Medicare's Impact on Cardiology Drugs and Devices During Clinical Research

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Overview

- Theme: Understanding Medicare reimbursement helps in budgeting sponsored clinical research, planning the financial viability of investigator-initiated studies, staying compliant with the law.

- Outline:

1. Why clinical research billing rules are important for investigators

1. High-level review of the basic Medicare rules for clinical research

1. Medicare & Cardiology Research

Hypothetical Study

	Screening	Procedure	Day 7	Day 30	Every 6 months for 3 years
CBC	X		X	X	X
EKG	X	X			
Device		X			
TTE		X	X	X	X
TEE	X	X	X		

Why?

- Audits & Investigations
- Medicare data mining of research billing data
- Industry expectations
- Heightened stakeholder scrutiny
- Confronting historical decentralization of research in the U.S.

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

Documents Used in Billing Audits by Government

1. Protocol
2. Funding Information:
   - Contract/Budget
   - NOGA
   - Other financial sources
   - Allocation through internal budgets
3. Informed Consent
4. FDA Documents
   - IND application status (drugs)
   - IDE category assignment (devices)

Achieving Compliance With Research Billing Rules

- Coordination of study information
- Communication of study information
- Clarity in study documents
- Understanding the background of the billing rules

Recent Medicare Developments

- Monthly data mining by CMS began April 2008
- Claims that “voluntarily” place clinicaltrials.gov on claim form are sent to the “Medicare Common Working File” (CWF)
- Monthly CWF generates report by clinicaltrials.gov number on all claims filed throughout country

Why Follow Medicare Rules?

- Medicare is the driver of reimbursement rules in the United States
- Not practical to budget on non-Medicare rules, because Medicare has “most favored nation” rule that if any Medicare patient is enrolled in the study, the “best deal” must be given to the Medicare patient.
- Medicare rules for research coverage are being adopted by commercial payors.
- Many States require commercial payors to follow rules similar to Medicare.
- Sponsors expect use of Medicare rules for budgeting; creates level playing field.

3 Myths About Medicare & Clinical Research

1. Myth: Medicare pays for standard of care during research studies

   - Reality: Medicare pays for “routine costs” during “qualifying clinical trials.”

3 Myths About Medicare & Clinical Research

2. Myth: Medicare is a public health program that invests in scientific progress

   - Reality: Medicare is an insurance program created by Congress to pay for acute and chronic care

3 Myths About Medicare & Clinical Research

3. Myth: NIH, Co-op Groups & CMS coordinate with each other

Important Medicare Basics

- 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

Important Medicare Basics

- Medicare is a complex blend of medical necessity, social policy, CMS budget, regulators' bias, and politics – and rules use clinical words drafted by lawyers!

- Medicare can use words that are also used clinically but have a different meaning for Medicare.

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

Structure of Medicare

- Medicare is a federal program administered through private contractors
- Medicare Administrative Contractors (MAC) pay claims on behalf of Medicare
- If CMS has not issued a rule on coverage of an item or service, then the MAC can issue its own rule
- MACs can (and do) disagree with each other
- Result: Medicare coverage differs by region

Maryland Medicare Contractor

MAC Conversion:

- Same contractor for Part A as Part B
- Maryland conversion: July 11, 2008
- Region 12: MD, PA, DC, NJ, DE

Region 12 MAC:

- Highmark Medicare Services, Inc.
- Highmarkmedicare.com

Various Medicare Billing Rules Relevant to Clinical Research

- Clinical Trial Policy (CTP)
- Device Trial Coverage Regulations
- National Coverage Determinations
- Local Coverage Determinations

Medicare Clinical Research Coverage

- Medicare requires a three-part conceptual process for clinical trial 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?

In order to bill Medicare…..

- √ Study must "qualify" coverage
- √ Service must meet definition of "routine cost"
- √ Medicare must normally pay for the service outside a clinical trial

Initial Qualifying Question

- Is the study funded by the federal government?
  - Use the CTP two part test
- Is the study a drug study?
  - Use the CTP two part test
- Is the study a device study?
  - Use device trial coverage rules: coverage depends on FDA status of device being studied
- Is the study an observational study?
  - Regions differ: In Maryland, medical director currently needs to be consulted

CTP Qualifying Analysis

- Part 1 – The study must be one of the following:

1. Studies funded by NIH, CDC, AHRQ, CMS, DOD, and VA
2. Studies supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
3. Studies being conducted under an IND application; or
4. IND exempt studies

CTP Qualifying Analysis

- Part 2 – All three of the following must be met:

1. The study must investigate an item or service that Medicare pays for
2. The study must enroll patients with diagnosed disease
3. The study must have therapeutic intent

Device Trial Qualifying Analysis

- IDE Category A devices: Yes, with Medicare medical director approval if used in “immediately life threatening disease or condition”
- IDE Category B devices: Yes, with Medicare medical director approval
- HUD: Only if approved by Medicare medical director
- Post-marketing approval FDA-required studies: Yes, with Medicare medical director approval
- Off-label use of FDA-approved device: Generally, no; needs IDE categorization

Approval by Medicare Medical Director

- Device trials must be approved by Medicare medical director
- Medicare medical director has discretion to approve device trial or not approve
- When Medicare medical director approves a device trial, the study qualifies for coverage but all Medicare rules still apply – many services, including the main procedure may not be covered by Medicare
- Medical directors can disagree on approval – Medicare medical director can impact budget and financial viability of study

Approval by Medicare Medical Director

- Approval needed for both Part A & Part B – consolidated now in Maryland to one Medicare medical director

- Even when device is provided without charge, Medicare medical director must still approve study for "routine costs" to be billable
  - Medicare Claims Processing Manual: "Providers receiving the device free of charge must bill the IDE charges as non-covered"

Clinical Research "Routine Costs"

- CMS considers "routine costs" to be:
  - Conventional care
  - Detection, prevention and treatment of complications
  - Administration of investigational item
- Audit Question: Will the item or service be used for the clinical management of every patient enrolled in the research study?
  - If "yes," then item or service is a routine cost.

What is “conventional care”?

- Conventional Care
  - Goal: Identify objective sources
  - Medical Societies; Professional Associations
  - Medical Literature (articles & textbooks)
  - guidelines.gov
  - Example: ACC/AHA guidelines

Conventional Care Guidelines

- Example:
  - "ACC/AHA/ESC Guidelines for the Management of Patients with Atrial Fibrillation"
    - Atrial fibrillation: "As an alternative to anticoagulation prior to cardioversion of AF, it is reasonable to perform TEE in search of thrombus in the left atrium or left atrial appendage."
    - Note: Medicare rules debate whether to proceed directly to TEE.

If no specific coverage rule is identified

- "Reasonable & Necessary" Rule:
  - 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?
- If "yes," then Medicare will cover the item or service if no other rule limits or prohibits coverage.

"All other Medicare rules apply"

Last Step: Any item and service that is a "routine cost" must be reviewed against normal Medicare rules to determine whether coverage would exist outside the trial

Medicare & Cardiology Research

1. Medicare coverage for study drugs during IND-exempt research

2. Examples of common Medicare rules in cardiology research

3. Medicare coverage of diagnostic procedures used to detect side effects and measure efficacy of cardiology study devices

Applying Medicare Rules

- Awareness of national and local Medicare rules helps understand when services may be conventional care (standard of care) but Medicare does not pay for them.

- When Medicare does not pay, it does not mean that the service should not be ordered or performed – it means Medicare does not pay.

IND-exempt research

- Many investigator initiated studies may qualify for coverage if use of study drug meets IND-exemption criteria (21 CFR 312.2(b)(1)):

1. **The study is not intended to support FDA approval of a new indication or a significant change in the product labeling.**
2. **The study is not intended to support a significant change in the advertising for the product.**
3. **The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that *significantly increases the risks* (or decreases the acceptability of the risks) associated with the use of the drug product.**
4. **The study is conducted in compliance with IRB and informed consent regulations.**
5. **The studies will not be used to promote unapproved indications.**

Examples of Common Medicare Rules in Cardiology

- Lipid Testing: NCD 190.23 (national rule):
  - "Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc."
    - Note: "screening" is Medicare-speak for "no signs or symptoms."

Examples of Common Medicare Rules in Cardiology

- Lipid Testing: NCD 190.23 (national rule):
  - Lipid panel or measured LDL covered "up to 6 times the first year of monitoring dietary or pharmacologic therapy."
  - "The LDL cholesterol or total cholesterol may be measured three times per year after treatment goals have been achieved."
  - "When monitoring long term anti-lipid dietary or pharmacologic therapy…, it is reasonable to perform the lipid panel annually."

Examples of Common Medicare Rules in Cardiology

- "Approved Drugs & Biologicals": LCD L27473 (local rule)
  - Coverage of off-label use of drugs is deferred to the local Medicare medical director.
  - LCD addresses coverage for off-label use of non-cancer drugs.
  - "If a use is identified as not indicated by CMS or the FDA or if a use is specifically identified as not indicated (in one or more of the three compendia [listed in the LCD] or if it is determined (based on peer reviewed medical literature that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered."
  - "Physicians…must be able to produce copies of relevant supporting full-text articles, guidelines, and/or supporting literature when an unlabeled use does not appear in at least one of the three major compendia…Abstracts, opinions, or book chapters are not acceptable."

Examples of Common Medicare Rules in Cardiology

- Transesophageal Echocardiography: LCD L27535 (local rule)
  - "Coverage for TEE is allowed and indicated…when TTE has not established the diagnosis, or in a patient where TTE is felt not to give adequate information."
  - TEE as an initial test is only covered for certain specific suspected conditions.
  - Specific rules for coverage listed for: valvular heart disease; intraoperative use; cardioversion

Examples of Common Medicare Rules in Cardiology

- Transthoracic Echocardiography: LCD L12914 (local rule)
  - Rule focuses on frequency coverage for 18 specific conditions.
  - Ventricular Function/Cardiomyopathies/Heart Failure: **"**In the absence of significant changes in signs, symptoms, or treatments, it is not generally medically necessary to repeat TTE more frequently than annually."
  - Prosthetic Heart Valves: "Reassessment following convalescence (3-6 months) is appropriate. Thereafter, absent discretely defined clinical events or obvious change in physical examination findings, annual stability assessment is considered medically reasonable and appropriate."

Side Effects

- Items and services related to detecting, preventing and treating side effects of study item are covered if no rule limits or prohibits coverage.
- Is the diagnostic service medically necessary to detect or prevent a complication? (if yes, then covered)
- Is there a nexus between the test and potential known side effect? (if yes, then covered)
- Example: Imaging tests for implanted devices (e.g., stents)
  - X-ray; CT; MRI
  - If the different images are needed of the same body area for different purposes, then each is covered – but reason must be documented in the medical record