Coverage Analysis at UTHealth

Clinical Research Finance and Administration

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What is a Coverage Analysis?
An itemized breakdown of each procedure in a Clinical Trial which identifies the appropriate payer of the procedure.
Why are CA’s Necessary?

- Multiple Payers for Clinical Research
- Federal Regulations
- Streamline scheduling and billing
Improper Billing

- Cost to Implement Corrective Action
- Loss of Trust
- Under Billing
- Loss of Governmental Funding
- Cost Associated with Investigation
- Civil Fines
- Criminal Penalties
- Increased Governmental Scrutiny

Cost to Implement Corrective Action

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Improper Billing
Consequences: Settlements/Fines

- **Rush University Settlement**
  - $1 Million
  - Improperly billed Medicare attributed to “the absence of synchronization of the Medicare rules, the compensation arrangements with the sponsor, & the financial discussion in the Informed Consent”

- **University of Alabama at Birmingham**
  - $3.39 Million
  - Falsely billed Medicare for researcher’s time spent on patient care when no patients had been seen
  - Falsely billed Medicare for clinical research trials that were also billed to the sponsor of the research grant

- **Emory University**
  - $1.5 Million
  - Falsely billing Medicare & Medicaid
  - Sponsor agreed to pay for services which were not invoiced by Emory
Who are the payers?

- Patient out of pocket expense
- Patient’s Insurance
- Government – Centers for Medicare and Medicaid (CMS)
- UTHealth
- Sponsor
Who pays for what?

- **Routine Costs (Standard of Care)**
  - Patient
  - Patient Insurance
  - CMS

- **Research Costs**
  - Sponsor
  - UTHealth
What is a Routine Cost?

- Provided when the patient is not on a clinical trial
- Required for the provision of the investigational item or service (Example: administration of the study drug)
- Items clinically indicated for the monitoring of the effects of the investigational item or service
- Needed for reasonable and necessary care arising from the provisions of an investigational item or service in particular, for the diagnosis or treatment of complications
What is not Routine Cost?

- The investigational item/service unless it is already covered outside of the clinical trial (Example: comparison trials)
- Provided solely for research purposes
- Provided solely to determine eligibility
- Provided/Paid by the Sponsor
- No cost items listed in the informed consent
- Items excluded from typical coverage
When do I start my CA?

Coverage Analysis

Contract Budget

Contract Execution Setup

Patient Enrollment

Patient Service Procedure

Charge Entry/Billing
What is the CA Routing Process?

**CRF**
Billing Risk Assessment by CRF using the protocol Submitted to iRIS

**CRF**
CRF enters the initial data into the CA tool. All study visits, services, and procedures will be listed out in Costs/CA tab. CRF sends to dept. and notifies them to complete CA, Costs, Effort, qualifying questions, and billing certification.

**Dept.**
Department completes coverage, budget, qualifying questions, and submits it for review.

**Both**
CRF reviews and works with department to finalize CA approval.

**CRF**
CRF emails contract specialist, PI, dept contact, CPHS, with approval notice.
How do I Perform a CA?

- Determine if it is a Qualifying Clinical Trial
- Review Documents
- Review Documents
- Meet with the PI, Research Nurses, Billing/Coding Specialists, CRF Team
- Complete the Cost Coverage Analysis
- Review Documents
What is a Qualifying Clinical Trial?

3 Requirements:

- Evaluate an item or service that falls within a Medicare benefit
- The trial has therapeutic intent
- Must enroll patients with disease diagnosis
What are Deemed Studies?

- Trials funded by federal sponsors or supported by their centers or cooperative groups (NIH, DOD, etc)
- Trials conducted under an investigational new drug application (IND)
- Drug Trials that are exempt from having an IND by the FDA
What About Devices?

- CMS requires **advance** designation for billing of routine costs to device trials.

- Submission includes the protocol, FDA approval of IDE, IRB approval letter and NCT#

- Memorial Hermann will require the CMS packet to be submitted along with the CA
What Documents Should I Review?

- Protocol
- Informed Consent
- Contract
- Previous Internal Budgets
- Investigator Brochure
- Sponsor Reimbursement Guide
- Clinic SOPs
- Internal Pricing
What happens when I meet with the PI and Admin?

- Which procedures are SOC/RES
- What does it costs to perform the procedure
- How much time/effort each takes
- Put it in writing
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Reach Out For Help
One on One Trainings Available
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