

**The Carle Foundation  
Research Institute Policy 110**

<b>Subject</b>	Billing Compliance for Research Studies			
<b>Approval</b>	Dec 2009	<b>Review</b>		<b>Revision</b>
<b>Purpose</b>	To assure Carle Foundation Hospital (CFH) research study-related activities (including services, drugs, devices and tests) are properly billed to the study sponsor, the appropriate third party payor, or the study subject. To ensure proper billing, a Medicare Coverage Analysis (MCA) will be performed if study subjects are likely to be Medicare beneficiaries. To assure that all research costs are captured and billed appropriately.			

**Policy Statement**

1. Items or services performed as part of a human subject research study are typically subject to different billing requirements than those provided during normal care. If a study sponsor will reimburse the costs for a service or item, then the CFH may not, under any circumstances, bill the item or service to the patient or any payor.
2. A MCA shall be performed so that the requirements of the Clinical Trial Policy National Coverage Decision (NCD) as may be amended from time to time are met. The Director of the Research office (Director) or designee shall approve the MCA completed by the Research coordinator in the Research Office prior to billing any items or services to Medicare. Items or services billed to other payors will be submitted in accordance with applicable coverage and billing requirements.
3. The NCD states that Medicare covers the routine costs of qualifying research studies, as further defined under Medicare, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all research studies. All other Medicare rules apply. The MCA is a tool, which may be changed from time to time, used to assist in understanding what items or services performed during a study are covered or not covered under Medicare.
4. The MCA must reconcile, at minimum, the items or services found in four (4) documents:
  - a. Informed Consent,
  - b. Contract and/or amendments,
  - c. Study Protocol including the schema or schedule of events, and
  - d. Budget.
5. The Research Coordinators and Director will be responsible for ensuring that all study-related documents (informed consent, contract, protocol and budget) are consistent with respect to the items or services that will be paid by the sponsor and those which will be billed to the subject or third-party payor.
6. The Research Coordinators and Director are responsible for ensuring that:
  - a. A billing plan is created for each study prior to enrollment of any subject into the study.
  - b. The billing plan is consistent with the signed study budget.
  - c. The billing plan delineates the services, drugs, devices and tests to be rendered in the context of the research study.
  - d. Determine if the study is a "qualifying" research study according to Medicare NCD/Provisions.
  - e. All study-related services are tracked as determined by policy.
  - f. An MCA is performed for each study prior to billing Medicare.
  - g. All affected departments and entities are fully informed about the billing determinations.
7. The investigator(s) is responsible for identifying which services, drugs, devices and tests are standard of care (also called conventional care, routine care or care normally paid by the insurance) items in the study. The national standard/ guidelines will be used by comparison and if the investigator's standard is very different a written explanation by the investigator is required.
8. In determining whether the study-related activity is routine or standard of care, the investigator should consider:
  - a. Any written policies that may exist which describe how patients are routinely treated for the service or test that the study subject is being provided, **and**
  - b. Treatment given to patients with the same diagnosis but who are not enrolled in a research study. For instance, if a single MRI is standard of care for a particular diagnosis and the study requires three (3) MRIs per six (6) months, then only one (1) of the MRIs will be covered as standard or routine care.
  - c. Therapeutic intent needs to be clearly stated as part of the primary study objectives.
9. Appropriate modifiers will be included on claims for standard of care services which are required as part of the study.

<b>Definitions</b>
<p><b>NCD:</b> Clinical Trial Policy National Coverage Decision</p> <p><b>MCA:</b> Medicare Coverage Analysis</p> <p><b>Researchers:</b> All CFH physicians, staff and agents involved in the conduct, reporting, supervision or management of research studies.</p>
<b>Procedure</b>
<ol style="list-style-type: none"> <li>1. A trained Research Coordinator in the Research Office will follow the Research Office Procedure 110b to complete the MCA MEMO and MCA Billing grid. The MCA will be completed within 2 weeks upon submission of a new and complete study to the Research Office.</li> <li>2. When the MCA Billing Grid and MEMO are completed, another staff person in the Research Office will review it before sending to the Director for final review and approval.</li> <li>3. After departmental approval the MCA will be part of the study file and emailed to all Hospital and Clinic departments involved in the study after the IRB approval is complete.</li> </ol>
<b>References</b>
<p>National Coverage Decision on Clinical Trials – September 19, 2000</p> <p>Clinical Trial Policy Final Decision (First Reconsideration) – July 9, 2007</p> <p>Updated NCD from the July 9 Final Decision – September 10, 2007</p> <p>Decision Memo on Second Reconsideration to Maintain Status Quo – October 17, 2007</p>
<b>Electronic Approval On File</b>

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