

Case Studies in Medicare Coverage and Research Billing

Ryan Meade, JD
Meade & Roach, LLP
312.498.7004
rmeade@meaderoach.com

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Goals

- Review Coverage Rules for Hypothetical Studies
- Identifying Information
- Selection of common issues

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Research Billing Compliance Risks

- Ignoring clinical research billing rules can lead to:
 - Billing for services that are already paid by the sponsor (double billing)
 - Billing for services promised free in the informed consent
 - Billing for services that are for research-purposes only
 - Billing for services that are part of a non-qualifying clinical trial

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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 research study?
- Plus:
 1. What is paid for by the sponsor?
 2. What is promised free in informed consent?

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Achieving Research Billing Compliance

- Themes:
 - Coordination of study information
 - Communication of study information
 - Clarity in study documents

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Hypothetical MCA

	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			M			
Patient Diary	N/A		NB	NB	NB	NB	

M=Medicare
S=Sponsor
NB=Not Billable

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Hypothetical MCA

	Screening	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Every 6 month
Physical Exam	M		M	M	M	M	M
EKG	M	M	M	M			NB
Drug 123		S	S				
Infusion		M	M				
Urinalysis	M		NB	NB			NB
Ultrasound				M			M
Patient Diary	NB		NB	NB	NB	NB	NB

M=Medicare
S=Sponsor
NB=Not Billable

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Performing the MCA: Proposed Study

1. Develop grid
2. Perform qualifying clinical trial (QCT) analysis
3. Identify items and services "hard-wired" free into protocol
4. Determine items and services that are routine costs
5. Determine if routine costs are covered by Medicare
6. Check proposed contract to determine if offered budget covers items and services that are not billable
7. Negotiate contract
8. Finalize "added costs" section of informed consent

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Performing the MCA: Active Study

1. Develop grid
2. What items and services are promised free in the informed consent?
3. What items and services are paid for by the sponsor?
4. Perform qualifying clinical trial (QCT) analysis
5. Determine items and services that are routine costs
6. Determine if routine costs are covered by Medicare
7. Apply Medicare rules to the routine costs

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Common Issues/Questions in MCAs

- Qualifying Clinical Trial Analysis
- What are Routine Costs?
- How to apply Medicare rules?
- How to interpret/draft documents?

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Document the QCT Analysis Process

Question	Yes	No	Comment
Deemed study?			
Item or service falls within a benefit category?			
Enrolls subject with diagnosed disease?			
Study designed with therapeutic intent?			
Qualifying Clinical Trial?			

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Document the QCT Analysis Process

Question	Yes	No	Comment
Deemed study?	X		Sponsored by NIH
Item or service falls within a benefit category?	X		Drugs and Biologicals
Enrolls subject with diagnosed disease?	X		Non-Hodgkin Lymphoma
Study designed with therapeutic intent?	X		"Assess anti-tumor activity of [Study Drug]."
Qualifying Clinical Trial?	X		

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What are Routine Costs?

- Conventional Care
- Detecting & preventing complications
- Administration of investigational item

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Conventional Care

- Objective clinical guidelines
 - Professional association guidelines
 - Peer-reviewed literature
 - Significant textbooks
 - Disease associations
 - NIH recommendations
 - Guidelines.gov

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Questions for Conventional Care

- QUESTION 1: Would physician perform this service at the required frequency for a patient not in the study?
- QUESTION 2: Is physician able to document the medical necessity of the item or service in the medical record for every subject?
- QUESTION 3: Will physician use the test for the direct clinical management of every patient enrolled in the research study?

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Detection & Prevention of Complications

- Tips:
 - Identify the purpose of the test
 - Identify the known potential side effect
 - Protocol?
 - Informed Consent?
 - Product Label?
- Example:
 - This test is performed to detect kidney dysfunction. The study drug is known to have renal toxicity (Protocol, p. 50)

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Detection & Prevention of Complications

- Identify some nexus between service and potential complication
- Drugs: look to pharmacology section of protocol
- Look to explanations in the informed consent

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Schedule of Events: Hypothetical Device Study

	Screening	Implant	Pre-discharge	2 weeks	12 weeks	24 weeks	Every 6 month
Physical Exam	X		X	X	X	X	X
EKG	X		X	X			X
Implant		X					
Device XYZ		X					
Urinalysis	X		X	X			X
CT				X			X
Patient Diary	X		X	X	X	X	X

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Schedule of Events: Hypothetical Drug Study

	Screening	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Every 6 month
Physical Exam	X		X	X	X	X	X
EKG	X	X	X	X			X
Drug 123		X	X				
Infusion		X	X				
Urinalysis	X		X	X			X
CT				X			X
Patient Diary	X		X	X	X	X	X

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Applying Medicare to the MCA Items & Services

- Statutory basis for Medicare coverage follows this principle:
 - Medicare covers items and services that are “reasonable and necessary to diagnose or treat illness or injury”
- Medicare is not a preventive care program – the patient must present with something wrong
- Congress has allowed limited exceptions for coverage of preventive care

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Words Matter

- “items and services...reasonable and necessary for the diagnosis or treatment of illness or injury” [SSA 1862\(a\)\(1\)\(a\)](#)
 - Items and services
 - Reasonable and necessary
 - Diagnosis or treatment
 - Illness or injury

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When Medicare is Silent

- CMS and local Medicare contractors have written rules for only approximately 15% of items and services that are covered by Medicare.
- If there is no Federal or local coverage rule and the item or service is not excluded from coverage, then Medicare covers the item or service if it is “reasonable and necessary” to diagnose or treat illness or injury.
- When utilizing the reasonable and necessary rule alone, it is critical that the medical necessity of the service be documented in the medical record and when assuming medical necessity for hypothetical patients (e.g., clinical trial enrollees), the file should contain the reasoning for why the service would be “reasonable and necessary” for every enrollee who receives the service.

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Words & Documents

- Informed Consent
- Clinical Trial Agreement

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Interpreting the Informed Consent

- Informed consent is interpreted from the perspective of the patient
- Ambiguities are interpreted against the drafter (in favor of the patient)
- Plain meaning of the words in the informed consent must be honored
- Promises made to research patients should be kept

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Problematic Added Costs Language

- “Your or your insurer will have no costs for participating in this research study.”
- “Your routine medical care will be billed in the usual way. However, you will not be charged for any study visits or services.”
- “You will be responsible for the costs of any services you would have received if you did not enroll in this research study. However, you will not be billed for lab services or imaging services.”

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Crafting the CTA Compensation Language

- **Tips (during negotiation):**
 - Be precise what the Sponsor is paying for
 - Be specific about frequency in which Sponsor is paying for a service
 - Avoid overly broad terms to describe what the services are paying for
 - Consider developing the compensation arrangement in line with the Medicare Coverage Analysis or protocol's schedule of events
 - Understand what activities in the protocol are contractual obligations

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Crafting the Compensation Language

- Tips (during negotiation):
 - Avoid “lump sum” payments
 - If must take “lump sum,” clarify whether any of the amount is targeted for clinical events or whether all is focused on data collection and research-only services
 - Describe milestones as merely time points for payment rather than payment for a procedure (unless it actually is payment for a procedure!)
 - Consider definitions section
 - Ensure main body of contract is in sync with “budget”/compensation in exhibit

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Crafting the Compensation Language

- Tips (during negotiation):
 - Ask yourself: If you had to pick up this Clinical Trial Agreement and “budget” 3 years from now, will you be able to know what the money is paying for without referencing your notes?
 - Ask yourself: If someone else had to read this Clinical Trial Agreement and “budget” 3 years from now, would he or she know what the money is for?

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Common “problem” language

- “Payments made by sponsor include all study costs.”
- “Payments set out in Exhibit B cover all services in the protocol schedule of events.”
- “Sponsor will pay for treatment of all adverse reactions.”
- “Institution will not bill Research Subject for any costs during study.”

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- Questions?

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