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deskbook

# Emerging Life Sciences Companies

second edition

## Chapter 17

## Medicare Coverage of Drugs and Devices Under Medicare Parts A and B

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# MEDICARE COVERAGE OF DRUGS AND DEVICES UNDER MEDICARE PARTS A AND B

**General Coverage Requirements for Drugs and Devices Under Medicare Parts A (Pertaining to Institutional Use) and B (Pertaining to Outpatient and Physician Office Use)**

A. A claim should be paid if

   1. The claim falls within a specified Medicare benefit category
   2. The claim is reasonable and necessary for the individual
   3. The claim is not otherwise statutorily excluded

**Additional Requirements for Drugs Covered Under Medicare Part B (Medical Insurance)**

A. The drugs must be furnished "incident to" the services of a physician or other practitioner.

   1. The drugs must be an integral, though incidental, part of the physician's service.
   2. The drugs must be of a type that is commonly furnished in a physician's office.
   3. The drugs must be furnished under a physician's direct supervision.

B. The drugs cannot be usually "self-administered."

C. The drugs must be reasonable and necessary for the diagnosis and treatment of the patient receiving them.

D. The drugs must not have been deemed as less than effective by FDA.

**Coverage of Unapproved Drugs and Devices Under the Clinical Trial Policy**

A. Unapproved drugs and devices are usually considered "experimental" and are not covered.

B. Coverage for such unapproved drugs and devices may be available under the 2000 Clinical Trial Policy (2000 CTP), adopted by the Centers for Medicare and Medicaid Services (CMS), which is the agency that administers the Medicare program.

C. The 2000 CTP requires that a study have the following characteristics, indicating adherence to good clinical trial practices:

1. The trial's principal purpose is to test whether the intervention potentially improves the participants' health outcomes.

2. The trial is not unjustifiably duplicative of existing studies.

3. The trial is sponsored by a credible organization.

4. The trial complies with federal regulations regarding the protection of human subjects.

D. These characteristics can be deemed to be met if any of the following is true:

1. The trial is funded by one of the federal agencies specified in the National Coverage Determination (including CMS, the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control, the Department of Defense, and the Veterans Administration), or by one of these agencies' centers or cooperative groups.

2. The trial is conducted under an investigational new drug (IND) application.

3. The trial is exempt from having an IND application, pursuant to 21 C.F.R. § 312.2(b)(1).

E. The 2000 CTP also requires that a study demonstrate certain "Medicare-specific" criteria. The study must

1. Involve an item or service that falls within a Medicare benefit category

2. Have a "therapeutic intent"

3. Enroll patients with a diagnosed disease rather than healthy volunteers if the study involves a therapeutic intervention (provided that diagnostic tests can have a control group)

F. Generally, only routine costs are included, such as

1. Items and services typically provided absent a clinical trial

2. Items and services, such as the administration of the product, required solely for the investigation of the item, including appropriate monitoring of effects and prevention of complications

3. Treatment of complications

4. The investigational item itself, assuming the item is covered outside of the clinical trial

G. Some other costs are explicitly excluded, such as

1. Data collection not directly related to clinical management

2. Items and services customarily provided by research sponsors free of charge to any enrollee in the trial

**Coverage of Investigational Device Exemptions**

A. Limited coverage is available for unapproved devices subject to an investigational device exemption (IDE). Such coverage is dependent on how the device is categorized by FDA.

B. Distinction between Category A and Category B devices

   1. Category A (experimental/investigational) devices are generally Class III and include innovative devices for which the questions of safety and effectiveness have not been resolved.

   2. Category B (nonexperimental/noninvestigational) devices are generally Class I or II, but sometimes Class III, and include devices for which the underlying questions of safety and effectiveness of that device type have been resolved.

C. Coverage of Category A devices

   1. Routine costs are covered, but not the device itself, provided that

      a. The trial involves the diagnosis, monitoring, or treatment of a life-threatening disease.

      b. The provider furnishes information regarding the clinical trial to the Medicare contractor.

      c. The trial meets scientific and ethical standards laid out in CMS's clinical trial policy.

      d. The device must be readily necessary for a given patient.

   2. Otherwise, Category A devices and services that are incident to the device, such as preparatory services and after-care, are not covered.

   3. Complications, however, are covered, so long as they are not a direct result of the receipt of the device itself.

D. Coverage of Category B devices

   1. Routine care is covered.

   2. The payment amount is capped at the amount that would be payable using an approved device.

   3. The device must be in an FDA-approved clinical trial.

   4. The device must be medically necessary for a given patient.

E. Services related to a noncovered device are not covered.

F. The same criteria apply to other unapproved devices that do not pose a significant risk, even if they are not IDE devices.

G. Medicare contractors are responsible for making the coverage determinations on these devices.

**Coverage of Off-Label Indications for Approved Products**

A. There is no outright prohibition on coverage for off-label uses of devices since there is no prohibition; coverage is presumed, absent a specific prohibition for a specific indication.

B. Coverage for off-label use of drugs is expressly allowed if:

1. Inpatient drugs

a. Basic requirements:

(i) Must represent a cost to the institution in rendering services to the beneficiary (i.e., cannot be free to provider)

(ii) The drug or biological must be included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia-National Formulary, the United States Pharmacopoeia Drug Information, or the American Dental Association Guide to Dental Therapeutics; alternatively, the drug or biological must be approved for use by a hospital's Pharmacy and Therapeutics Committee

(iii) Must be safe and effective and otherwise reasonable and necessary

b. Even if inpatient drugs meet the above requirements, they are subject to local coverage decisions based on generally accepted medical practices.

2. Outpatient drugs

a. Must meet all of the general conditions of coverage applicable to all Part B drugs

b. The drug or biological must be included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia-National Formulary, the United States Pharmacopoeia Drug Information, or the American Dental Association Guide to Dental Therapeutics

c. Medicare contractors have discretion to approve off-label uses, based on whether they are "medically accepted," as determined by reference to the specified compendia, authoritative medical literature, and accepted standards of practice

d. Acceptable off-label outpatient use of anticancer drugs is broader, and includes additional compendia, as determined by CMS, as well as peer-reviewed literature

**Local Coverage Determinations and National Coverage Determinations**

A. All drugs and devices can have their coverage determined by a local coverage determination (LCD) or national coverage determination (NCD), off-label or labeled.

B. Even if a drug or device is labeled, it may not be covered.

C. NCD

1. A decision that CMS makes regarding whether to cover a particular service nationally under Medicare
2. Binding on all fiscal intermediaries, carriers, and Medicare administrative contractors (MACs)
3. Must comply with specific timelines for creation
4. Can be initiated by manufacturer, other stakeholder, or CMS
5. Can create, limit, or deny coverage for off-label or even labeled uses of a product
6. Can be appealed, but only by aggrieved parties, which do not include manufacturers

D. LCD

1. A decision by a fiscal intermediary or carrier under Medicare whether to cover a particular service on an intermediarywide/carrierwide basis
2. Does not include:
    a. Code assignments
    b. Payment level determinations
3. Implemented by local contractors
4. Not controlling during a claims appeal, but rather provides a framework to allow consistency of claims treatment
5. In the event of a conflict between an LCD and an NCD, the NCD governs

E. Appeals (reconsiderations and challenges)

1. Reconsiderations
    a. Any individual or entity may request a reconsideration of an entire LCD or NCD.
    b. The reconsideration may be based on either (i) new and additional medical/scientific information or (ii) an argument that the existing evidence was materially misinterpreted.
2. Appeals process
    a. LCDs
        (i) Initial complaints must be filed with an Administrative Law Judge.
        (ii) Appeals are then made to the Departmental Appeals Board (DAB), and then to Federal District Court.

b. NCDs

(i) Initial complaints must be filed with the DAB.

(ii) Appeals are made to Federal District Court.

3. Claim-by-claim basis

a. A beneficiary or his or her service provider can challenge an individual claim by pursuing the claims appeal process.

b. The decision applies only to the claim under appeal.