Title: Clinical Research Billing: Compliance with Medicare Requirements

Section No. 4 COC4  Section Name: Clinical Operation Compliance

Approval Date:
07/10/08; 03/28/13; 06/12/15

Approval:
Paul R.G. Cunningham, MD, FACS

I. Purpose Statement
The purpose of this policy is to establish uniform requirements with respect to billing Medicare for items or services provided in connection with any Clinical Research Study performed within the Brody School of Medicine (BSOM) and Vidant Health (as applicable for any Clinical Research Study that may require items or services to be provided by Vidant Health) or any other facility in which a Clinical Research Study is performed and BSOM bills Medicare for items or services performed as part of such Clinical Research Study.

II. Policy Statement
It is the policy of BSOM that any charges for clinical services performed or items provided as part of a Clinical Research Study are billed to Medicare and other payors appropriately and in accordance with applicable laws and regulations governing the payment of such services or items, including but not limited to the Clinical Trial Policy issued July 9, 2007 by the Center for Medicare and Medicaid Services (CMS) (the “Clinical Trial Policy”) and the Medicare Secondary Payer Rules.

III. Definitions

Category A Device – Any innovative device that has received a Food and Drug Administration (FDA)-approved Investigational Device Exemption (IDE) for which initial questions of safety and effectiveness have not been resolved. Only routine costs associated with use of a Category A device (and not the device itself) may be payable by Medicare.

Category B Device – Any newer device of already proven technology which has received an FDA-approved IDE. Initial questions for safety and effectiveness of this type of device have been resolved. Devices in this category represent evolutionary changes in proven technologies and will be reviewed as potentially reasonable and necessary by Medicare. These devices may be eligible for coverage and payment by Medicare, along with the routine costs associated with use of these devices.
Clinical Research Study – any human subject research which includes the provision of items or services that have the potential to be billable to Medicare.

Qualifying Clinical Trial – a clinical trial that meets certain requirements imposed by CMS pursuant to the Clinical Trial Policy and for which items or services that constitute “routine costs” may be billed to Medicare (see attached Appendix I).

Routine Costs – certain costs for items or services performed as part of a Qualifying Clinical Trial or investigational device trial which may be billed to Medicare if not otherwise (i) paid for by the sponsor of the Clinical Research Study; (ii) typically provided free to study subjects by the sponsor; or (iii) promised free to the study subject in the informed consent form (ICF) (see attached Appendix II).

IV. Scope
This policy applies to services or items billed by BSOM as part of a Clinical Research Study regardless of where any such Clinical Research Study is conducted.

V. Procedures

A. Clinical Research Studies Involving the Investigation of Drugs or Biologics

1. Each principal investigator (PI) or designee must perform an analysis for every Clinical Research Study involving the investigation of drugs or biologics to determine if such study constitutes a Qualifying Clinical Trial under Medicare using the chart in Appendix I. If the Study is “deemed” qualified for Medicare coverage of Routine Costs, a further analysis using Appendix II must be completed and documented as listed in Section V(C).
2. If the Clinical Research Study is not a Qualifying Clinical Trial, items or services provided as part of such clinical trial are not permitted to be billed to Medicare even if such services would otherwise be considered Routine Costs.

B. Clinical Research Studies Involving Category A or Category B Devices

1. For clinical trials involving the use of any Category A or Category B device, the PI or designee must provide Vidant Health (or any other outside location, as applicable) with sufficient information with respect to such device (including the FDA letter acknowledging IDE status and number) so the relevant institution may obtain approval from its Medicare Administrative Contractor (“MAC”) related to billing for Routine Costs associated with such device, as applicable.

2. If a Category B Device will be billed to Medicare by BSOM, the PI or designee must obtain prior written approval from Palmetto GBA before charging for any such device. For further information see “Jurisdiction 11 Part B Billing Instructions for Investigational Device Exemptions (IDEs)” http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Jurisdiction-11-Part-B-8EELD83717

Contact information for Palmetto GBA is:
Palmetto GBA – J11 Medical Affairs
Post Office Box 100238
Columbia, SC 29202-3238
J11.IDE@palmettogba.com
Fax: (803)699-3582
Phone: (855) 696-0705

Patient Financial Services must receive a copy of any written coverage determination by Palmetto GBA for any such Category B Device prior to submitting a claim for payment to Medicare for such device.

<table>
<thead>
<tr>
<th>Date:</th>
<th>Signature</th>
<th>Contact Person/Reference Source: Chief Institutional Integrity Officer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date: 04/01/13; 07/01/15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revision/Review Date: 06/12/15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Page 3 of 13
3. Any Category B Device that is provided by the sponsor at no cost to the PI shall not be billed to Medicare or other payors. Category A Devices are not eligible for payment by Medicare.

4. Each PI or designee must perform an analysis for every Clinical Research Trial involving Devices to determine if Routine Costs are billable to Medicare or other payors. Any items or services provided to the PI or patient free of charge are not billable to Medicare even if otherwise covered as Routine Costs.

C. All Clinical Research Studies

1. As part of the document submission requirements for the University and Medical Center Institutional Review Board (UMCIRB), the PI or designee must accurately complete the Financial Services Review Form

   ![Financial-Services-Review-Form-template-updated-with-changes-2013-12-03.doc](Financial-Services-Review-Form-template-updated-with-changes-2013-12-03.doc)

   The PI or designee must indicate on the Financial Services Review Form (among other things) whether the Clinical Research Study is a Qualifying Clinical Trial and whether language in the ICF promises items or services to the study subject at no additional cost (i.e., free). All items and services to be provided in the study must be listed on this form and the reimbursement source. Additionally, the PI or designee must indicate whether the items and services will be billed by BSOM or Vidant Health. The form must be signed by the PI indicating agreement with the designations and dated.

2. The Financial Services Review Form is submitted through ePirate for ancillary review and approval then to the UMCIRB for approval of the study. Once
approved, Clinical Financial Services is responsible to track the account of each study subject participating in the applicable Clinical Research Study to ensure that Category A or Category B Devices, Routine Costs, and all other costs associated with items or services provided to study subjects as part of a Clinical Research Study are billed in accordance with the information provided on the Financial Services Review Form. Patient Financial Services shall ensure that any claim submitted to Medicare or other payors for a Qualifying Clinical Trial or Device is submitted with the appropriate diagnosis codes and modifiers, as required by CMS.

3. Each PI or designee shall be required to provide Clinical Financial Services and Vidant Health Financial Department (as applicable) the names of each newly enrolled study subject (and the relevant trial name) within two (2) business days of enrollment in the clinical trial. The Vidant/ECU Clinical Trial Participant List form may be used for this purpose:

![Clinical-Trial-Participant-List-Form-2014-11](image)

Such notification is paramount to maintain compliance with proper billing procedures as items or services provided to study subjects may be billed as regular clinical services absent timely notification of enrollment within a clinical trial.

**D. Clinical Research Studies Involving Locations other than VH or Clinical Research Studies Involving other Institutional Review Boards**

<table>
<thead>
<tr>
<th>Recommending Body:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECU Physicians Board of Directors</td>
</tr>
<tr>
<td>Signature</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Effective Date:</td>
</tr>
<tr>
<td>04/01/13; 07/01/15</td>
</tr>
<tr>
<td>Contact Person/Reference Source:</td>
</tr>
<tr>
<td>Chief Institutional Integrity Officer</td>
</tr>
<tr>
<td>Extension:</td>
</tr>
<tr>
<td>744-5200</td>
</tr>
<tr>
<td>Revision/Review Date:</td>
</tr>
<tr>
<td>06/12/15</td>
</tr>
<tr>
<td>Revision/Review Person/Source:</td>
</tr>
<tr>
<td>Chief Institutional Integrity Officer</td>
</tr>
<tr>
<td>Page 5 of 13</td>
</tr>
</tbody>
</table>
1. For Clinical Research Studies performed at any outside location other than VH, the PI shall follow any procedures established for proper billing at such location; provided, however, that this Policy shall be followed for any items or services billed by BSOM but provided at any such outside location.

2. For any Clinical Research Study that may be approved by an institutional review board other than the UMCIRB, the relevant PI or designee shall be required to complete the steps as set forth in Sections V(A), V(B), and V(C) as relevant.

VI. References

- CMS Decision Memorandum for Clinical Trial Policy (October 17, 2007)
- CMS Clinical Trials Policy (July 9, 2007)
- “Investigational Device Exceptions (IDEs) and Form”, Palmetto GBA, Jurisdiction 11 Part B, Clinical Trials (May10, 2011)
- 21 C.F.R. Sect. 812.1, et. seq.
- Medicare Benefit Policy Manual, Pub. 100-02, Chapter 14
- Medicare Secondary Payer Rule
APPENDIX I

WHAT IS A “QUALIFYING CLINICAL TRIAL” UNDER MEDICARE? (NOT APPLICABLE TO DEVICE TRIALS)

Does the subject or purpose of the trial evaluate an item or service that falls within a Medicare benefit category (e.g., physician’s services, diagnostic tests) and it is not statutorily excluded from coverage (e.g. cosmetic surgery, hearing aids)?

Yes

No

Does the trial have a therapeutic intent (i.e. not designed exclusively to test toxicity or disease pathophysiology)?

Yes

No

Does the trial enroll only patients with diagnosed disease as opposed to healthy volunteers? Trials for diagnostic interventions may enroll healthy patients in a control group.

Yes

No

3. Answer the following to determine if the trial falls into one of the following categories:

a. Is trial funded by NIH, CDC, AHRQ, CMS, DOD, or VA OR
b. A cooperative group that is funded by the NIH, CDC, AHRQ, CMC, DOD, or VA OR
c. Is trial conducted under an IND application reviewed by the FDA OR
d. Exempt from IND application under 21 CFR 312.2(b)(1)?

Yes

No

The trial is “deemed” qualified for Medicare coverage of routine costs.

Trial is not a qualifying clinical trial – not permitted to bill Medicare for routine costs.

If the trial is not a “qualifying clinical trial” and you would like to be able to submit claims to Medicare for routine costs associated with such trial, you may want to contact Palmetto GBA, the J11 MAC. Please contact the Office of Institutional Integrity for more information.
APPENDIX II

ROUTINE COSTS UNDER A MEDICARE QUALIFYING CLINICAL TRIAL

1. Is item or service “generally available” to Medicare beneficiaries (and the item or service is not otherwise excluded under Medicare)?
   - Yes
   - No

2. Is the item or service characterized as one of the following:
   a. The cost of the “non-covered” investigational item or service itself (Unless otherwise covered outside of the clinical trial)
   b. Item or service is used solely to satisfy data collection and analysis needs and is not used in direct clinical management of patient (e.g., monthly CT scans for a condition requiring only one CT scan)
   c. Item or service is customarily provided by research sponsors free of charge for any study subject in the trial
   d. Item or service has been promised at no additional cost to the study subject in the informed consent; or
   e. Item or service is provided solely to determine trial eligibility
   - Yes to any
   - No to all statements

3. Is the item or service contained within one of the following categories:
   a. Item or service is typically provided absent a clinical trial (e.g., conventional care)
   b. Item or service required solely for the provision of investigational item or service (e.g., administration of a non-covered chemotherapeutic agent)
   c. Item or service required for the clinically appropriate monitoring of the effects of the investigational item or service or the prevention of complications from item or service
   d. Item or service is medically necessary for reasonable and necessary care arising from the provision of an investigational item or service – in particular, for the diagnosis or treatment of complications
   - Yes to any

The item or service is not covered as routine cost under Medicare and should not be billed to Medicare.

Service or item qualifies for coverage as routine cost under Medicare.
ECU Brody School of Medicine/Vidant Health
Financial Services Review Form for Research

Principal Investigator:
Study Coordinator (if applicable):
UMCIRB #:
Research Title:
Sponsor:

Please list the ECU/Vidant contact responsible for billing below:
Contact Person: 
Address:
Phone Number:

National Clinical Trials Number (from ClinicalTrials.gov website):

Medicare Coverage Analysis: Qualifying Clinical Trial (See attached flow sheet for coverage analysis.)
Yes ☐ No ☐ Device ☐ N/A ☐

If No or N/A is selected here based on an analysis of the attached flow sheet, permission must be obtained from the MAC and/or insurance companies prior to billing Medicare or other 3rd party payors.

For studies involving Category B devices, patients cannot be enrolled in the study until approval from CMS has been received to bill for the device. Once IRB approval has been obtained, the Study Coordinator must contact Vidant Health Finance to complete the CMS packet. Vidant Health Finance will submit the packet to CMS and notify the Study Coordinator when approval for billing the device has been received. Once this has been completed, Vidant Health Finance will work with Materials and the Study Coordinator to set up a service code number for the device and patients can be enrolled in the study. For studies involving Category A devices, the sponsor must pay for the device and related charges. CMS does not pay for Category A devices since they are experimental (have no similar devices already on the market).

Are Study Services Promised at No Additional Cost to the Study Subject (i.e., free) in the Informed Consent
Yes ☐ No ☐

This question must be answered YES if the Sponsor is paying for an item or service. These items or services cannot be billed to Medicare, Medicaid, patients, or insurance (any 3rd party payor) as routine even if they are normally routine costs. Only items or services that meet the requirements in the attached flow charts, applicable policies, and Medicare guidelines may be billed as routine costs to 3rd party payors or patients.

<table>
<thead>
<tr>
<th>Procedures, tests, medications and all other study related requirements</th>
<th>Study Visit #</th>
<th>Routine Cost (see attached flow sheet) – paid for by 3rd party payer</th>
<th>Paid for by Sponsor</th>
<th>Provide CPT/Service Code for all non-routine procedures</th>
<th>Place of Service (BSOM, ECHI-VMC, ECHI-ECU, FITT, LJCC, VMC, ECU, etc)</th>
<th>Additional Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>-------</td>
<td>-------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes ☐</td>
<td>Yes ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

By signing this document I acknowledge that the above information and conditions are accurate and true and if applicable I have permission from the appropriate 3rd party payors to bill routine costs as evidenced by the attached document(s).

________________________________________  _____________________
PI signature (no electronic or typed signatures or dates accepted)                                             Date
WHAT IS A “QUALIFYING CLINICAL TRIAL” UNDER MEDICARE? (NOT APPLICABLE TO DEVICE TRIALS)

Does the subject or purpose of the trial evaluate an item or service that falls within a Medicare benefit category (e.g., physician’s services, diagnostic tests) and the item or service is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids)?

Yes

Does the trial have a therapeutic intent (i.e. not designed exclusively to test toxicity or disease pathophysiology)?

Yes

Does the trial enroll only patients with diagnosed disease as opposed to healthy volunteers? Trials for diagnostic interventions may enroll healthy patients in a control group.

Yes

Answer the following to determine if the trial falls into one of the following categories:

e. Is trial funded by NIH, CDC, AHRQ, CMS, DOD, or VA OR
f. A cooperative group that is funded by the NIH, CDC, AHRQ, CMC, DOD, or VA OR

Yes

The trial is “deemed” qualified for Medicare coverage of routine costs.

No

If the trial is not a “qualifying clinical trial” and you would like to be able to submit claims to Medicare for routine costs associated with such trial, you may want to contact Palmetto GBA, the J11 MAC. Please contact the BSOM Compliance Office or Vidant Health Revenue Integrity for more information.
ROUTINE COSTS UNDER A MEDICARE QUALIFYING CLINICAL TRIAL  
(NOT APPLICABLE TO DEVICE TRIALS)

1. Is item or service “generally available” to Medicare beneficiaries (and the item or service is not otherwise excluded under Medicare)?
   - Yes
   - No to all statements

2. Is the item or service characterized as one of the following:
   - f. The cost of the “non-covered” investigational item or service itself (Unless otherwise covered outside of the clinical trial)
   - g. Item or service is used solely to satisfy data collection and analysis needs and is not used in direct clinical management of patient (e.g., monthly CT scans for a condition requiring only one CT scan)
   - h. Item or service is customarily provided by research sponsors free of charge for any study subject in the trial
   - i. Item or service has been promised at no additional cost to the study subject in the informed consent; or
   - j. Item or service is provided solely to determine trial eligibility (screening)
   - Yes to any
   - No to all statements

3. Is the item or service contained within one of the following categories:
   - e. Item or service is typically provided absent a clinical trial (e.g., conventional care)
   - f. Item or service required solely for the provision of investigational item or service (e.g., administration of a non-covered chemotherapeutic agent)
   - g. Item or service required for the clinically appropriate monitoring of the effects of the investigational item or service or the prevention of complications from item or service
   - h. Item or service is medically necessary for reasonable and necessary care arising from the provision of an investigational item or service – in particular, for the diagnosis or treatment of complications
   - Yes to any
   - Service or item qualifies for coverage as routine cost under Medicare.

Revised 11/19/13
ECU Brody School of Medicine/Vidant Health Research Participant List

**Use one form per patient for the duration of the study. Update the form after each visit and send to the appropriate contact listed below.**

<table>
<thead>
<tr>
<th>Vidant Financial Services</th>
<th>ECU</th>
<th>LJCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lewanna Locke</td>
<td>Karen Tripp</td>
<td>Kathryn Nichols</td>
</tr>
<tr>
<td>Sarah Jones</td>
<td>Clinical Trials</td>
<td>Professional Billing</td>
</tr>
<tr>
<td>Revenue Integrity</td>
<td>ECU Financial Services</td>
<td>Vidant Medical Group</td>
</tr>
<tr>
<td>Vidant Financial Services</td>
<td>Fax 744-3679</td>
<td></td>
</tr>
</tbody>
</table>

Brandy Styron
Lauren Perry
Office of Institutional Integrity

**SEND VIA SECURE EMAIL**
Lewanna.Locke@vidanthealth.com
TrippK@ecu.edu
Kathryn.Nichols@vidanthealth.com
Sarah.D.Jones@vidanthealth.com
Styronb@ecu.edu
Perryl@ecu.edu

<table>
<thead>
<tr>
<th>UMCIRB:</th>
<th>Billing Address for Invoices:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Short Name:</td>
<td></td>
</tr>
<tr>
<td>PI:</td>
<td></td>
</tr>
<tr>
<td>Study Coordinator:</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td>Contact Person for Billing Phone Number:</td>
</tr>
<tr>
<td>Enrollment Date:</td>
<td>Completion of Study Date:</td>
</tr>
<tr>
<td>Patient Name:</td>
<td></td>
</tr>
<tr>
<td>Date of Birth:</td>
<td>8 Digit Clinical Trial Number:</td>
</tr>
<tr>
<td>Vidant MRN:</td>
<td></td>
</tr>
<tr>
<td>ECU MRN:</td>
<td></td>
</tr>
</tbody>
</table>

**PROCEDURES**

- Date of Service
- Study Visit Number
- Place of Service (BSOM, ECHI, VMC, ECHI-ECU, FITT, LJCC, VMC, ECU, etc)
- Date Notification Sent to Contact(s)
- Procedures
- Paid by Sponsor OR Routine/SOC?

**DRUGS**

- Drugs
- Paid by Sponsor OR Routine/SOC?

**LABS**

- Labs
- Paid by Sponsor OR Routine/SOC?
- If paid by Sponsor and sent to VMC, was the "Special Study Lab Request Form" submitted with the specimen?

Revised 11/03/2014

L:\FinServ\FinServ\CDM - EPIC\IRB MEETINGS\FORMS\FORM REVISIONS\Clinical-Trial-Participant-List REVISED.xls