CRITICAL CONCEPTS FOR CLINICAL RESEARCH BILLING

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Office of Compliance Services
Agenda

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➢ Informed Consent Elements that may impact the CRB process

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➢ What is the Centralized Research Business Partners department?

➢ Clinical Research Charge Resolution New Workflows Effective 11/5/15

➢ Research Transaction Reports

➢ Clinical Research Billing Top 10 List (what not to do)
Key Determinations

A. Study-level determination
   - Is your study a Medicare-qualifying drug study or approved device study?
   - Is your study Medicare non-qualifying?
     - Does sponsor cover all costs?
     - Are there any extra items done for research only purposes?
   - Is your study another type of study (chart review; observational?)

B. Patient-level determination
   - Is this a Medicare recipient?
   - Is this a Medicare Advantage Plan participant?
   - Is this patient privately Insured?

C. Encounter-level determination
   - Is this encounter research-related?

D. Charge-level determination
   - Is this non-codeable item invoiceable to sponsor?
   - Is this non-codeable item non-billable?
   - Is this codeable service covered by study? (research-related, bill to study)
   - Is this codeable service a routine cost, as classified by Medicare? (research-related, bill to Ins/Pt)
   - Is this codeable service not related to the study? (not research-related, bill to Ins/Pt)
   - Is this a non-billable item?
Informed Consent Elements that may impact the Clinical Research Billing process (from OHRP)

- **Basic Elements**
  - For research involving more than minimal risk – the informed consent should contain an explanation regarding any compensation and/or medical treatment available, if injury occurs.

- **Additional Elements as Appropriate**
  - Any additional costs to the subject that may result from participation in the research

- The language in the benefits sections of the consent may not allow billing if language states the subject will not receive benefit from participation in study

- Language in the informed consent form should be clear and precise, and should not over-promise. (structure in a way that does not allow for misinterpretation that may prevent billing during research studies)
“Standard of Care”
(not a Medicare or Other Payor Concept)

• Under the Medicare Clinical Trial Policy (National Coverage Determination 310.1), Medicare covers items and services which meet the definition of a “routine cost” during a “qualifying clinical trial.”

• The Medicare term “routine costs” comes close to being what the research community means by “standard of care,” but it’s not a one-for-one interchangeable concept.
Key Concepts

Medicare covers “routine costs” during “qualifying clinical trials”?

- the items/services are not paid for by the sponsor
- the items/services are not promised free in the informed consent
- the items/services are generally covered by Medicare outside of a clinical study.

What are Routine Costs (of a Qualifying Clinical Study)?

- “Items or services that are typically provided absent a clinical trial (e.g., conventional care)

- “Items or services 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

- “Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service used to detect and monitor known side effect”
Qualifying Clinical Trial (=approved device trial)

- A qualifying clinical trial is a study that meets the following criteria:
  - Is one of the four types of “deemed” studies
    - Studies an item or service that is generally covered by Medicare under a “benefit category”
    - Enrolls subjects with diagnosed disease
    - Is designed for therapeutic purposes
Clinical Documentation

- **Clinical documentation should be:**
  - **Accurate** - Accurate, consistent and real representation of facts
  - **Complete** - Complete till that point in time.
  - **Legible** - Readable and signatures identifiable.
  - **Attributable** - It should be clear who has documented the data.
  - **Contemporaneous** - The information should be documented in the correct time frame along with the flow of events. Acceptable amount of delay should be defined and justified.
  - **Original** - Original, if not original should be exact copy; the first record made by the appropriate person. The investigator should have the original source document.
  - **Available and accessible** - Easily available for review of treating physicians and during audits/inspections. The documents should be retrievable in reasonable time.

- **Source document should speak for itself.**

- **What is not documented is not done!** *(Document what is done as well as what is not done)*

- **Be careful when using “copy and paste” function**

- **Make sure your documentation supports the items/services billed**
Medicare - Medical Records Documentation Requirements

Per Medicare Claims Processing Manual, Chapter 32, Section 69.3: The billing provider must include in the beneficiary's (subject’s) medical record the following information:

- Trial name
- Sponsor
- Sponsor-assigned protocol number

**This information does not need to be submitted with the claim but must be provided if requested for medical review.**
Devices – Special Considerations

- **Devices that may be covered under Medicare include:**
  - those approved by the FDA through the Pre-Market Approval (PMA) process
  - those cleared by FDA through 510(k) process
  - FDA-approved Category B devices

- **Criteria for coverage on FDA-approved IDE category B devices:**
  - The device must be used in FDA approved trial
  - The device must be used in accordance with protocol
  - There may be an established national policy as contained in existing manual instructions (e.g., National Coverage Determinations Manual instructions, etc.)
  - In the absence of national policy, there may be a local policy for similar FDA-approved devices
  - There may be Policy/Position papers or recommendations made by pertinent national and/or local specialty societies.

** On and after January 1, 2015 interested parties (i.e. study sponsors) seeking Medicare coverage for Category A and Category B IDE studies must submit their request for review and approval to CMS.
What are the Special Billing Rules?

**NCT# - reported at claim level**
- Registration Number issued upon study registration with ClinicalTrials.gov
- Required on claims for items/services provided as part of a CMS approved study or Registry

**Condition Code 30 - reported at claim level**
- “Qualified clinical trial”
- Must appear on the hospital claim for items/services related to a Qualified Clinical Trial regardless of whether all services are related to the clinical trial or not.

**ICD-10 code Z00.6 – reported at charge level**
- Encounter for examination of normal comparison and control in clinical research program
- Reason for the experimental or investigational service should be first-listed diagnosis.

**Q0/Q1 Modifiers – reported at charge level**
- Used on the billing claim form to characterize the line-item service as investigational or a routine cost in a Qualified Clinical Trial.
- Q0 - investigational (object of the trial) drug, device or procedure
- Q1 - routine

**Investigational Device Codes, Modifiers, and Condition Codes**
- **0624** – investigational device revenue code reported with IDE number
- **FB modifier** (and assign nominal charge) – appended to the procedure associated with the device to designate that the device was provided at no cost
- **CC 53** - used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due a clinical trial or a free sample.
The Rules are Complicated

The Centralized Research Business Partners (CRBP) team provides medical coding and billing support to the UCLA Research Community.

We are here to help you.

UCLAHSCCRBP@mednet.ucla.edu
What is the Centralized Research Business Partners department?

A financial team designed to provide research-related Revenue Cycle support to Clinical Research leadership, investigators, study teams, and other support areas

- Adjudicate and direct charges for patients enrolled in studies
  - Serve as primary point of contact for research-related hospital and professional charge management and various clinical research billing issues
- Provide clinical coding expertise and connect study teams to other technical resources to support study assessment and build efforts
- Ensure coding and billing* accuracy and compliance for all UCLA research clinical study charge activity
- Provide coding expertise and acquire research-related CPT/HCPCS codes and prices for Research Coding and Pricing Requests
- Develop billing calendars in OnCore to facilitate automated research charge traffic

* Billing refers to directing charges to the correct payor, whether study or not.
Clinical Research Charge Resolution
New Workflows Effective 11/5/15

4 Stages:

1. **Charge Review Management – Automated**
   - Technological tools (CareConnect and OnCore CRMS) interface to initially direct research charges

2. **Charge Review Management – Manual**
   - CRBP team reviews and directs charges via the CareConnect Research Review Report (R3)

3. **Research Transaction Reports**
   - Study teams review and validate weekly HB and PB reports to ensure charge direction accuracy – see the User Guide embedded in each report

4. **Research General Ledger Reports (coming soon)**
   - Study teams review monthly HB and PB reports to ensure accurate posting to the study FAUs on the General Ledger
HB Research Transaction Reports
ACTIONABLE

HB Research Transaction Report - 11/15/2015

Note: The 11/15/2015 report reflects posted charges for greater than 7 calendar days, inclusive of charge posting dates 11/5/15 (go-live date) - 11/7/15 and calendar week 11/8/15 - 11/14/15. Future reports will...

Includes research charges directed to study accounts during the previous calendar week
Reports are distributed to impacted study teams every Monday and require review/response

Response Deadlines:
HB Reports – 9 business days
PB Reports – 4 business days
PB Research Transaction Reports

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HB Reports – 9 business days
PB Reports – 4 business days

<table>
<thead>
<tr>
<th>Study Code/ IBB #</th>
<th>Study Name/Account</th>
<th>Study FAU #</th>
<th>Study PI Name</th>
<th>Patient Name &amp; MIN</th>
<th>Standard Charge Amount</th>
<th>Service Date</th>
<th>Post Date</th>
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<th>Servicing Department</th>
<th>Billing Provider</th>
<th>Service CP/NRCS Code</th>
<th>Service Modifier</th>
<th>Procedure Code/ NRCS Code</th>
</tr>
</thead>
</table>

Note: The 11/15/2015 report reflects posted charges for greater than 7 calendar days 11/5/15 (go-live date) - 11/7/15 and calendar week 11/8/15 - 11/14/15. Future reports are for informational purposes only. Research charges were posted to the identified FAU account on the previous calendar Friday.

Contact the Centralized Research Business Partners (CRBP) Team (UCLAHSCRBP@MedNet.UCLA.edu) for all questions related to this report.

- Includes research charges directed to study accounts during the previous calendar week
- Reports are distributed to impacted study teams every Monday and require review/response
Study Team Engagement is Critical

- PIs and study teams “own” their studies and are **ultimately responsible** for charge direction accuracy in the context of their study management.

- Technology and CRBP support will perform the initial study-specific charge direction actions based on existing billing grids and other documentation.

- Study teams must review and respond to the HB and PB Research Transaction Reports in a timely and thorough manner, to ensure accurate charge posting and to minimize institutional risk.
Clinical Research Billing Top 10 List
(what not to do)

10. Do not bill insurance for anything that is not “reasonable and necessary.”

9. Do not “GUESS” at your research budget.

8. Do not bill Medicare for items/services associated with an investigational device UNLESS you have written prior approval from the local Medicare contractor and carrier (Part A & B).

7. Do not bill Medicare for any items/services provided within the context of a clinical research study if the study does not meet the Centers for Medicare & Medicaid Services (CMS) “qualifying” criteria.
7. Cont’d

“Qualifying” clinical trials must meet the criteria established in the CMS National Coverage Decision (NCD).

- The subject or purpose of trial must be the evaluation of an item or service that falls within a Medicare benefit category.

- The investigational intervention must have therapeutic intent (not be designed exclusively to test toxicity or disease pathophysiology).

- The study must enroll subjects with a diagnosed disease (trials of diagnostic interventions may enroll healthy patients as “controls”).

- Meet the seven desirable characteristics. Some studies have been deemed to meet these characteristics by CMS.

“Deemed” clinical studies =

1. Funded by the NIH, CDC, AHRQ, DOD, DHHS, or the VA.
2. Supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, DOD, DHHS, or the VA.
3. Conducted under an IND or is a drugs trial that is exempt from having an IND.
Clinical Research Billing Top 10 List
(what not to do)

6. Do not use money from a sponsor for any non-trial related effort or anything other than the intended use.

5. Do not bill insurance or the subject for any item or service that the informed consent form (ICF) states will be provided by the study or sponsor.

4. Do not bill insurance or the subject for any item or service for which someone else has agreed to pay.

3. Do not bill insurance or the subject for any item that you receive for free.

2. Do not get paid by a sponsor more than “fair market value.”

1. Do not keep money to which you know the institution is not entitled.
Resources


- CMS guidance on investigational device approval - https://www.cms.gov/Medicare/Coverage/IDE/


- MM8401 Revised re Reporting of 8-Digit NCT# and billing requirements for institutional and professional claims for services provided under a clinical trial, clinical study, or registry - http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1344.pdf
Questions?