

**The Carle Foundation  
Research Institute Policy 110**

<b>Subject</b>	Billing Compliance for Research Studies		
<b>Approval</b>	Nov 2010	<b>Review</b>	Feb 2011
<b>Purpose</b>	To ensure that The Carle Foundation research study-related activities (including services, drugs, devices and tests) are appropriately captured, and billed to the appropriate party. To ensure proper billing, a Medicare Coverage Analysis (MCA) will be performed for all studies that have events that are billed to patients.		
<b>Revision</b>	Feb 2011		

**Statement of Policy**

1. This policy applies to all government payors including, but not limited to, Medicare, Medicaid and VA.
2. Items or services performed as part of a human subjects' research study or clinical trial are subject to additional billing requirements than those provided during normal care.
3. If a study sponsor will reimburse the costs for a service or item, then The Carle Foundation may not, under any circumstances, bill the item or service to the patient or any payor.
4. The Clinical Trial Policy National Coverage Decision 310.1 (NCD) states that Medicare covers the routine costs of qualifying clinical trials, as further defined under Medicare, as well as reasonable and necessary items and services used to diagnose, treat and monitor complications arising from participation in a qualifying trial. All other Medicare rules apply.
5. 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 billable to government payors. The MCA includes a qualifying clinical trial and billing analysis.
6. In order to qualify for Medicare coverage, the clinical trial must meet all of the following criteria:
  - a. The investigational item or service falls into a Medicare benefit category.
  - b. The study has therapeutic intent that is clearly stated as part of the study objectives.
  - c. The study enrolls patients with diagnosed disease. The Carle Foundation believes that if a trial enrolls patients with high risk for a disease that this criteria is met.
  - d. The study is a deemed trial.
7. An MCA shall be performed so that the requirements of the NCD, which may be amended, are met. MCA's shall be completed for all clinical trials unless:
  - a. The sponsor pays for all study-related costs, or
  - b. The study does not include any events that are billed to patient accounts.
8. The MCA must reconcile, at minimum, the items or services listed 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.
9. A staff member from the Research Department ("Research Staff") is responsible for ensuring that an MCA is performed for each trial prior to billing government payors.
10. The Principal Investigator 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.
11. In determining whether the study-related activity is routine or standard of care, the Principal Investigator should consider:
  - a. The national standard/care guidelines,
  - b. 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.

If neither a nor b exist, the Principal Investigator may determine standard of care by considering practice standards for treatment given to patients with the same diagnosis but who are not enrolled in a research study. This must be documented in writing by the Principal Investigator and/or Research Staff.
12. Items or services billed to non-government payors will be submitted in accordance with applicable coverage and billing requirements.

**Definitions**

**The Carle Foundation** – Includes all legal entities part of The Carle Foundation such as Carle Foundation Hospital, Carle Physician Group, Mills Breast Cancer Institute, and Carle Cancer Center.

**Definitions (cont.)**

**Medicare Coverage Analysis (MCA)** – MCA is the analysis of a research study to determine if the study qualifies for Medicare billing.

**National Coverage Decision (NCD)** – Clinical Trial Policy NCD is used to determine if a research study is deemed and can be billed to Medicare.

**Principal Investigator** – The investigator/ researcher who is responsible for the conduct of a research study at an institutional site.

**Procedure**

1. Trained Research Staff will follow the Billing Compliance Policy and Procedure to complete the MCA including the Billing Grid prior to billing any items or services on the clinical trial.
2. The Research Staff are responsible for ensuring that:
  - a. A determination is made whether the trial is a “qualifying” clinical trial according to Medicare NCD/provisions.
  - b. A billing plan is created for each study prior to enrollment of any subject into the study.
  - c. The billing plan is consistent with the signed study budget, if applicable.
  - d. The billing plan delineates the services, drugs, devices and tests to be rendered in the context of the clinical research study.
  - e. They work collaboratively with all affected and financial department(s) within The Carle Foundation.
  - f. Outside entities providing services for the clinical trial are informed about clinical trial participation and applicable billing determinations.
3. When the MCA and Billing Grid are completed, it is recommended that another Research Staff review it before sending to the VP of Research and Chief Academic Officer or designee for final review and approval.
4. After VP of Research and Chief Academic Officer or designee approval and the study itself has obtained IRB approval, the MCA including the Billing Grid becomes part of the study file and shared with the Principal Investigator and appropriate departments of The Carle Foundation involved in the study.
5. Patient care staff and/or Research Staff will ensure that appropriate Q modifiers and clinical trial participant (V70.7) ICD9 codes are included on all orders for services that are part of a clinical trial.
6. Research Staff will coordinate with the finance department to ensure proper billing.

**References**

- Updated NCD from the July 9 Final Decision – September 10, 2007

**Electronic Approval On File**

Supersedes CCA policy 5310 and CFH policy 110.

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