Clinical Trials – Budgeting and Billing

Presented by:
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Manager, Clinical Trial Financial Analyst
Rules and Regulations

- Medicare Clinical Trials Coverage Policy - National Coverage Decision (NCD)
  - Originated in September 2000 and was called the Clinical Trial Policy NCD
  - Renamed the Clinical Research Policy and revised July 9, 2007
Issues Relating To The Costs of Clinical Research

- **Billing Medicare (or the patient) for items or services that are otherwise reimbursable (or free) to the hospital through federal or private grant funds – a.k.a. “double billing”**
- Billing Medicare for experimental drugs, devices or procedures
- Charging for an investigational drug in a clinical trial under an investigational new drug application without approval of the FDA
- Waiving Medicare co-payments and deductible obligations for study participants
- Up-coding of billable services
- Receiving remuneration from research sponsors that could be viewed by Medicare as kickbacks
- Coding and billing for non-covered items or services as a covered benefit by an insurer
- Billing for items and services solely to satisfy data collection needs
- **Billing for items and services provided solely to determine trial eligibility**
- Inadequate medical record documentation for items or services billed
National Coverage Decision (NCD)

**Basic rule:**

- Medicare covers *routine costs* during **qualifying** clinical trials
  - Coverage is not automatic (don’t assume)
  - Insurer and/or Contractor may deny
  - Does not affect device billing category (A & B)

- **Qualifying Trials**
  - 3 Requirements; 7 desirable characteristics
  - Federal and IND studies qualify, others by agency qualification
Routine Clinical Services

- Routine clinical service costs are associated with patients enrolled in qualifying clinical trials and include:
  - Items and services otherwise available to beneficiaries;
  - Not statutorily excluded by Medicare;
  - No national non-coverage decision.

- Routine costs includes items and services that are:
  - **Typically furnished absent clinical trial (SOC)**
  - Necessary to provide investigational item/service;
  - Required for clinically appropriate monitoring of effect of investigational item/service or for prevention or treatment of complications
Costs that are not considered routine:

- Investigational item/service itself
  - But NCD does not supersede Local Coverage Determinations (LCDs) or Category B device rules

- Items and services furnished solely to determine trial eligibility or satisfy data collection and analysis needs not used in clinical management of patient

- Items and services customarily provided by research sponsors free of charge for any enrollee in the trial.
NCD – Qualifying Requirements

**Part 1: The 3 “necessary requirements”**

- The study must investigate an item or service that is in a Medicare benefit category
  - Note: NCD does not supersede local coverage determinations (LCD)—if Item or service is excluded by LCDs, study doesn’t qualify
- The study must enroll patients with diagnosed diseases
- The study must have therapeutic intent – it must not be designed solely to test the safety or toxicity of the investigational item or service

**Part 2: The study must be “deemed” to meet the 7 “desirable characteristics” – only certain types of studies are “deemed”:**

- Funded by certain government agencies (NIH, DOD, VA)
- Funded by co-op groups that receive funding from government
- Conducted under an FDA-approved IND application
- Exempt from IND requirements
Compliance Settlements

U. of Alabama at Birmingham ($3.39 M)

Allegations

- Falsely billed Medicare for:
  - Researcher’s time spent on patient care when no patients had been seen; and
  - Clinical research trials that were also billed to the sponsor of the research grants

- Overstated percentage of effort devoted to the grants and falsely reported T/E of employees who did not work on the grants
Prior to Award

- Determine routine services vs research related
- Obtain correct pricing for services
- Create a budget and billing grid with a list of all patient services required in protocol, include all CPT codes
- Make sure everything is in the contract
Routine vs. Research Related Services

- Determination should come from the PI:
  - Examine each procedure in the protocol and the frequency it is being performed
  - Use CRP definition of routine clinical services to help guide you
  - Do not just go with what the sponsor is telling you
Where do I get prices?

- Technical Fees - Research rates are posted on website (Fed and non-Fed), contact CTFA
- Professional Fees - Each professional group determines pricing
- Investigational Drug Services - annual fee charged to the study, IDS will give an estimate
- IRB fees - standard rates set by IRB and WIRB
- Time and Effort - Comes from the department
- Indirect Costs - Check with BMC or BU grants office
- Other - Storage fee, shipping, dry ice, central lab fees, pass thru fees, patient stipends, etc
Hospital rates

- Federally negotiated rates apply, charges revised annually
- Industry rates are set at either the Federal level or 38%, whichever is higher. Example:
  - Radiology: Federal 36.1%, Industry 38%
  - Pulmonary: Federal 65.9%, Industry 65.9%
- Research prices are posted on internal website
- Build your budget
# Clinical Trial Budget

<table>
<thead>
<tr>
<th>Procedures</th>
<th>CPT4 Codes</th>
<th>Unit Cost</th>
<th>Baseline</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Month 2</th>
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## Personnel

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<td>Principal Investigator</td>
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## Other

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## Totals

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<td>Total Cost Per Visit</td>
<td>$1,802.48</td>
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## Total Cost of Baseline, Treatment, & Follow-Up For Each Patient

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Billing Grid

- Details patient procedures performed during each subject visit
- Drives where the service should be billed, who is financially responsible
- Each charge clearly identified as SOC or Research
- Billing grid should be used for each study participant
- Vital tool when reconciling studies
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</table>

**SOC - Billed to the Patient’s Insurance**

**GRANT - Billed to the Research Grant & Paid by the Sponsor**

*If any SOC procedures are denied by a patient’s insurance, please contact the clinical trial financial analyst as soon as possible.*
Are you ready to start?

- Contract has been signed.
- Budget has been approved.
- IRB approval letter received.
- Account number has been assigned by BMC/BU.
- Study team is ready to begin research protocol.

What’s next???
Set Up Research Study in SDK

Prior to enrolling first patient, the study must be set up in SDK.

New Research Carrier Request Form for SDK

This sets up the specific study in SDK as a type of insurance so patients and 3rd party payors are not billed for research related services.
New Research Carrier Request Form for SDK

Boston Medical Center
New Research Insurance Carrier Request for SDK

Date: 
Form initiated by: 
Phone: 
Admin/Study Coordinator: 
Email: 
Grant Title: 
PI: 
IRB #: 
Department: Section: 
What would you like to name this study in SDK? (up to 16 characters): 
Is this Inpatient, Outpatient or Both? drop down 
Is this a Federal agreement? drop down 
PAYOR ID# (the 7-digit AU for BMC or 10-digit Internal Order # for EU): 
Effective Start Date: Effective End Date: 
Where will study take place? 
Building: Floor: Room: 

**Please attach a copy of the budget with all the clinical tests being performed **
Scheduling and Registration

- Call department for the appointment
- Give them the research information as the insurance
- Registration is decentralized, anyone can register, staff may not understand what a research insurance is
Outpatient Registration Form

**Boston Medical Center**
Research Registration Form

Date: ______________

Form initiated by: __________________ Phone: ___________ Fax: ___________

Research Patient Information:

<table>
<thead>
<tr>
<th>Subject Name: __________________</th>
<th>MRN #: ___________________</th>
<th>(Leave blank if a new patient)</th>
</tr>
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<tbody>
<tr>
<td>SS#: __________________________</td>
<td>DOB: <em><strong>/</strong></em>/____</td>
<td>Sex: M  F</td>
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If a new patient or if information has changed, fill in address information below:

<table>
<thead>
<tr>
<th>Street Address: ___________________________________________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Town/City: __________________ State: _____ Zip: ___________</td>
</tr>
<tr>
<td>Day Telephone: (         ) __________________ Evening Telephone: (         ) _______________</td>
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SDK Insurance Set Up Information:

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<tr>
<th>Carrier:</th>
<th>Research Grant No: (check one)</th>
<th>1 2 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of Study: ________________________________</td>
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</tr>
</tbody>
</table>

| Research Plan Mnemonic (Primary Insurance Plan): ________________________________ | (16 Characters max) |
| (Primary Insurance Plan): ________________________________ | (use 9999999 if unknown) |

| Primary Insurance Policy # (Payor ID#): _________________________ | (This will be either the 7-digit AU number for BMC grants or the 5-digit Source Code for BU grants) |

Visit/Admit Date: ___/___/_____ Time: _______ Clinical Research Investigation ICD9: V70.7

Service Area Location: __________________________________________________________________

Attending Physician: ________________________________________ Tel#: __________________

Please fax completed form to: Central Registration - Yawkey Pavilion: 617-414-5871

SDK Account #_____________________________

**Registration will assign an account number and fax back to sender listed above.**
Patient Care Report and Invoice

- A monthly patient care report is generated and distributed to the Administrator of each study. This report contains:
  - Detail grant charges for each date of service
  - Detail grant charges for each patient
- Compare these reports to Billing Grid – only Grant charges should appear on these reports
- Verify accuracy of charges
  - Are SOC charges being charged to Grant?
  - Are Grant charges being charged to SOC?
- Problems!! - Contact the CTFA
What to Watch Out For!

- Are these patients truly part of the study?
- Are there any patients that you do not see on your list that you know participated?
- Are there any charges missing?
- Are some of these charges not grant related?

Contact the CTFA if there are any issues.
## Example Patient Care Report

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<th>INSURANCE POLICY NUMBER</th>
<th>ACCOUNT NUMBER</th>
<th>PATIENT NAME</th>
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<th>ADJ.</th>
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<td>DX X-RAY</td>
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<td>4567-8</td>
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| subtotal          |                |                        |               |             |           | 960.00  |         |      |         |          |              |                          |          |          |                          |         |

| Total Amount to charge the grant | 960.00 |
What if routine clinical care and research services are performed on the same day?

- 2 visits must be created in SDK
  - Patient’s insurance or self pay
  - Research study insurance

- Charges must be separated in SDK and allocated to the correct visit number
Inpatient Registration

- Charges related to inpatient stays are usually covered by third party payors, unless the patient is also part of a clinical research study.

- Research charges must be flagged in the system so they are not released with the regular inpatient claims to third party payors

- Study Coordinators must inform the CTFA of any research charges by using the Inpatient Notification Form

- Communication between the Study Coordinator and the CTFA is vital!
Inpatient Notification Form

Research Study Inpatient Notification

Please fill out the following information regarding your inpatient research subject. This will notify our office of any charges that should be billed to the study and not charged to a third party or the patient. This is a crucial step to ensure compliance when doing research billing.

- Patient MRN#:
- Patient Name:
- SDK Account # (if available):
- Date of Service
- Study Coordinator/Administrator
- Email Address:
- Phone #:
- Title of Study
- Plan Name in SDK
- Payor ID# (BMC AU/BU Source)
- Research Procedures Performed:

Submit Form
Financial Close Out

- Has everything been billed to the sponsor? All payments received?
- Have salaries been allocated properly?
- Patient reconciliation completed?
- All vendors have been paid? Professional groups, IDS, GCRC, etc.

- Cash balance after everything should be close to break even point
Any Questions???