



**RESEARCH  
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**The Medicare Local Coverage  
Determination Process  
and Clinical Trials**

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## What the Law says...

### SSA 1862(a)(1)(A)

- **“No payment may be made under Part A or Part B for any expenses incurred for items or services...which...are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”**

## What the Law says...

### 42CFR411.15(a)(1)

#### Excludes from coverage:

**“Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury.”**

## What the Law says...

**SSA 1142(a)(1)(A) provides authority for DHHS to “conduct and support research with respect to the outcomes, effectiveness, and appropriateness of health care services...”**

**SSA 1862(a)(1)(E) excludes “research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section”**

## What is Medical Necessity?

- **“Medical Necessity” is defined as: “Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease or its symptoms in a manner that is in accordance with medical practice clinically appropriate in terms of type, frequency, site, and duration; and not primarily for the convenience of the patient, physician, or other health care provider.”**

(AMA House of Delegates, 12/9/98)

## What is Screening?

- **“Screening” is defined as: “Health care services or products provided to an individual without apparent signs or symptoms of an illness, injury, or disease for the purpose of identifying or excluding an undiagnosed illness, disease, or condition.”**

(AMA House of Delegates, 12/9/98)

## Local Coverage Determinations (LCDs)

- **An LCD is a decision by a Medicare contractor... whether to cover a particular service on an contractor-wide... basis in accordance with Section 1862(a)(1)(A).**

(Adapted from CMS IOM Publication 100-08,  
Chapter 13, Section 1.3)

## Local Coverage Determinations (LCDs)

- **“LCDs... are administrative and educational tools to assist providers in submitting correct claims for payment.”**
- **“LCDs consist of only ‘reasonable and necessary’ information.”**
  - **Criteria (indications and limitations) for reasonable and necessary tests, items and services;**
  - **ICD-9-CM codes for tests, items, services;**
  - **Documentation requirements.**

(CMS IOM Publication 100-08, Chapter 13 Section 1.3)

## Supplemental Instructions Articles

- **Contain coding guidelines and other instructions not related to medical necessity**
- **Not every LCD will have a related SIA**
- **An SIA may be published independently of an LCD**

## Development of LCDs

- **Reasons for LCD development:**
  - **Data shows utilization aberrancy**
  - **High dollar/high volume;**
  - **Deviation from other states;**
  - **Widespread increase in frequency, charges, etc.**
  - **New Technology / New Procedure / New Drug**
  - **Claims Processing Automation**
  - **Template Policy**
  - **CMS Directive**

## Development of LCDs – External Comment

- **Contractor Advisory Committees (CAC)**
  - CMS IOM Publication 100-08, Chapter 13, Section 7.4.1(C) instructs contractors to solicit comments and recommendations on the draft LCD and get input from at least:
    - Groups of health professionals and provider organizations that may be affected by the LCD
    - Representatives of relevant specialty societies

## Development of LCDs – External Comment, cont.

- Other intermediaries/carriers
- QIOs (formerly known as PROs) within the region
- Other contractor medical directors (CMDs) within the region
- Representatives from state medical societies and medical practice associations
- General public
- The CMS regional office

## Development of LCDs – External Comment, cont.

- **Public comment**
  - **Draft policy is posted on the CMS coverage database and the National Government Services Web site for 45-day public comment period**
  - **Public open meeting**
    - **Information on National Government Services Web site**
    - **Interested parties may present scientific information**
    - **Meeting is held 3-4 times per year in various National Government Services locations**

## Development of LCDs – External Comment, cont.

- **All CAC, and public comments are considered.**
- **Substantial changes require additional formal comment period.**
- **Policy is revised as needed.**
- **Medical Director makes final determination for policy content.**

## Publication of LCDs

- **LCD Notice Process**
  - Medicare *Program Integrity Manual* (Chapter 13, Sec. 7.4.3) requires a minimum notice period of 45 days.
  - LCD becomes effective 45 days following publication on the NGS Web site.
  - Comment and response articles are published on NGS Web site

## National Coverage Determinations (NCDs)

- **Nationwide coverage**
- **Published as program instruction and on the CMS and NGS Web sites**
- **Are binding on all contractors, PSCs, QIOs, ALJs and others**
- **Can be appealed**

## CMS Clinical Trials Policy (NCD)

- **President Clinton’s executive order in 2000 directed CMS to cover routine costs in clinical trials for Medicare beneficiaries. CMS’ Clinical Trials NCD set forth the rules for implementation of this executive order.**
- **For approved clinical trials, Medicare covers the “routine costs” and the prevention, diagnosis, and treatment of complications.**
- **Within Medicare approved clinical trials, Medicare covers all items and services that would otherwise be available to the Medicare beneficiary.**

## CMS Clinical Trials Policy (NCD)

- **Items not covered in a clinical trial:**
  - **The investigational item or service itself, unless otherwise covered outside the clinical trial**
  - **Items and services provided solely to satisfy data collection and not necessary for clinical management**
  - **Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial**

## CMS Clinical Trials Policy (NCD)

- **“Routine costs” include:**
  - Items or services typically provided absent a clinical trial (e.g., conventional care)
  - Items or services required solely for the provision of the investigational item or service
  - Clinically appropriate monitoring of the effects of the investigational item or service
  - Prevention of complications,
  - Items or services for reasonable and necessary care arising from the provision of an investigational item or service, especially for the diagnosis and treatment of complications

## CMS Clinical Trials Policy (NCD)

- **Local Coverage Determinations (LCDs)**
  - CMS Clinical Trials NCD “does not withdraw Medicare coverage for items and services that may be covered *according to* local medical review policies (LMRPs).” (emphasis added)

## Clinical Trials Policy – Other Coverage Provisions

- For non-covered items and services, including items and services for which payment is statutorily prohibited, Medicare covers only the treatment of complications...
- For investigational items and services in a qualifying clinical trial not covered by virtue of a NCD, the routine costs will still be covered

## 4 Requirements for Coverage

- The trial must evaluate an item or service that falls within a Medicare benefit category.
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have a therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease, not healthy volunteers.
- Trials of diagnostic interventions may enroll healthy patients as a control group.

## 7 Desirable Characteristics of Clinical Trials

- Tests whether the intervention potentially improves the participants' health outcomes
- Is well supported by available scientific literature, or is intended to clarify... the health outcomes of interventions already in common clinical use
- Does not unjustifiably duplicate existing studies
- Design is appropriate to answer the research question
- Is sponsored by a credible organization or individual
- Is in compliance with Federal regulations on protection of human subjects
- All aspects are conducted according to the appropriate standards of scientific integrity

## Qualification Process for Clinical Trials

- **Self-certification**
  - A multi-agency Federal panel will establish qualifying criteria for clinical trials eligible for Medicare coverage of routine costs. The principal investigator will certify the trial meets the criteria and enroll the trial in the Medicare Clinical Trials Registry.
- This process is not yet in place.

## Qualification Process for Clinical Trials

- **Trials that are deemed to be automatically qualified:**
  - Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
  - Trials supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
  - Trials conducted under an investigational new drug application (IND) reviewed by the FDA
  - An IND exempt drug trial under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the self-certification process is in place.

## Coverage with Evidence Development

- **CMS, through its NCD process, may establish clinical trials to determine whether certain items and services, for which there is some evidence of significant clinical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination. Such services are only reasonable and necessary when provided in a clinical trial defined in the NCD.**

## Coverage for Non-deemed Trials

- **“Trials that do not meet the existing criteria for deemed trials should contact their local Medicare contractors to determine whether items and services will be covered in that geographic area.”  
(CMS Final Decision for Clinical Trial Policy Q’s and A’s)**

## LCDs & Clinical Trials Policy

**QUESTIONS ?**