

The Basics of Clinical Research Billing: A Team Effort

University of California
Clinical Research Billing Education Series
September-October 2010

Session 2

9-15-2010

9-16-2010

9-28-2010

9-30-2010

1

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2

Structure of CRB Webinars

- Session 1: Opportunities & Challenges
- **Session 2: CRB: A Team Effort**
- Session 3: Clinical Trial Agreements
- Session 4: Informed Consents
- Session 5: Study Budgets & CRB Billing Rules
- Session 6: Medicare Advantage & CRB
- Session 7: Specific Issues in Billing & Coding

3

Objectives

1. Introduce an information flowchart that identifies how multiple parts of an organization are involved in processes that influence clinical research billing
2. Explain Medicare research billing rules as a foundation for clinical research billing processes
3. Discuss how Medi-Cal and California state laws interact with clinical research billing
4. Review unique aspects of pediatric research studies and how they fit into billing rules

4

The 3 C's of Research Billing Compliance

- **Coordination** of study information across multiple study documents
- **Communication** of relevant study information to the billing process
- **Cooperation** among departments and offices that may not usually work together

5

Compliance Risks

- Not having a consistent clinical research billing process or operations safeguards can lead to:
 1. Billing for services that are already paid by the sponsor (double billing)
 2. Billing for services promised free in the informed consent
 3. Billing for services that are for research-purposes only
 4. Billing for services that are part of a non-qualifying clinical trial and do not qualify for coverage
 5. Billing Medicare Advantage Plans (Part C) when claims should be directed to the Medicare Administrative Contractor (Palmetto)

6

Coordinating, Communicating, Cooperating

- Information that must be coordinated to minimize CRB compliance risks is traditionally in “silos”
 - ✓ What is billable and not billable
 - ✓ Who is enrolled in a research study
 - ✓ Which services are required by the protocol
- Within academic medical setting, many different functions interact with research study and develop study documents that have important information for billing:
 - ✓ University/Campus
 - ✓ Schools of Medicine
 - ✓ Medical Center
 - ✓ Physician Offices
 - ✓ Sub-contractors
 - ✓ CROs

7

A Team Effort to Get it Right

- Principal Investigator
- Clinical Research Coordinator
- IRB process
- Budget negotiators
- Clinical Trial Agreement negotiators
- Grant administration
- Information Technology
- Health Information Management
- Registration/Scheduling
- Medical center billing and coding
- Physician professional fee billing and coding
- Study fund managers
- Managed care contract negotiators
-and others!

8

Synchronizing Study Document Information

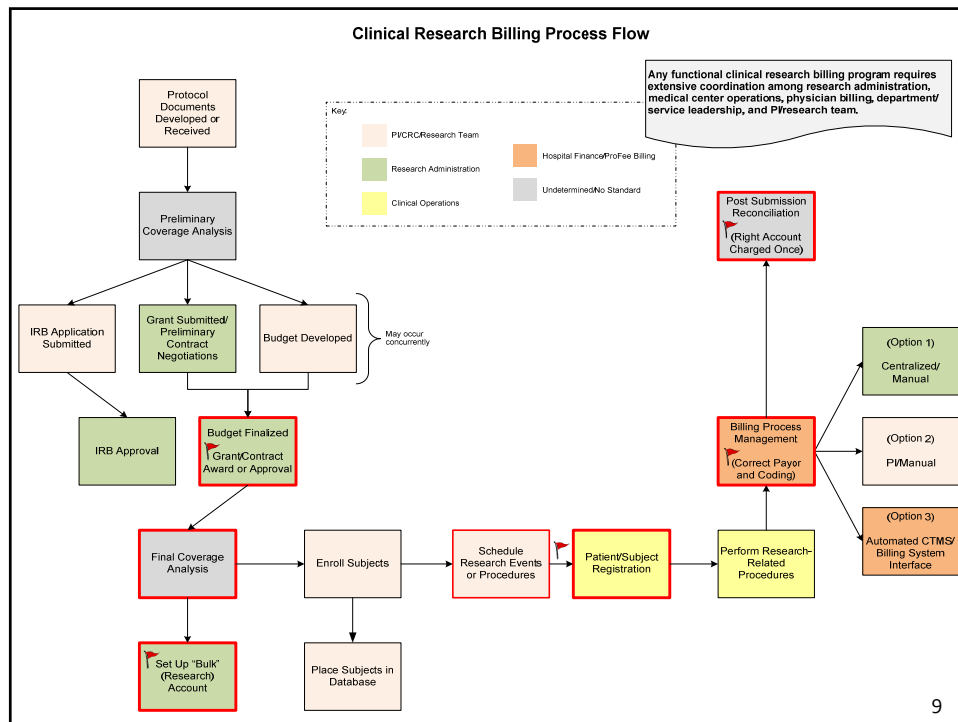
- Clinical research billing rules rely on multiple study documents to determine what is billable to patient or insurance
- Study document language should be in harmony, but documents are often developed for different reasons and by different individuals and units
- If the billing process is contemplated early, then there is a better chance for clear and consistent study documents

9

Study documents may be created for one purpose but used for another: The protocol as example

- Patients enrolled in a research study receive core services according to the protocol's schedule of events
- The protocol is a "road map"
 - Up side: each study can follow a consistent tool
 - Down side: billing errors replicate easily
- Study documents may not be written with billing in mind and can create systemic issues
 - Example: A diagnostic test may be characterized in an investigator-initiated protocol as being performed for "research" and regulator may consider that to mean data collection only and the service not billable

10



What is billable to insurance and what is not billable depends on patient's insurer

- Medicare:
 - As a general rule, covers "routine costs" during "qualifying clinical trials"
- Medi-Cal:
 - Requires coverage of cancer clinical trials but mostly silent for non-cancer
- Commercial Insurance:
 - State requirement to cover cancer clinical trials but for non-cancer it is a matter of contract and coverage policy
- Employer Group Health Plans:
 - Specific to each coverage policy

Medicare as the driving force for a framework for clinical trial coverage

- Most clinical trial billing rules in the United States are generally shaped by the Medicare Program's Clinical Trial Policy and Medicare's device trial coverage regulations
- Many States have adopted clinical trial coverage laws similar to Medicare, including California
- While Medicare has complicated rules, there is logic to them and generally allows billing for medically necessary services as long as all subjects in a study billed the same way Medicare is

13

California State Law

- SB 37 requires commercial insurance policies and Medi-Cal to cover "routine patient care costs" in a cancer clinical trial which the patient's physician believes "has a meaningful potential to benefit" the patient.
- California law has a structure very similar to Medicare
- Focuses on cancer clinical trials
- Does not address employer-sponsored group health plans (these are regulated by federal law)

14

Common Approach:

Use Medicare rules for consistent approach

- Medicare requires that it not be billed for a trial-related service if any enrollee or enrollee's insurer is not billed for the service
 - ✓ Example: Chest x-ray at 6 weeks is not billed to commercial insurance patient, then it cannot be billed to Medicare
- Utilize Medicare clinical research billing rules as a baseline for budget negotiations and for billing
- Use pre-authorization process for commercial and group health plans as additional way to put payors on notice

15

Medicare Clinical Research Coverage

- Medicare requires a three-part process for clinical research services coverage:
 1. Does the study "qualify" for coverage?
 2. What items and services are "routine costs"?
 3. Do Medicare rules allow coverage of specific "routine costs" within a clinical trial?

16

What are “qualifying” studies?

- Will be reviewed in more depth during live workshops
- Generally:
 - Drug studies that are under an IND application or are IND exempt
 - Studies funded by certain HHS agencies, DOD, or VA
 - IDE Category B devices
 - IDE Category A devices addressing life-threatening conditions

17

Medicare Clinical Research Billing Rules

- The relevant Medicare rule for “qualification” of study depends on what is being investigated and who is funding the research:
 - Drugs: Clinical Trial Policy (NCD 310.1)
 - Devices: Device trial regulations
 - Funded by NIH, CDC, AHRQ, CMS, DOD, VA or Co-op Group: Clinical Trial Policy
 - Outcomes Studies: Local Medicare contractor discretion, but study does not usually involve an investigational article and medically necessary services are generally covered

18

Documenting Reasoning

- A provider should document why it believes the study is “qualifying”
- The qualifying status for a study is the same for a medical center as for physician billing
- Documenting the reasoning process is important because each research study has a different configuration under billing rules

19

Documenting Reasoning

- A Medicare Coverage Analysis (MCA) provides a tool to document reasoning
- MCA can have multiple parts:
 - Documentation of the study’s qualifying status
 - Review of protocol services and whether they meet the definition of “routine cost”
- Developing the MCA requires input from multiple sources, including the PI and CRC

20

Medicare Clinical Research Billing Rules

- In qualifying studies, Medicare covers items and services scheduled by the protocol that are considered “routine costs”
- Routine costs are:
 - Conventional care items and services
 - Detection, prevention and treatment of complications
 - Administration of investigational item

21

Identifying “Routine Costs”

- Note that “routine cost” does not necessarily mean what the physician routinely does
- “Routine costs” does not equate to “standard of care”
- Sometime “routine costs” allows more than standard of care, such as the administration of a study drug
- It is important to document why the provider determined the protocol service is a “routine cost”

22

What is not a “Routine Cost”?

- Services that are performed only for data collection
- Services that occur more frequently than would be performed for the same treatment outside a research study
- Services that are performed only to determine inclusion or exclusion in the study
- Services that are paid for by the sponsor or promised free to the patient
- Services not for the clinical management of the patient
- Services performed only to determine toxicity of the study drug

23

A note on coding rules & Medicare Advantage

- All protocol-scheduled services must be identified in the billing process
- Specific coding rules exist for “routine cost” services that are billed to Medicare
- Also, special claims processing rules must be used for patients enrolled in a Medicare Advantage Plan (Medicare Part C)
- Specific education sessions will treat coding and Medicare Advantage in more detail

24

A note on pediatric clinical research studies

- The same compliance risks exist for pediatric research as adult research
- Pediatric research studies have a small percentage of Medicare enrollees
 - Higher percentage of Medi-Cal and commercial payors
- Coverage analysis for pediatric studies can use the same concepts as Medicare rules to keep process and reasoning consistent

25

Documenting Reasoning

- A provider should document why it believes the items and services are “routine costs”
- The status of a protocol-scheduled service as a “routine cost” should be the same for all enrollees in the study
- Providers should use objective reasons why an item or service is a “routine cost” and not the subjective reasoning of the principal investigator
 - Common approach: Coordinate with Principal Investigator for agreed-upon guidelines

26

Study Document Implications

- The clinical trial agreement and informed consent form have additional impact on the ability to bill for **services** (covered in more detail in other webinars)
- Anything paid for by the sponsor cannot be billed
 - How the CTA and budget are drafted are critical because they can override Medicare billing rules
- Anything promised free to the patient cannot be billed
 - Interpreted from the perspective of the patient

27

Operational Suggestions

- Consider identifying the “team” that must interact with study information in order to bill correctly
- Many organizations establish steering committees with representatives from School of Medicine, medical center, and physician practices to coordinate initiatives and integrate CRB process
- Consider identifying research subjects in a database

28

Operational Suggestions

- Develop a coverage analysis grid with a consistent format to document reasoning
- Share grid between medical center and physician billing
- Ensure billing for enrollees within a study occurs in a consistent manner

29

Hypothetical MCA: managing study information

	Code	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Comment
Physical Exam	99201-99215		M	M	M	M	
EKG	93000	M	M	M			
Drug 123	J0123	S	S				
Infusion	96400	M	M				
Urinalysis	81000		NB	NB			
Ultrasound	93990			NB			

M=Medicare
S=Sponsor
ICF=Free in Informed Consent
NB=Not billable to Medicare

30

Take-away Points

- Compliant clinical research billing cannot rely on one person: many people in different offices must work together
- Establish processes to coordinate information between School of Medicine, Medical Center, physician practice
- Medicare rules provide a consistent framework for determining what is billable
- Document the reasoning for billing in a coverage analysis and treat enrollees consistently

31

References for further reading

- CMS National Coverage Determination 310.1 (“Routine Costs in Clinical Trials”)
- 42 USC 1395y(m) (“Coverage of Routine Costs Associated With Certain Clinical Trials of Category A Devices”)
- 42 CFR 405.201-215 (“Medical Services Coverage Decisions That Relate to Health Care Technology”)
- Medicare Benefit Policy Manual, Ch. 14 (“Medical Devices”)
- Cal. Ins. Code 10145.4 (Commercial Insurance Cancer Clinical Trials)
- Cal. Welf. & Inst. Code 14132.02 (Medi-Cal Cancer Clinical Trials)
- Cal. Welf. & Inst. Code 134137.8 (Medi-Cal & Inpatient Clinical Trial Care)

32

