Title:	Medicare Coverage Analysis for Clinical Research Studies
Department:	Research Management
Applies to:	Partners and its Affiliated Institutions and Their Employees and Agents ("Partners HealthCare")
Approved by:	Research Administration Management Project Steering Committee Barbara E. Bierer, MD, Senior Vice President, Research, BWH Richard Bringhurst, MD, Senior Vice President, Research, MGH Peter K. Markell, PHS Vice President, Finance
Approval Date:	October 24, 2008
Effective Date:	January 1, 2009

PURPOSE:

The purpose of this policy is to set forth the requirements and processes for determining the appropriate party (Medicare, research sponsor, institution, patient, or other) responsible for the costs of clinical services provided to human participants enrolled in clinical research studies. This Policy relies upon rules, regulations, and policies of the Centers for Medicare and Medicaid ("CMS") to determine the coverage of costs by Medicare.

POLICY:

It is the policy of Partners and its Affiliated Institutions (collectively "Partners") to bill Medicare for Routine Costs of clinical services provided to research subjects participating in clinical research studies only as allowed by CMS through the Medical Device Coverage Policy (1995) and the National Coverage Decision (2007). No research subject may be enrolled in a clinical research study that may involve billing of third-party payers for Routine Costs of clinical services at a Partners affiliated institution until: (a) it has been determined, through the completion of a Medicare Coverage Analysis ("MCA"), which clinical services are Routine and can be billed to Medicare, and (b) a budget for the research-related costs for a study has been developed. In addition, no research subject may be enrolled in a clinical research study at a Partners affiliated institution involving an investigational medical device being studied under an Investigational Drug Exemption ("IDE") until (1) the Medicare Fiscal Intermediary has approved the proposed clinical research study for invoicing, or (2) an alternative funding source has been identified for expenses related to the clinical research project. The final billing grid resulting from the MCA is provided to and used by study, billing, and compliance personnel to determine the appropriate party to be billed and to monitor clinical research study expenses.

A reasonable fee is charged to corporate sponsors for the completion of a Medicare coverage analysis and preparation of a billing grid.

PROCEDURES:

Each Partners Affiliated Institution is responsible for establishing a review mechanism to ensure that Medicare coverage analyses are provided for all clinical research studies involving billing of third-party payers for Routine Costs of clinical services provided to clinical research subjects.

For all Partners studies[1] reviewed and approved by the Partners Human Research Committee, the Institutional Review Board ("IRB") for BWH, Faulkner, and MGH, the following procedures apply:

1. The Partners Clinical Research Office ("PCRO") is responsible for determining which clinical services involve Routine Costs billable to Medicare by completing a Medicare Coverage Analysis ("MCA"). Routine Costs are determined through protocol review and the use of objective treatment guidelines as standards (i.e. accepted treatment protocols) in consultation with the Principal Investigator and study staff.
2. Investigators and clinical research study teams are responsible for submitting necessary information, including but not limited to the research protocol, the Informed Consent Document, Clinical Trial Agreement or sponsor's Notice of Award, and the documentation of the status with FDA (e.g. IND, NDA, orphan drug, IDE, HDE) to the Partners Human Research Committee and to PCRO for appropriate review and approvals.
3. For non-device studies, PCRO undertakes a qualifying study analysis to determine if the study meets the qualifying study criteria as set forth in the CMS 2007 National Coverage Decision.
4. For studies that meet the criteria of a qualifying clinical trial, PCRO reviews the study documentation, creates a spreadsheet to mirror the schedule of events, includes required activities omitted from the schedule of events and places appropriate markings and notes of explanation for each event designating whether CMS can be billed for the charges.
5. If the clinical research study involves an investigational medical device being studied under an Investigational Device Exemption, PCRO prepares and submits a petition to the CMS Fiscal Intermediary for review and approval. No Medicare patient may be enrolled in a clinical research study until the CMS Fiscal Intermediary has approved the study or an alternative funding source has been identified for research-related expenses.
6. PCRO reviews the sponsor agreement, proposed budgetary information, and other documents to determine and document if any research subject care costs are promised at no charge.
7. PCRO reviews the cost/payment and subject injury sections of the Informed Consent Document to ensure its consistency with the institution's obligation under the Clinical Trial Agreement or the sponsor's Notice of Award.
8. PCRO provides billing grids that it prepares as a result of Medicare Coverage Analyses to Principal Investigators and clinical research study teams, and to appropriate Research Compliance associates at the hospitals.
9. The Partners Human Research Committee shall not activate a study protocol until it has been informed by PCRO that (1) a study does not involve billing third party payers for clinical services provided or (2) the study is non-qualifying and no grid will be prepared or (3) an MCA has been completed.

[1] Certain Hematology/Oncology Studies conducted at Partners entities are reviewed and approved by the Dana Farber Cancer Institute on behalf of the Dana Farber/Partners Cancer Center. This review includes IRB review and approval as well as Medicare Coverage Analysis and provision of billing grids to the study teams. Investigators, clinical research coordinators, and other clinical research study staff are responsible for using the billing grids provided by DFCI to ensure that research-related charges are billed only to the study fund and not to any third party payer.

10. Investigators, clinical research coordinators and other clinical research study staff are responsible for using the billing grids provided by PCRO to ensure that research-related charges are billed only to the study fund and not to any third party payer.
11. For studies that do not qualify for clinical research billing under the appropriate CMS policies, grids may be created to clearly identify those research activities that cannot be billed to Medicare.

CONTACTS:

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DEFINITIONS:

Affiliated Institutions or Institutions
The Massachusetts General Hospital, The Brigham and Women's/Faulkner Hospitals, Inc., McLean Hospital, The North Shore Medical Center, Inc., Newton-Wellesley Hospital, Spaulding Rehabilitation Hospital and all of their respective affiliates; Partners Community Healthcare, Inc. ("PCHI"); and other institutions and entities designated in the future by Partners as Affiliated Corporations.

Centers for Medicare and Medicaid Services ("CMS")
The agency within the Department of Health and Human Services ("HHS"). CMS has authority over the two largest Federal health care programs, Medicare and Medicaid under unified leadership.

Clinical Trial Agreement
The written agreement or contract between the study sponsor (or Contract Research Organization working on behalf of the sponsor) and the Partners affiliated institution. This document contains information (exhibits or attachments) including the study budget. It may include the study protocol.

Fiscal Intermediary ("FI")
The business entity contracted by CMS to process claims and perform bill processing functions and benefit payment functions for Part A Medicare claims for hospitals.

Humanitarian device exemption ("HDE")
FDA authorization that allows marketing of a device to treat a condition that affects only a small number of people.

Informed Consent Document
The document provided to a potential research participant to describe the clinical research study's purpose, objectives, investigational products, procedures, costs, risks, benefits, and relevant contacts.

Institutional Review Board ("IRB")
The federally mandated committee charged with reviewing all proposed protocols involving human subjects research to protect the rights and welfare of the research participants.

Investigational device exemption ("IDE")
Approval by FDA to allow the investigational device to be used in a clinical study to collect safety and effectiveness data required to support a Pre-market Approval application or a Pre-market Notification [510(k)] submission to FDA.

Investigational New Drug ("IND")
Application required by the US FDA before clinical trials of a new drug or new biological agent may be initiated.

New Drug Application ("NDA")
Vehicle through which drug sponsor formally proposes that FDA approve a new pharmaceutical for sale and marketing in the U.S. Data gathered during animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.

Notice of Award
Legally binding document that notifies a grantee and others that a federal grant has been funded; contains or references all terms and conditions of an award; and documents the obligation of federal funds.

Routine Costs
Includes items and clinical services:

- A Medicare benefit category exists;
- Covered by Medicare outside of a clinical research study;
- Typically provided absent a clinical research study (e.g., conventional care);
- Required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- 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;
- Not investigational in nature;
- Not statutorily excluded;
- For which there is not a national non-coverage decision;
- Not provided solely to satisfy data collection and analysis needs and are not used in the direct clinical management of the participant (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Not customarily provided by the research sponsors free of charge for any participant in the research study.

REFERENCES:

21 CFR sec. 405.201

Medicare Clinical Trial Policies - Overview
http://www.cms.hhs.gov/ClinicalTrialPolicies/

National Coverage Decision for Routine Costs in Clinical Trials ("NCD")
Manual 310.1 Version 2 effective July 9, 2007; CMS Publication 100-3
http://www.cms.hhs.gov/mcd/viewncd.asp?ncdid=310.1&ncdversion=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials

Devices

- Medicare Benefit Policy Manual, Chapter 14
  www.cms.hhs.gov/manuals/downloads/bp102c14.pdf
- Medicare Claims Processing Manual, Chapter 32 section 68
  www.cms.hhs.gov/manuals/downloads/clm104c32.pdf
- Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices
  September 15, 1995 (D95-2)
  http://www.fda.gov/cdrh/d952.html