

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



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# Medicare Coverage Analysis?



Required for all clinical trials in which tests, procedures, and interventions associated with a clinical trial are invoiced to third party payers.

# Medicare Coverage Analysis?



- Process
- Determine the underlying eligibility of the study for Medicare coverage
- Review clinical events specified in the protocol to determine which can be reimbursed by Medicare.

# History



- October 17, 2007 Centers for Medicare & Medicaid Services (CMS) issued the Clinical Trial Policy (CTP) in the form of a National Coverage Determination
- National Coverage Determination (NCD 310.1) declared Medicare covers routine costs incurred during “*qualifying*” Clinical Trials

# Structure of Medicare



- Medicare is a federal program administered through private contractors
- **Center for Medicare & Medicaid Services (CMS)**
- **Regional Based Medicare Administrative Contractors (MAC)** pay claims on behalf of Medicare
- **MAC** for Texas – Novitas Solutions

# Medicare- vocabulary



- **CTP-Clinical Trial Policy-** Medicare covers routine costs during qualifying clinical trials (NCD 310.1)
- **Modifier Code V70.7** - indicates claim occurs during a clinical trial.
- **Modifier Condition Code 30-** Qualifying Clinical Trial
- **Both need to be on claim forms to Medicare**

# National Coverage Determination?



- An NCD sets forth the extent to which Medicare will cover specific services, procedures, or technologies on a national basis.
- Cited From [CMS.gov](https://www.cms.gov)

# Local Coverage Determination (LCD) ?



- Policy created by Medicare Administrative Contractor (MAC).
- LCDs are carrier developed coverage policies, pertaining to services or items not addressed in NCDs or program manuals.

# Why Follow Medicare Rules?

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- **True or False:** Medicare pays for STANDARD OF CARE during research studies
- **False:** Medicare pays for “**Routine Costs**” during a “**Qualifying Clinical Trial.**”

# Important Medicare Basics



- 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

# Medicare Rules Relevant to Clinical Research



- Clinical Trial Policy- A National Coverage Determination (NCD 310.1) delineating routine costs in a qualifying Clinical Trial final version 2008
- Device Trial Coverage Regulations-
  - Regulations found in Medicare Benefit Policy Manual, Ch. 14

# What is a Qualifying Clinical Trial?



- 3 “necessary requirements”

AND

- Is 1 of 4 types of trials “deemed” to have 7 “desirable characteristics”

# Determining a Qualifying Clinical Trial



Must be one of **4 types of trials** deemed to meet 7 desirable characteristics

Funded by NIH, CDC, AHRQ, DOD, VA

or

Supported by center or cooperative group funded by the NIH, CDC, AHRQ, DOD, VA

or

Conducted under an IND reviewed by the FDA

or

IND exempt under 21 CFR 312.2(b)(1)



Must meet all **three necessary requirements**

Evaluate an item or service that falls within a Medicare Benefit Category

Have therapeutic intent

Enroll patients with diagnosed disease

# “DEEMED” STUDIES



1. Is the study funded by the federal government? (CDC, NIH, AHRQ, CMS, VA)
2. Is the study supported by centers or cooperative groups that are funded by (CDC, NIH, AHRQ, CMS, VA)?
3. Is the study being conducted under an IND application
4. IND exempt studies

# Part 2-3 Necessary “Requirements”

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1. The study must investigate an item or service that Medicare pays for (falls in a benefit category)
2. The Study must enroll patients with a diagnosed disease
3. The study must have therapeutic intent

# Requirement 1

## Benefit Category

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- The investigational item or service falls within a Medicare benefit category.
- This means that the it must be something Medicare pays for generally.
- Ex 1. Medicare pays for a Ct scan under certain circumstances- therefore it falls in a benefit category.
- Ex 2. Medicare pays for most chemo therapy drugs- therefore the investigational item falls under a benefit category.

# Requirement 2

## Therapeutic Intent



- CMS has not defined what is sufficient for therapeutic intent
- The trial must not be designed to exclusively to test toxicity or disease pathophysiology
- Principally an issue for Phase I drug studies

# Requirement 3

## Diagnosed Disease



- Medicare only covers items and services that are reasonable and necessary to “diagnose or treat” illness or injury
- CTP: Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group
- Preventive care if patient is not diagnosed with any disease is not covered

# Routine costs



- CMS considers “Routine Costs” to be:
  - Items and services that would be provided to a similar patient for similar therapy outside a clinical research study (Conventional Care)

# Routine Costs



- Detection, prevention and treatment of complications (adverse events)
- Administration of the investigational item
- Do not include items or services that are for research only

# Conventional Care Guidelines

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- This clinical trial will compare traditional therapy for treating acute myeloid leukemia to traditional chemotherapy plus the addition of the investigational drug. The investigational drug is FDA approved for treating patients with CD33 positive acute myeloid leukemia in relapse.
- A chest x-ray is ordered per protocol to be performed at the baseline visit.

# Justification



- A chest X-ray is recommended prior to treatment. (Protocol, p. 57). The investigational drug can cause damage to lung tissue.
- However, LCD (#), will not provide coverage for a chest x-ray absent signs and symptoms.

# Local Coverage Determination (Novitas Solutions)



- Each Medicare contractor has the discretion to establish which services are reasonable and necessary and therefore covered as a Medicare benefit. These coverage policies are issued in a document called a Local Coverage Determination

# Conventional Care #2



1. The protocol requires a CBC/Diff/Plts to be performed at Baseline, Prior to administration of the investigational drug and at the end of the study

# Justification



- Acute myeloid leukemia is a disease that affects the blood cells. An initial CBC is conventional care according the NCCN Guidelines. Additionally, all of the study drugs used during induction cause myelosuppression. (Informed Consent, pp. 10-12 ). This test is performed both to manage the patient's disease state, but also to detect and treat complications related to the use of these study drugs. (NCD 310.1).

# Where Do You Start?



Protocol

Budget  
Template

CPT Codes

Cost





# Why Is This Important?



- Office of the Inspector General (OIG) FY 2010 federal budget requests over \$2 billion for fraud and abuse audits
- Medicare “double billing” has been the subject of numerous OIG/DOJ investigations/settlements
- From a research and business perspective, it is important to determine conventional care vs. “research only” items and services

# Why Follow Medicare Rules?

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- Medicare is the driver of reimbursement rules in the United States
- Not practical to budget on non-Medicare rules
- Medicare is considered the “Golden Standard by which many commercial payers base their coverage decisions, including clinical research services
- Any Medicare patient enrolled in the study must be given the best “deal”

# The False Claims Act



To violate the False Claim Act, a provider must have demonstrated:

- Knowledge
- Deliberate ignorance
- Reckless disregard

# False Claims Act(con't)



- No proof of specific intent to defraud is required in order to violate
- Penalty:
  - \$5,500-\$11,000 for each false claim
  - Possible triple charges
  - Possible criminal charges
  - Possible exclusion from Federal Healthcare Programs

# Examples of Possible Violations



- Claims for services never provided
- Altering diagnosis for payment purposes
- Claims for higher levels of service than documented
- Claims for services provided by unlicensed individuals
- Claims for service provided by the Sponsor

# OIG/DOJ Settlements and Fines

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- Rush University Medical Center- \$1 Million settlement for improperly billing Medicare for physician and hospital out-patient research services
- University of Alabama @ Birmingham-\$3.35 Million settlement for falsely billed researchers time spent on patient care.

**WRONG**  
is **WRONG,**

even if *everyone*  
is doing it.

**RIGHT**  
is **RIGHT,**

even if *no one*  
is doing it.

# Conclusion



- UT Health will begin MCA with Internal Medicine first
- Remaining departments over the next year.

# For Questions please contact:



- Clinical Trial Resource Center
- 713-500-3578
- <http://www.uthouston.edu/ctrc/index.htm>

THANK YOU!

