Course Objectives

- Understand CMS coverage requirements for Medicare approval to bill for routine care for patients enrolled in an IRB-approved clinical trial
- Understand DUHS policy and procedures for billing for services provided to patients enrolled in an IRB-approved clinical trial
- Understand Category A vs Category B Investigational Device Exemption (IDE) definitions under CMS and FDA regulations

Social Security Act – Medicare Rules

Sec. 1862. Exclusions From Coverage And Medicare As Secondary Payer

SEC. 1862. [42 U.S.C. 1395y] (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

- (1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member
CMS’ Coverage Rules

1. Benefit category

The scope of benefits under Part A and Part B is defined in the Act. See sections 1812 (scope of Part A), 1832 (scope of Part B), and 1861(s) (definition of medical and other health services).

(Federal Register / Vol. 68, No. 187 / Friday, September 26, 2003 / Notices)

2. 100% non-covered statutory exclusions

Items and 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 are not covered

(CMS Pub 100-2, Chapter 16 lists excluded services)

3. Medically reasonable and necessary

The primary authority for all coverage provisions and subsequent policies is The Social Security Act (the Act). Contractors use Medicare policies in the form of regulations, NCDs, coverage provisions in interpretive manuals, and LCDs to apply the provisions of the Act. (CMS Pub 100-8, Chapter 13, §13.1)

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CMS – Clinical Trials Coverage

President Clinton issued an executive memorandum on June 7, 2000, directing the Secretary to "explicitly authorize (Medicare) payment for routine patient care costs…and costs due to medical complications associated with participation in clinical trials".

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CMS National Coverage Determination

310.1 - Routine Costs in Clinical Trials

Effective for items and services furnished on or after September 19, 2000, 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*. 

CMS Pub 100-3, Chapter 1, Part 4, §310.1
Qualifying Clinical Trials

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians’ service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

7 Desirable Characteristics

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes;

2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

3. The trial does not unjustifiably duplicate existing studies;

4. The trial design is appropriate to answer the research question being asked in the trial;

5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;

6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and

7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

CMS National Coverage Determination

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

1. The investigational item or service, itself;

2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

3. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
Routine costs in clinical trials

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service - in particular, for the diagnosis or treatment of complications.

CMS Pub 100-3, Ch 1, Part 4, §10-1

Coverage of Medical Devices

The Food and Drug Administration (FDA) defines a medical device as:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

CMS Pub 100-2, Chapter 14, §10

FDA Definitions

For the purposes of consideration for reimbursement under the Medicare program, FDA categorized all FDA-approved IDEs into either Category A (experimental) or Category B (non-experimental/investigational). Only those IDEs placed in Category B by FDA would be eligible for Medicare coverage consideration.

Guidance on IDE Policies and Procedures

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850
FDA Device Categorization

Under the Food, Drug, and Cosmetic Act, devices are categorized into three classes:

- **Class I** devices are the least regulated. These are devices that the FDA has determined need to be subject only to general controls, such as good manufacturing practice regulations.
- **Class II** devices are those which, in addition to general controls, require special controls such as performance standards or post-market surveillance, to assure safety and effectiveness.
- **Class III** devices are those which cannot be classified into class I or class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. **Class III devices require pre-market approval.**

For purposes of assisting CMS in determining Medicare coverage, the FDA will place all approved IDEs in one of two categories.

Category A IDE

Experimental (Category A) device refers to an innovative device believed to be in Class III for which "absolute risk" of the device type has not been established; i.e., initial questions of safety and effectiveness have not been resolved, and FDA is unsure whether the device type can be safe and effective.

The CMS does not cover Category A devices under Medicare because they do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary.

Routine costs in Category A IDE Trials

**Routine costs** (as described in The National Coverage Determinations Manual, section 310.1) of clinical trials involving **Category A IDE devices** are covered when the Medicare contractors determine that the device is used in the trial for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Both institutional providers and practitioners are required to bill for the routine costs of clinical trials involving Category A devices as specified in §68.3 of this chapter.

CMS Pub 100-04, Medicare Claims Processing Manual, Chapter 14, §68.3
Category B IDE

Category B device refers to a device believed to be in Class I or II, or a device believed to be in Class III for which the incremental risk is the primary risk in question; i.e., underlying questions of safety and effectiveness of the device type have been resolved, or it is known that the device type can be safe and effective because, e.g., other manufacturers have obtained FDA approval of that device type.

Category B IDE

Unlike Category A devices, Category B devices are newer generations of proven technologies that have had questions about its safety and effectiveness resolved. The CMS may cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Humanitarian Devices

- A Humanitarian Use Device (HUD) is defined as a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the U.S. per year.
- Humanitarian Device Exemption (HDE) is the FDA application for marketing of a HDE.
- Requires CMS approval for qualifying patients.
Compassionate use of an unapproved device

- Single patient or small group use of an unapproved device
- Compassionate use is not research
- Unapproved device for serious disease or condition
- No alternative
- Patient does not meet inclusion criteria

Emergency use of an unapproved device

- All conditions must exist
  - Life-threatening disease or serious condition requiring immediate use
  - No generally accepted alternative for treating the condition is available
  - There is no time to use existing procedures to obtain FDA approval of an IDE.


IDE Coverage Requirements

Medicare contractors are responsible for making the coverage determinations on all FDA-approved Category B devices. Coverage decisions should be made for FDA-approved investigational device exemptions (IDEs), as they currently are made for FDA-approved devices, i.e., the contractor shall apply Medicare’s usual criteria and procedures for making coverage decisions (refer to the CMS Medicare Coverage Web page at http://www.cms.hhs.gov/medicare).
### Hospital IRB Approved IDE Devices

Clinical trials for **non-significant risk devices** (devices which do not require an FDA-approved IDE) are the responsibility of the hospital’s IRB. While these devices do not require an FDA-approved IDE, many of the FDA approved IDE requirements apply to these non-significant risk devices (e.g., they may not be legally marketed). **Medicare contractors are responsible for making the coverage determinations on non-significant devices** that are the responsibility of the hospital’s IRB. Contractors should apply the same coverage criteria, where appropriate, to these devices as is applied to FDA approved IDE Category B devices.

CMS Pub 100-2, Chapter 14, §60

### Pre-market Notification (Sponsor responsibility)

- Each person who wants to market Class I, II and some III devices intended for human use in the U.S. must submit a 510(k) to FDA at least 90 days before marketing unless the device is exempt from 510(k) requirements.
- A 510(k) is a pre-marketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to pre-market approval (PMA).

http://www.fda.gov/cdrh/devadvice/314.html

### Prohibition of promotion and other practices

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:

- Promote or test market an investigational device, until after FDA has approved the device for commercial distribution
- Commercialize an IDE by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling
- Unduly prolong an investigation, if data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified...
- Represent that an IDE is safe or effective for the purposes for which it is being investigated...

Title 21 – Food and Drugs
Chapter 1 – Food and Drug Administration
Subchapter H – Medical Devices
FDA Withdrawal of IDE Approval

Potential Medicare coverage of Category B IDE devices is predicated, in part, upon their status with the FDA. In the event a sponsor (e.g., a manufacturer) loses its Category B status, or violates relevant IDE requirements necessitating FDA’s withdrawal of IDE approval, all payment for the device should cease. Contractors should inform the provider community that billing for the IDE means that the provider attests that the study was approved at the time the service was rendered.

The CMS master file will be updated to reflect withdrawals of FDA IDE approvals.

CMS Pub 100-2, Ch 14, §90

NCD – Compliance Summary

You can’t get paid by Medicare if:
– Clinical Trial not approved by Medicare Contractor
– Not a Qualifying Trial
– You are getting paid from another source
  • Sponsor
  • Grant
– An Unapproved Drug or Device
– A Different Grant
– Research Misconduct
– Failure to collect deductibles/coinsurance
– Do not meet IRB requirements
– Do not keep accurate records

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Proposed Rule Changes:
• Centralized review process to reduce burden for stakeholders
  – FDA approval letter
  – IDE study protocol
  – IRB approval letter(s)
  – The ClinicalTrials.gov identifier
• Notification
  – Studies eligible for coverage posted to ClinicalTrials.gov
• Establish IDE study and trial standards (13 standards)
• CMS definitions to drop Class I, II, III designations (too confusing)
• Clarify ‘Therapeutic Intent’ requirement to address life-threatening cases