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## **Improving Study Budgets by Using Research Billing Rules**

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## 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

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## Objectives

- Review sometimes overlooked Medicare rules which allow billing during research studies
- Understand how to use Medicare rules when budgeting for federally sponsored research studies or investigator-initiated studies
- Discuss how using a breakdown of specific protocol-scheduled items and services that are paid for by the sponsor may be more beneficial than accepting milestone payments
- Examine case scenarios in which billing rules help negotiate more financially viable studies

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## Brief Review of Relevant Medicare Rules for Clinical Research Billing

- Medicare pays for “routine” costs during “qualifying clinical trials”
- Important questions for each study:
  1. Is the study a “qualifying clinical trial”?
  2. If yes, then which services are considered “routine costs”?
  3. Then, for the services that are “routine costs,” do any Medicare rules generally prohibit billing for those services?
    - Note: Medi-Cal and private payers may have different rules on general coverage for items and services and the potential demographics of the study may need to be considered when budgeting.

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## Brief Review of Relevant Medicare Rules for Clinical Research Billing

- Whether a study is a Medicare “qualifying” study depends on what is being studied, the purpose and design of the study, and other factors.
- The CMS Clinical Trial Policy (CTP) and device trial regulations provide criteria on whether a study is qualifying
- Medicare rules defer to the definition of “routine costs” in the CTP to determine what is covered during a qualifying study:
  - Conventional care;
  - Detection, prevention and treatment of complications; or
  - Administration of investigational item

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## Using the Medicare CRB Rules in Budgeting

- Theme: Know what is or is not billable during negotiations and use this information during negotiations to have sponsor pay for the non-billable services
- Common approach:
  1. Develop a preliminary Medicare Coverage Analysis (MCA) when the study is proposed in order to determine what is billable and not billable
  2. Assume that the sponsor is not paying anything for study related services
  3. Compare the preliminary MCA against the proposed offer from the sponsor
  4. Negotiate with sponsor to have all non-billable services paid for by the sponsor

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## Using the Medicare CRB Rules in Budgeting

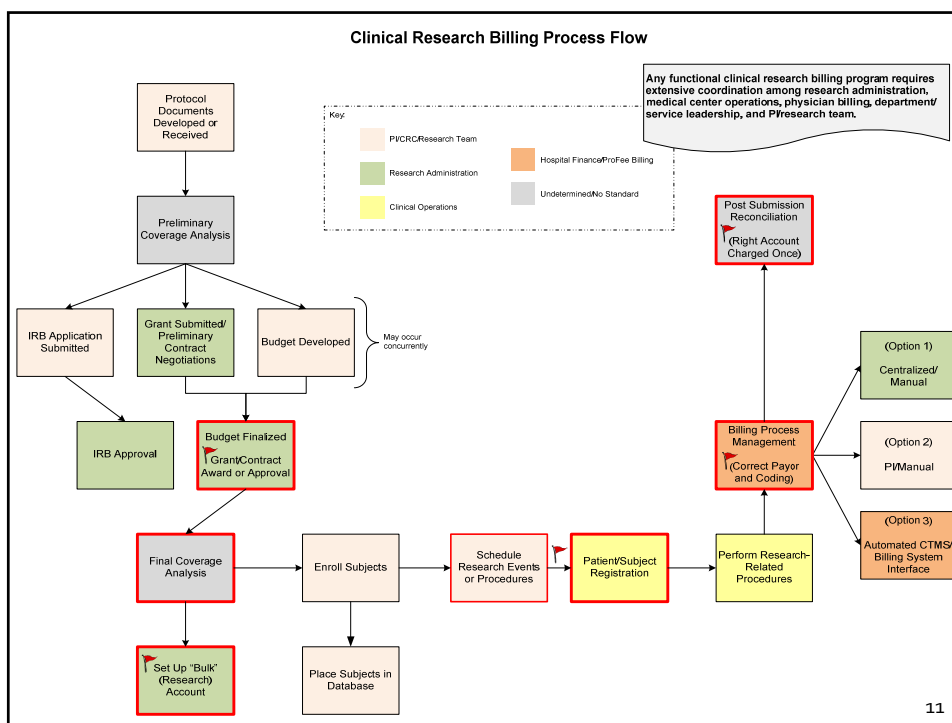
- Operational Considerations:
  - Identify who/where in operations will develop the preliminary MCAs and work with budget negotiators and clinical trial agreement negotiators
    - *(note: workshop will discuss options for who develops MCAs)*
  - Use a consistent format for documenting the reasoning why a service is billable or not billable
  - Keep track of common situations which may not be billable and whether specific sponsors will or will not pay for the service
    - if sponsor has paid in the past, then that is precedent to use in negotiations
  - Consider adopting policy specifying who (or what office) must approve studies with protocol services that are not funded by the sponsor or billable to payors

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## External budgets versus internal budgets

- The “external budget” is usually the compensation arrangement with the sponsor which shows the amount and timing of funding
- Meanwhile, an “internal budget” may be prepared which shows in detail all the costs associated with the study, including not only the protocol services, but also time and effort, and other administrative support costs (e.g., space needs, etc)
- Some organizations require PIs to develop both internal and external budgets
- The MCA format could provide a structure for the initial internal budget and then a simplified version of the internal budget could provide the framework for the external budget associated with the CTA

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## Overlooked Medicare CRB Rules: Administration of Investigational Item

- CMS CTP definition of “routine costs” includes the following:
  - “Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent)....”
- In other words, during qualifying studies, Medicare pays for services that are performed to administer the investigational item
- For drug studies, this typically means administering the drug. For device studies, this typically means the implant of the device.
- Note: If the method of administering the investigational item would not normally be covered outside of a research study, then it will not be covered during a study under the CTP

### Overlooked Medicare CRB Rules: Administration of Investigational Item

- Administration of study drugs is often overlooked as a billable service when negotiating a study budget
- If the CTA or study budget indicates that the sponsor's payment includes the costs for administering the study drug, then the administration is not billable
- Likewise, if the ICF promises not to charge for administering the study drug, it is not billable
- Tip: If the organization desires to bill for the administration of the investigational item, then the CTA/budget should be clear that the sponsorship funds are not paying for this service

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### Overlooked Medicare CRB Rules: Detecting, Preventing & Treating Complications

- CMS CTP definition of "routine costs" includes the following:
  - "[T]he clinically appropriate monitoring of the effects of the item or service, or the prevention of complications ; and...Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications."
- In other words, during qualifying studies, Medicare pays for items and services to detect, prevent or treat complications.
- Note: "Treating" complications is rarely scheduled in the protocol. Treatments of complications will be unscheduled events and need to be flagged in CRB process when they occur. (*Further discussion on unscheduled events in Session 7.*)

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## Overlooked Medicare CRB Rules: Detecting, Preventing & Treating Complications

- Documentation tips:
  - Identify the potential complication the service is designed to detect or prevent.
  - Cite where in the study documents it has been established that the condition is a known potential complication.
  - Note why or how the service is designed to detect or prevent complications.
- A Note on the Medical Record: When the PI charts, the record should indicate that the service is for the clinical management of the patient. If the physician believes that the service may not always be conducted for the clinical management of each subject in the study, then do not consider the service billable in the MCA.

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## Overlooked Medicare CRB Rules: Detecting, Preventing & Treating Complications

- Places which may identify potential side effects
  - Protocol
  - Informed Consent
  - Product Label
  - Drug compendium discussion
  - Investigator's Brochure
- Examples of documenting reasoning:
  - This test is performed to detect kidney dysfunction. The study drug is known to have renal toxicity (Protocol, p. 50)
  - The CT scan at Week 8 is conducted to confirm that study device has not dislodged after placement. (Discussed in Informed Consent on p. 8)

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## Overlooked Medicare CRB Rules: Detecting, Preventing & Treating Complications

Example incorporating Medicare rules (white blood cell differential count):

- “Cetuximab has known hematological toxicities, including: neutropenia, leukopenia, infection, fever and fatigue. (Protocol, pp. 41, 77, 78). This test is being performed to monitor and detect potential complications related to cetuximab. Coverage supported by NCD 190.15.”

Example in which no support exists in the study documents for the service:

- “The protocol indicates that the study drug had no cardio-toxic side effects among the Phase 1 and Phase 2 subjects. The EKG required by the protocol appears to be performed only for data collection purposes. (Protocol, p. 75) This service is not covered by Medicare.”

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## When the study documents are quiet

- If the study documents do not explain well the reason for performing a service, then the PI should consider the following questions to determine if the service would be considered reasonable and necessary:
  - QUESTION 1: Would physician perform this service at the required frequency for a similarly situated 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?
- Note: These questions can also be useful documenting routine costs.

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## Using the MCA as a budgeting tool

- Approach: Use grid to plot out the schedule of events and demonstrate to the sponsor which items and services are not billable
- The next several slides provide examples of how MCA grids may be used in the course of budgeting

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## A hypothetical schedule of events

	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				
Urinalysis	X		X	X			X
Ultrasound				X			X
Patient Diary	X		X	X	X	X	X

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### Preliminary MCA: Assume no sponsorship funds

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

Goal: Negotiate the NBs with the sponsor

M=Billable to Medicare  
NB=Not billable to Medicare

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### Preliminary MCA: Compare to sponsor's "offer"

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

Goals:  
•Turn an NB into an S  
•Consider allocating sponsorship offer to pay for billable services to non-billable services

M=Billable to Medicare  
NB=Not billable to Medicare  
S=Sponsor offer  
(-)=disposition if sponsor were not to pay

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### Final MCA: After Successful Negotiations

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

Outcome: The NBs were negotiated with the sponsor

M=Billable to Medicare  
S=Paid by sponsor

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### Final MCA: After Negotiations When Sponsor Will not Pay for All Non-billable Services

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

Outcome: The PI must find funding for the remaining NBs

M=Billable to Medicare  
NB=Not billable to Medicare

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## Using the MCA for identifying sponsor payments

- Many sponsors want to pay for services on a per patient basis or at milestones
- Consider using the MCA grid as a way to identify the specific services and rates which the sponsor is paying
- Consider using the MCA grid as the basis for the study budget that will become part of the CTA
- (Example on next slide)

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## Using MCA as Break-down of Payments from Sponsor

	Screening	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Every 6 month
Data Collection from clinical care or data collection services	\$50	\$50	\$50	\$50	\$50	\$50	\$50
EKG	\$100	\$100	\$100	\$100			\$100
Drug 123		Provided by sponsor	Provided by sponsor				
Infusion							
Urinalysis							\$50
Ultrasound							
Patient Diary	\$75		\$75	\$75	\$75	\$75	\$75

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## What should go into a final study budget with the sponsor?

- Best practice: As much detail as possible to demonstrate what the sponsor is paying for and to be able to show later that the payments for the specific services are fair market value
- Examples (not exhaustive):
  - Clinical services
  - Data collection services
  - PI time and effort value
  - Research staff value
  - Other support services performed by institution (e.g., pharmacy fees)
  - IRB fees
  - Start-up costs
- And if the sponsor will not agree to all that detail? Then, use the MCA to document how the sponsor's funds will be consistently applied.

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## What if there is no industry sponsor?

- If the study has no sponsor, then the preliminary MCA process helps the department understand what the costs may be for the study
- Decisions can be made as to whether to:
  - charge the subject (which must be disclosed in the “added costs” section of the ICF for those items/services that are provided only because of the subject’s participation and not as part of conventional care)
  - seek additional outside funding
  - cover study deficit with department or other internal funds (beware of cost transfer issues)

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## Using the preliminary MCA for budgeting government-sponsored studies

- Most federal agencies do not coordinate with CMS to determine what is billable or not billable when the agency designs or funds a research study
- Do not assume that unfunded services are automatically billable to Medicare
- Do not assume that Medicare will pay for all “standard of care” services in a federally sponsored study

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## Using the preliminary MCA for budgeting government-sponsored studies

- The preliminary MCA process can be used when budgeting for a government sponsored study: assume the grant pays for no clinical services and determine what could be billed
- When to conduct the MCA: As early in the process as possible!
- Once the grant is awarded: The MCA must be finalized so that the billing tool shows what the grant covers and what is billable

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## Steps in Developing Preliminary MCA & Budgeting

1. Develop grid based on schedule of events and protocol
2. Determine whether a study is a “qualifying” study
3. Identify items and services “hard-wired” free into protocol (e.g., study drug or equipment provided by the sponsor)
4. Determine which items and services are “routine costs”
5. Determine if there are any reasons why routine costs would not be covered by Medicare (e.g., generally not covered)
6. Check proposed sponsor offer to determine if offered budget covers items and services that are not billable
7. Negotiate CTA and study budget
8. Finalize “added costs” section of informed consent
9. Create a “final” MCA

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## Take-away Points

- Leverage the MCA process to assist the budgeting process
- Consider using billing rules to help negotiate the study budget
- Assume sponsor is paying for no services and identify what would be billable and not billable, then work with sponsor on offer to ensure non-billable services are paid
- If there is no outside funding or insufficient sponsor funding, use the MCA process to identify potential losses
- Document reasoning on how determination was made that the protocol service is or is not billable
- A preliminary MCA should only be used in the process for deciding whether to take a study or negotiate a study; a final MCA must be prepared after all the study documents (including budget) are final

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## References for further reading

National Coverage Determination 310.1 (“Routine Costs in Clinical Trials”)

Dilts, D. M., Sandler, A. B., Cheng, S. K., et al. (2009). “Steps and Time to Process Clinical Trials at the Cancer Therapy Evaluation Program.” *J Clin Onc* 27: 1761-1766

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Iltis, AS. (2005) “Third-party payers and the cost of biomedical research.” *Kennedy Inst Ethics J*. Jun; 15(2):135-60.

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## • Questions

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