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**Addressing Specific Billing &
Coding Challenges for Research Billing**

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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

- Discuss implications of non-qualifying determinations
- Explain Medicare clinical research coding and modifier rules
- Discuss the importance of identifying all research study-related encounters
- Review case scenarios for the Q1 versus Qo modifiers
- Examine the impact of how payment by sponsors for specific services affects different PPS settings

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What happens when a study is not a qualifying clinical trial?

- From the current Medicare Clinical Trial Policy (CTP):
 - “Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.” (emphasis added)
- A “qualifying clinical trial” (QCT) is a research study which meets specific criteria under the CTP
 - Note: reference Session 2 and Workshops for more information on QCTs
- The most common reason a research study may not be a QCT is because the study is not designed to investigate therapeutic benefit

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Therapeutic Intent in the CTP

- There are two discussions of therapeutic intent in the CTP:
 - “The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.”
 - “The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes.”
- The first bullet point seems clear that any therapeutic intent is sufficient, but the second bullet point is not clear as to what happens if the primary objective is not to investigate outcomes
 - Note: It is very difficult for Phase 1 studies to meet the second bullet point criterion

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Regional Differences

- When a Medicare policy is not clear, the local Medicare Contractor is allowed to interpret the policy
- Medicare Contractors have been slow to articulate clear rules on what is sufficient “therapeutic intent” in a trial to meet QCT criteria
 - However, there appears to be a consensus that CMS expects the therapeutic intent criterion to be met in the design of the study and not merely by the physician’s intent or on a subject-by-subject basis
- Common approach:
 - If the objectives of the study measure therapeutic benefit (and not merely record anecdotal evidence of benefit), then the study is designed with sufficient therapeutic intent to meet the QCT therapeutic intent criterion

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Impact

- The most important impact of the therapeutic intent criterion on CRB is in Phase 1 drug studies
- Most Phase 1 studies are designed to identify a maximum tolerated dose (MTD) as quickly as possible so that the study may move into Phase 2 and test the benefit
- Many Phase 1 studies are designed with “dose-escalation” so that the subjects receive different doses of the drug in order to find the MTD
- The goal of dose-escalation is not benefit but to identify the toxicities and locate the MTD

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Impact

- If the study employs dose-escalation or is seeking to find the MTD, does that mean the study never has therapeutic intent? NO
- Since CMS does not give clear rules on what constitutes sufficient evidence of therapeutic intent in the design of the study, an institution should document its reasoning why it believes the study is designed with therapeutic intent
- Non-cancer Phase 1 studies: often difficult to document therapeutic intent
- Cancer Phase 1 studies: easier to document therapeutic intent because most cancer studies enroll patients with diagnosed disease in hopes of benefit while identifying MTD

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Approaches for Documenting Therapeutic Intent in the Design of the Study

- Institutions have adopted different approaches for documenting the therapeutic intent in the design of the study, including:
 - If an investigator-initiated study, consider whether protocol can more clearly state potential therapeutic benefit for subjects
 - Cite in the MCA the protocol objective or endpoint that evidences therapeutic intent
 - Confirm with PI the following: Every subject enrolled in the study may potentially benefit from the study drug
 - Have review conducted by a committee of other PIs (some AMCs have established a “Phase 1 Committee” for this purpose)

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What happens if the study is not a QCT?

- The Medicare Program pays for items and services that are “reasonable and necessary to diagnose or treat illness or injury...”
- CMS is allowed to refine its understanding of what is “reasonable and necessary”
- Local Medicare Contractors can further refine CMS’s “reasonable and necessary” policies as long as the Contractor does not contradict CMS
- If there is ambiguity or silence in a Medicare policy, then a provider may bill if Medicare generally pays for the category of item or service and the provider can justify the item or service as “reasonable and necessary” (i.e., medically necessary)

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What is not billable in a non-QCT?

- Services that are done for research purposes only
- Services to administer the investigational item
- The investigational item or service itself
- Services to detect or prevent complications when the subject has no signs or symptoms
- Services that are more than “standard of care”

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What is billable in a non-QCT?

- Services that are being performed which are not necessary for studying the investigational item or service
- Services that are “reasonable and necessary” for all subjects in a study
 - It is vital that documentation support that the service would be reasonable and necessary for all subjects and is not a deviation from what the patient would have received if he/she was not enrolled in the research study
- Note: This is an area of risk in which CMS has not been clear. Developing regular audits of documentation during a non-QCT is best practice

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Avoiding non-QCT problems

- Best practice is to develop an MCA early in the process of a proposed study and identify right away whether the study is or is not a QCT
- If the study is not a QCT, then negotiation posture should be to ask for all protocol services to be paid for by the sponsor
- If the sponsor pays for all protocol services, then the non-QCT problems are mitigated since nothing scheduled for the study should be billed to Medicare
- If negotiations with the sponsor do not succeed in obtaining payment for all protocol studies, then proceed with caution and document reasoning why services would be medically necessary even if the patient was not enrolled in the research study

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Treating Complications During Non-QCTs

- What happens if the study is a non-QCT and the patient experiences complications?
- Medicare covers treatment of complications during a non-QCT:
 - “Medicare covers the routine costs of qualifying clinical trials,...as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.” NCD 3101.1 (emphasis added)
- Medicare covers not only the treatment but the diagnosis of complications during a non-QCT, but patient must have signs and symptoms in for coverage to exist (a general Medicare principle)
- Note: If the sponsor will pay for treatment of complications, or it has been promised free in the ICF, then the CRB process must know of the complications (workshop will discuss ways to identify)

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CRB Coding

- Medicare requires certain codes and modifiers to be used for claims submitted for routine costs during
 - January 18, 2008 Transmittals
 - Q0/Q1 Modifiers (Transmittal 310)
 - Clinical Trial Number Option (Transmittal 1418)
- Status:
 - V70.7 code: required
 - Modifiers: required in outpatient setting
 - Clinical Trial Number: optional
- Note: if there is billing during a non-QCT, then the services would not need the CRB coding because the services would only be billed because they are scheduled for the patient's care and only secondarily may be used for data collection.

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V70.7 Code

- V70.7 is a diagnosis code which means "examination of participant in clinical trial"
- The V70.7 is required for all Medicare claims which contain "routine costs"
- The V70.7 is the provider's attestation that the claim contains routine costs during qualifying clinical trials
- For billing "routine costs," the V70.7 is listed as the secondary diagnosis
- If the V70.7 is listed as the primary diagnosis, then the claim will be denied

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Condition Code 30

- Institutional Inpatient Claims:

“Institutional providers billing clinical trial service(s) must report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer) and a condition code 30 regardless of whether all services are related to the clinical trial or not.”

- Outpatient Claims:

“On all outpatient clinical trial claims, providers need to do the following:

- Report condition code 30,
- Report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer)”

Medicare Claims Processing Manual, Ch. 32, Sec 69.6

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Clinical Research Modifiers

- Medicare CRB Modifiers:

- Q0: “investigational clinical service”

- Q1: “routine clinical service”

- Applied to claim form per CPT code

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The timing of the Research Modifiers

- The research modifiers only apply to the routine costs being billed to Medicare or the rare instances of an investigational clinical service being billed to Medicare
- The research modifiers' timing is triggered by the patient signing a research informed consent form, but only the study-related services require a research modifier
- Services that occur after consenting which are not related to the study, do not require a modifier
- (Also: an encounter that has no relation to the study and contains no "routine costs," does not require a V70.7)

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Q0 Modifier

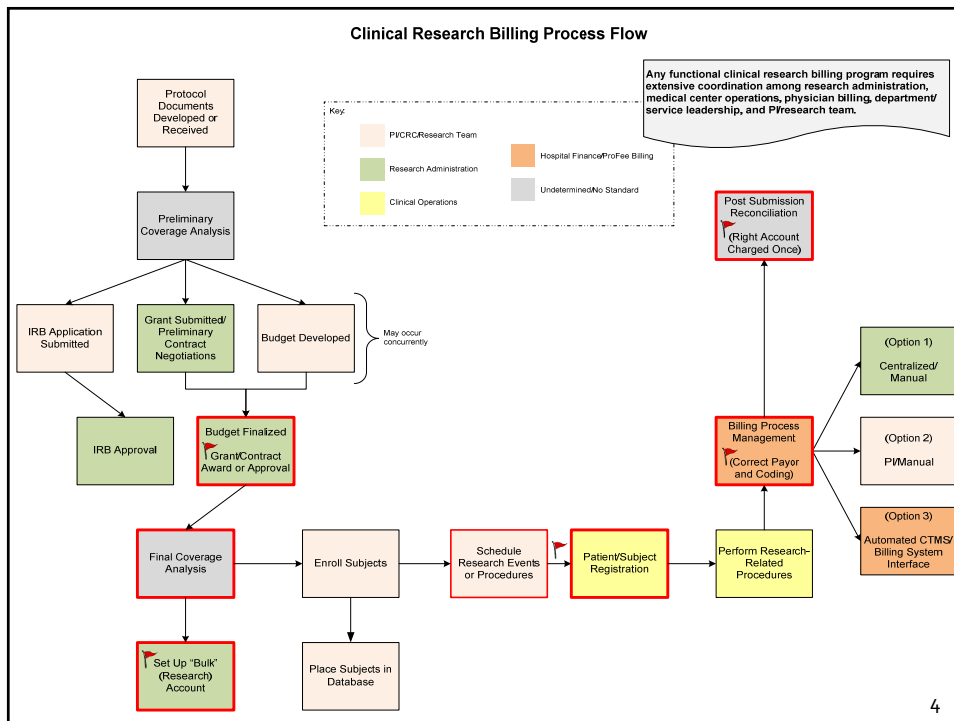
- "Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare."

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Q1 Modifier

- “Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent); clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).”

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Modifiers Examples

- Drug Study:
 - Diagnostic testing: Q1
 - Treating complications: Q1
 - Adminstrating study drug: Q1
 - “Imaging service at Week 8 to determine effectiveness of timing of image”: Q0

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Medicare & the Medical Record

- The Medicare Program requires the following:
 - “The billing provider must include in the beneficiary's medical record the following information:
 - trial name
 - sponsor, and
 - sponsor-assigned protocol number. “
 - “This information does not need to be submitted with the claim but must be provided if requested for medical review. “

Medicare Claims Processing Manual, Ch. 32, Sec. 69.3

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CRB in Different Provider Settings

- Inpatient Cases:
 - Medicare reimburses based on patient's discharge diagnosis (and some other factors) – these are grouped into “Diagnosis Related Groups” (DRGs)
 - Costs are accumulated on the claim form even if the item or services does not impact the DRG payment
 - However, if costs reach a certain level, the inpatient case may be eligible for an “outlier payment” – extra money on top of the DRG payment
 - CRB risk: If an item or service that should not be billed is on the inpatient claim form, it could contribute to the accumulation of costs that could inappropriately trigger an outlier payment

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CRB in Different Provider Settings

- Hospital Outpatient Cases:
 - Medicare reimburses based on bundles of procedures the patient receives – these are grouped into “Ambulatory Payment Classifications” (APCs)
 - Some items, such as drugs, are paid outside of APCs and may be paid closer to a traditional fee-for-service
 - Costs are accumulated on the claim form even if the item or services does not impact the APC payment
 - However, if costs associated with the services bundled into the APC reach a certain level, the APC case may be eligible for an “outlier payment” – extra money on top of the APC payment
 - CRB risk: If an item or service that should not be billed is on the outpatient claim form, it could contribute to the accumulation of costs that could inappropriately trigger an outlier payment or it may trigger an inappropriate payment directly for the item or service

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CRB in Different Provider Settings

- A note on professional fees associated with hospital outpatient services:
 - A hospital outpatient service must be related to physician care in some fashion
 - There will almost always be a physician professional fee associated with the care provided in a hospital outpatient setting
 - The CRB posture is the same for the hospital's outpatient services (facility fees) and the physician's professional fees
 - Coordination is critical: For example, if the sponsor is paying for a chest x-ray, the payment is for the hospital's technical fees and for the radiologist's professional fees
 - The MCA is a way to coordinate the information and maintain consistency

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CRB in Different Provider Settings

- Main points about CRB in different provider settings:
 - Claims forms must be accurate even if specific items and services do not directly impact the payment
 - Hospital and physician CRB claims should be consistent for the services provided in a hospital setting
 - Hospital and physician bills are increasingly audited together by Medicare Contractors and oversight agencies
 - The hospital billing office and the physician billing office are critical members of an academic medical center's CRB initiative and should be in the same room for strategic planning of CRB initiatives

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Take-away Points

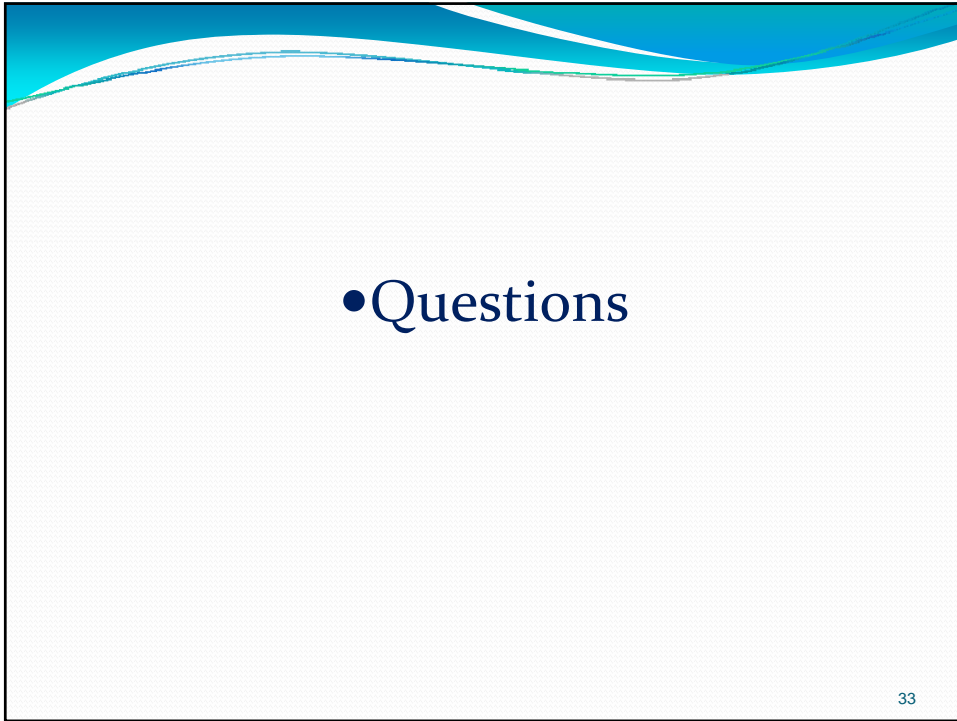
- The MCA process is a critical component of documenting consistent reasoning on qualifying clinical trial determinations
- If the study is not a qualifying clinical trial, then the organization should ask sponsor to pay for everything required by the protocol
- If there are unfunded items and services required by a non-qualifying clinical trial protocol, then think through whether the services are “reasonable and necessary” for all subjects and would be necessary to treat the patient even if the patient was not on the study
- The CRB process must include a point in the process when the Medicare clinical research codes are added
- Utilize MCAs to ensure that the hospital and physician billing is consistent during the CRB process

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References for further reading

- CMS National Coverage Determination 310.1 (“Routine Costs in Clinical Trials”)
- Social Security Act, Sec. 1862(a)(1)(A)
- Medicare Claims Processing Manual, Ch. 32, Sec. 68 & Sec. 69
- CMS MLN 5790 (“Use of an 8-Digit Registry Number on Clinical Trial Claims”)
- CMS Transmittal 1518 (“New HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies”) (January 18, 2008)

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•Questions

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