitted to Medicare pursuant to the **NCD** should contain the appropriate coding modifiers and diagnosis code related to **clinical trial** claims. The determination that an item or service is reasonable and necessary is a medical decision that must be made by the Principal Investigator and must be documented in the patient's medical chart.

C. Medicare (Device Trials)

1. Regarding investigational devices, Medicare may be billed for certain costs associated with non-experimental/investigational device trials if the device is used in an FDA-approved **clinical trial** and its application is reasonable and medically necessary. Claims submitted to Medicare for covered devices must include information about the device under study, as well as applicable coding modifiers. Participants cannot be enrolled in a device trial until a **MAC** provides a price coverage determination.

2. FDA **Investigational Device Exemption (IDE)** approvals classify devices as either Category A or Category B devices. The classification of the device affects the ability to bill Medicare. Services related to the use of a non-covered device may not be billed to Medicare.

   a. **Category A devices** may not be billed to Medicare, though routine costs associated with the device may be billable if the **MAC** determines the device is used in the trial for the diagnosis, monitoring and treatment of an immediately life-threatening disease or condition.

b. **Category B devices** may be billed to Medicare if those devices are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met, including approval of the **MAC**. The process for obtaining approval from the **MAC** is to submit the following information: study name, general device information (e.g. **IDE** number), **protocol** information (e.g. description of the device), practitioner name and facilities where the service will be provided. The UR "MAC Approval Template" must be used for requesting MAC approval, even I f the sponsor provides a template.

ROLES AND RESPONSIBILITIES

Certain tasks and internal controls are required in order for **clinical research** teams to ensure compliance with this policy. These are presented in the following table:

Key

PI Principal Investigator
SC Study Coordinator
DA Department Administrator

	PI*	SC	DA
BUDGET DEVELOPMENT			
Perform an analysis to determine payers for protocol procedures	X	X	X
Create a grid of protocol procedures to be paid by the sponsor		X	X
Obtain cost estimates for all study activity requiring sponsor reimbursement using the appropriate fair market value and negotiated rates			X
PARTICIPANT REGISTRATION			
Schedule participants for visits/procedures, and ensure points of encounter are informed of responsible payer		X	
SERVICES PROVIDED			
Ensure (a) participant's medical record contains documentation of the service provided and (b) associated Medicare bills have the proper modifiers applied		X	
Ensure all fees related to the protocol procedures grid (and only those fees) are charged to the sponsor account and at the correct amount		X	X
STUDY CLOSE OUT			
Ensure any residual is not caused (in part or in whole) by billing errors			X

* Includes co-investigators and sub-investigators who might provide billable services

Note that the University of Rochester Clinical Research Standard Operating Procedures Regarding Financial Oversight and Billing Compliance document also incorporates more detailed tasks and controls that help ensure compliance with this policy.

DEFINITIONS

CATEGORY A DEVICE: Experimental device where the underlying questions of safety and effectiveness of the device have not been resolved

CATEGORY B DEVICE: Non-experimental and/or investigational device where the underlying questions of safety and effectiveness of the device have been resolved

CLINICAL RESEARCH: Research that either directly involves a particular person or group of people or uses materials from humans, such as their behavior or samples of their tissue, and that can be linked to a particular living person

CLINICAL TRIAL: A clinical trial is a type of clinical research—a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (synonymous with "clinical research study" or "study") are used to determine whether new drugs or treatments are both safe and effective.

HUMAN SUBJECT: A person with whom an investigator interacts or obtains personal and private health information.

INVESTIGATIONAL DEVICE EXEMPTION (IDE): An IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Pre-market Approval (PMA) application or a Pre-market Notification [510(k)] submission to FDA. Clinical studies are most often conducted to support a PMA. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE **before** the study is initiated.

INVESTIGATIONAL NEW DRUGS (IND)/INVESTIGATIONAL BIOLOGICS: A new drug or biologic that is used in a clinical investigation. The term investigational biologic also includes a biological product that is used in vitro for diagnostic purposes.

MEDICARE ADVANTAGE: Also known as Medicare Part C and Medicare + Choice, it is program in which individuals who are eligible for Medicare elect to receive Medicare benefits through a plan issued by a private insurance company rather than through Medicare Part A and Medicare Part B.

MEDICARE ADMINISTRATIVE CONTRACTOR (MAC): A private company that has a contract with Medicare to process claims submitted for services under Medicare Parts A and B (for example, bills from hospitals). Formerly these functions were performed by Medicare Fiscal Intermediaries and Medicare Carriers.

NATIONAL COVERAGE DETERMINATION (NCD): A decision issued by the Center for Medicare and Medicaid Services to allow Medicare to cover 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 the clinical trial. The National Coverage Determination related to clinical trials can be found in Section 310 of the Medicare National Coverage Determination Manual (http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf).

PROTOCOL: This is a study plan on which a particular clinical trial is based. The plan is carefully designed to safeguard the health of the participants as well as to answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study.

STANDARD OF CARE: Treatment regimen or medical management based on generally accepted principles of medical care.

STATEMENT OF ENFORCEMENT

The University of Rochester Medical Center (URMC) Compliance Office will perform ongoing reviews and audits of **clinical research** to monitor compliance with this policy. The URMC Compliance Office will also have primary responsibility for investigating situations of alleged noncompliance.

Consistent with the University's Code of Conduct for Business Activities, the consequences of violations by faculty or staff vary in severity.

INTERNAL CONTACTS AND RESOURCES

University of Rochester Medical Center Compliance Office
Corporate Compliance Officer
Compliance Program Medical Director
http://www.urmc.rochester.edu/urmc/compliance/

University of Rochester Office of University Audit
Director of University Audit
http://www.rochester.edu/adminfinance/audit/people.html

Office of Research and Project Administration
Associate Vice President for Research Administration
Research Compliance Officer
http://www.rochester.edu/ORPA/

Clinical and Translational Science Institute/Office of Regulatory Support
Executive Director for Research Services
Director, Office of Regulatory Support
http://www.urmc.rochester.edu/ctsi/research/regulatory-support/index.cfm

University of Rochester Research Subjects Review Board (RSRB)
Executive Director, RSRB
http://www.rochester.edu/rsrb/indexs.html

REFERENCES

National Coverage Determination (Routine Costs in Clinical Trials)
http://www.cms.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials

Medicare Benefit Policy Manual – Medical Devices (Chapter 14, Section 20)
http://www.cms.hhs.gov/manuals/Downloads/bp102c14.pdf

Department of Health and Human Services Grants Policy Statement
Research Patient Care Costs (Federally Funded Clinical Trials)
Grants2.nih.gov/grants/policy/nihgps_2001/part_iib_8.htm#_Toc504812231

APPENDIX
National Coverage Determination Synopsis

In order for a clinical trial to be eligible for coverage under Medicare's National Coverage Determination, the trial must be a **qualifying trial**. A **qualifying trial** satisfies the following requirements:

- The subject or purpose of the clinical 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 test) and is not statutorily excluded from coverage (e.g. cosmetic surgery, hearing aids).

- The clinical trial must have therapeutic intent. It must not be designed exclusively to test toxicity or disease pathophysiology.

- Clinical trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Clinical trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

- The clinical trial must be a **deemed trial**.

A **deemed trial** has one of the following characteristics:

- Trials funded by the NIH, CDC, AHRQ, CMS, DOD and Veteran's Administration (VA)

- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA

- Trials conducted under an investigational new drug (IND) application reviewed by the FDA

- Drug trials that are exempt from having an IND application under 21 CFR 312.2(b)(1) will be deemed automatically qualified.

Routine costs associated with clinical trials include the cost of items and services:

- Typically provided absent a clinical trial (e.g. medically necessary conventional care)
- For which there exists a Medicare benefit category
- That are covered by Medicare outside of a clinical trial
- Required for the provision of the investigational item or service
- Required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- That are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service

Routine costs exclude:

- The investigational item or service
- Items and services for which there is no Medicare benefit category, which are statutorily excluded or that fall under a national non-coverage determination
- 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
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial
- Items and services provided solely to determine trial eligibility