Clinical Research Finance

Medicare Coverage Analysis

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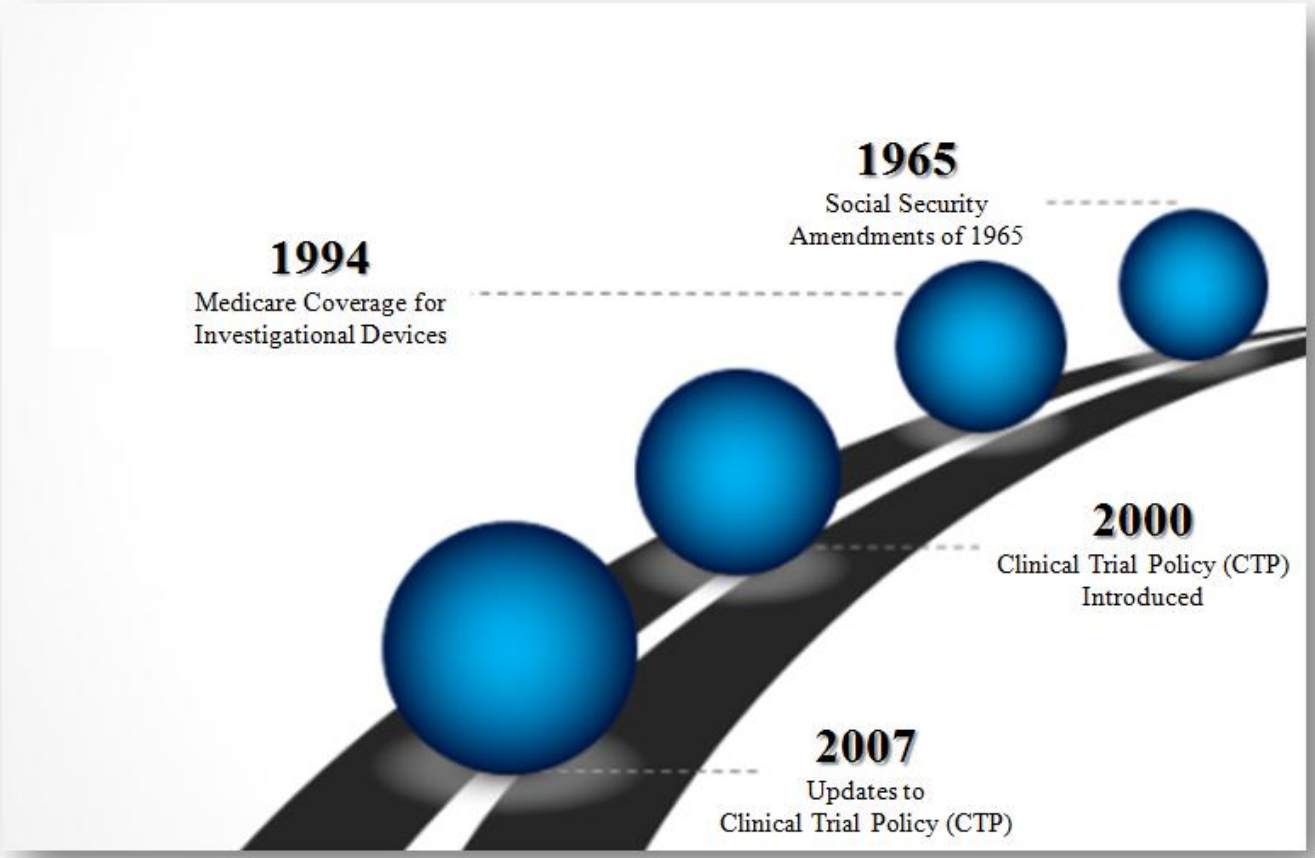
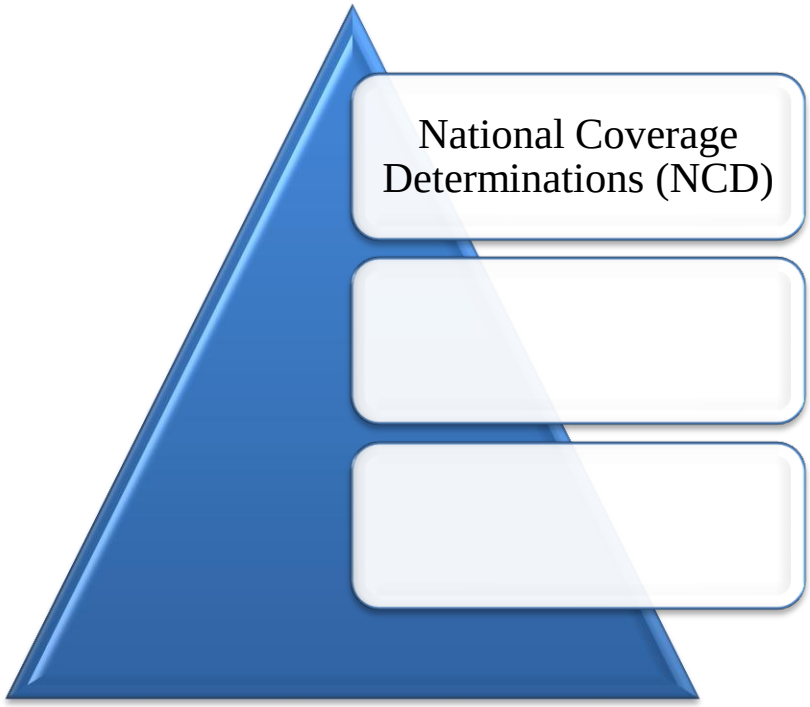
Historical Context



NCDs

Who Makes Medicare Coverage Decisions?



1. Determine nationwide Medicare coverage for:
   - Medical items
   - Services
   - Treatment procedures
2. Developed by CMS
3. Created through evidence-based process

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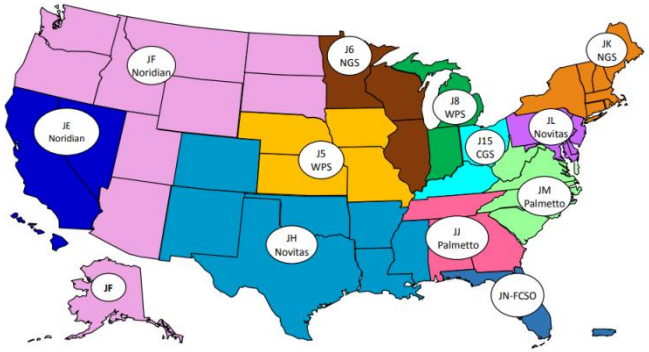
LCDs

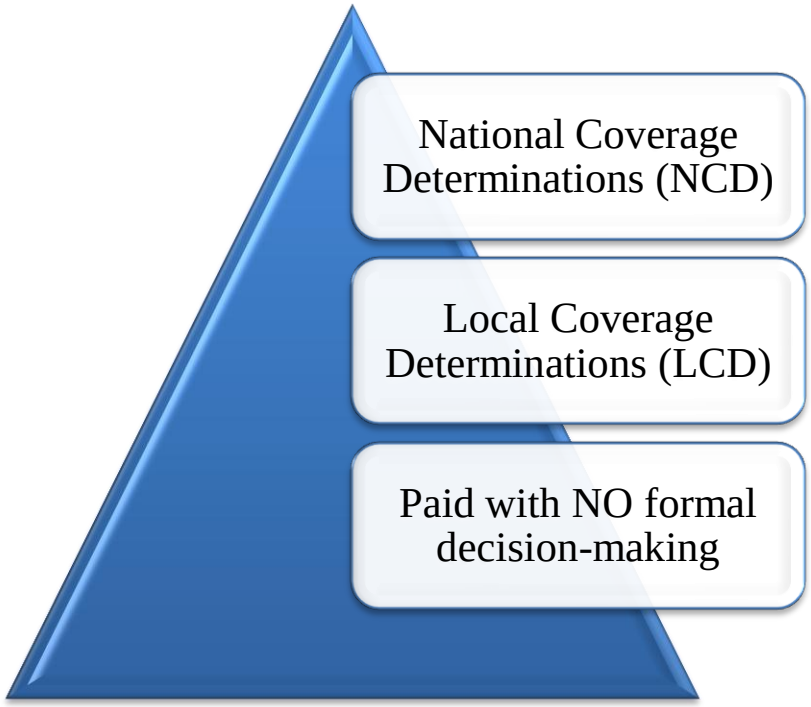
Who Makes Medicare Coverage Decisions?



1. If item or service is new, or not defined by an NCD, the local contractor is responsible for the decision for coverage
2. LCD determination is always based on medical necessity
3. LCDs only apply to the area served by the contractor
4. LCDs may vary region to region

Provider

Who Makes Medicare Coverage Decisions?



1. If no NCD or LCD determination and patient desires treatment, physician must answer all three questions for research:
    1. Would physician perform this service at the required frequency for a patient not in a study?
    2. Is physician able to document medical necessity of the item or service in the medical record for every research participant?
    3. Will physician use the test for the direct clinical management of every patient enrolled in the research study?

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What is a Coverage Analysis?

- A document that identifies and analyzes who the appropriate payor is for each item and service required by a clinical research protocol
  - Sponsor
  - Medicare
  - Third party payor

Medicare Billing Rules

- General Rule: Medicare will pay for the “routine costs” of “qualifying clinical trials”

Medicare Billing Rules

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- What is a “qualifying clinical trial”?

- The subject or purpose of the trial must be the evaluation of a Medicare Benefit Category

Medicare Billing Rules

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- What is a "qualifying clinical trial"?

- The trial must have therapeutic intent; it cannot exclusively text toxicity or disease pathophysiology

Medicare Billing Rules

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- What is a "qualifying clinical trial"?

- Must enroll patients with a diagnosed disease

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Medicare Billing Rules

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- What is a "qualifying clinical trial"?

- Trial must be "deemed"
  - Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA
  - Trials supported by centers or cooperative groups funded by one of the above governmental entities
  - Trials conducted under an IND reviewed by the FDA
  - Drug trial that are exempt from having an IND under 21 CFR 312.2(b)(1)

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Medicare Billing Rules

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Pop Quiz

- The trial is sponsored by NCI and is evaluating the safety and toxicity of a drug in patients with metastatic adenocarcinoma of the colon

Routine Cost

Routine Costs Are:	Routine Costs Are Not:
• Items/services that are typically provided absent a clinical trial • Items/services required solely for the provision of the investigational item • Clinically appropriate monitoring of the effects of the item or service, or the prevention of complications • Items/services needed for the reasonable and necessary care arising from the provision of the investigational item/service, in particular for the diagnosis or treatment of complications	• The investigational items or service itself, unless otherwise covered outside the clinical trial • Items and services provided solely for the purpose of research • Items or services provided by the Sponsor free of charge

Pop Quiz

- Patients with colorectal cancer enrolled in a trial receive the experimental drug combined with the standard regimen of FOLFOX. The intravenous infusion of the experimental drug is considered a routine cost.

TRUE

- The Medicare Clinical Trial Policy covers “items and services required solely for the provision of the investigational item or service”
- Covers the tubing, fluids and nursing needed for the administration of the experimental drug

What about Non-Drug Trials?

- Device Trials
  - Coverage for items/devices on device clinical trials depends on whether the device itself is covered

Significant Risk Devices	Non-Significant Risk Device	Humanitarian Use Device

• Category A
  • Experimental; safety and effectiveness not established
  • Never covered by Medicare
• Category B
  • Non-Experimental; safety and effectiveness established
  • Local Medicare contractor makes determination
	• Responsibility of Institutional Review Board (IRB) to make risk determination
	• Treated as Category B device for coverage determination
		• Sponsor needs to demonstrate effectiveness
		• Treated as Category B device for coverage determination

- Surgical Trials
  - Do not fit drug or device guidelines
  - Appeal to the local Medicare contractor

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