Medicare Benefit Policy Manual

Chapter 14 - Medical Devices

Table of Contents

10 - Coverage of Medical Devices

(Rev. 1, 10-01-03)

B3-2484, B3-4122.1

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:
    - º Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
    - º 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
    - º 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.

For dates of service on or after November 1, 1995, Medicare may cover certain FDA-approved and Institutional Review Board (IRB) approved investigational devices and services incident to, provided the investigational device meets the following conditions:

- Appears on the listing of devices eligible for coverage/payment on CMS' master file of IDE devices;
- Is reasonable and necessary for the individual patient;
- The device or services associated with the use of a device were provided to the beneficiary within the start and end dates contained in the master file; and,
- There is no national coverage policy that would otherwise prohibit Medicare coverage.

Devices that may be covered under Medicare include the following categories:

- Devices approved by the FDA through the Pre-Market Approval (PMA) process;
- Devices cleared by the FDA through the 510(k) process;
- FDA-approved IDE Category B devices; and

- Hospital Institutional Review Board (IRB) approved IDE devices

20 - FDA Approval Investigational Device Exemptions (IDEs)

B3-2484.A

(Rev. 1, 10-01-03)

The FDA assigns a special identifier number that corresponds to each device granted an investigational device exemption (IDE). 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.

20.1 - Category A

B3-2484.A.1

(Rev. 1, 10-01-03)

Experimental - Innovative devices 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 the FDA is unsure whether the device type is safe and effective).

20.2 - Category B

B3-2484.A.2

(Rev. 1, 10-01-03)

Nonexperimental and/or investigational devices believed to be in classes I or II or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

30 - Coverage of FDA-Approved IDEs

B3-2484.B

(Rev. 1, 10-01-03)

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.

The CMS may cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Refer to the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180 - "Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare."

40 - Providers Seeking Reimbursement for Investigational Devices

B3-2484.C

(Rev. 1, 10-01-03)

It is the responsibility of the provider participating in the clinical trial to furnish all necessary information concerning the device, the clinical trial and participating Medicare beneficiaries that the contractor deems necessary for a coverage determination and claims processing. (See samples 1 and 2 of FDA approval/clearance letters you may receive from the provider seeking Medicare reimbursement).

50 - Coverage Requirements

B3-2484.D

(Rev. 1, 10-01-03)

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). The following criteria must also be applied when making coverage determinations on FDA-approved IDE Category B devices:

- The device must be used within the context of the FDA-approved clinical trial;
- The device must be used according to the clinical trial's approved patient protocols;

- There may be an established national policy as contained in existing manual instructions, e.g., National Coverage Determinations Manual instructions, etc.;

- In the absence of national policy, there may be a local policy for similar FDA-approved devices;

- There may be Policy/Position papers or recommendations made by pertinent national and/or local specialty societies.

Contractors should also consider, among other factors, whether the device is:

- Medically necessary for the particular patient and whether the amount, duration, and frequency of use or application of the service are medically appropriate; and

- Furnished in a setting appropriate to the patient's medical needs and condition.

This policy does not provide coverage for any devices that would otherwise not be covered by Medicare; e.g., statutorily excluded devices or items and services excluded from coverage through regulation or current manual instructions.

60 - Hospital Institutional Review Board (IRB) Approved IDE Devices

B3-2484.E

(Rev. 1, 10-01-03)

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 nonsignificant risk devices (e.g., they may not be legally marketed). Medicare contractors are responsible for making the coverage determinations on nonsignificant 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.

70 - Payment for IDE Category B Devices

B3-2484.F

(Rev. 1, 10-01-03)

Payment for a Category B IDE device or an IRB approved device (provided to a nonhospital patient) and the related services may not exceed what Medicare would have paid for a comparable approved device and related services.

80 - Services Related to and Required as a Result of Services Which are Not Covered Under Medicare

B3-2484.G

(Rev. 1, 10-01-03)

Services related to the use of a noncovered device are not covered under Medicare.

90 - FDA Withdrawal of IDE Approval

B3-2484.H

(Rev. 1, 10-01-03)

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.

100 - Confidentiality of IDE Information

B3-2484.I

(Rev. 1, 10-01-03)

Contractors may **not** release claims information or information received from the provider that is proprietary in nature, i.e., information contained in the FDA IDE approval letter (and conditional approval letter) to the sponsor (e.g., a manufacturer). Since the IDE number as well as other information will be necessary to process claims, the contractor must take appropriate action to ensure that the confidentiality of the information is protected. Because this information is proprietary in nature, the contractor may not release it under the Freedom of Information Act.

Sample Approval Letter

Mr. John Doe
Vice-President
Maintara Medical
1 Main Street
Any Town, USA 11101

RE: IDE Number: G_____
Maintara Medical Device
Indications for Use: Treat Medical Conditions
Date: January 1, 1999
Received: January 1, 1999
CMS Reimbursement Category: B2

Dear Mr. Doe:

The Food and Drug Administration (FDA) has received your investigational device exemption (IDE) application. Your application is approved, and you may begin your investigation at an institution in accordance with the investigational site waiver granted below. Your investigation is limited to 3 institutions and 100 subjects.

The FDA will waive those requirements regarding submission and prior FDA approval of a supplemental application and receipt of certification of institutional review board (IRB) approval for the addition of investigational sites (21 CFR 812.35(a)) provided:

1 - The total number of investigational sites does not exceed 3, and the total number of patients does not exceed 100; and

2 - The current records are present and include:

- The names and addresses of all investigational sites;
- The names and addresses of all investigators, identifying those who are currently participating;
- The names, addresses and chairpersons of all IRBs; and
- The dates of first shipment or first use of investigational devices for all participating institutions.

Section 812.150(b)(4) will contain the information specified in 2 above.

3 - Within 5 days of reaching the investigational site limit, you must submit to the FDA a current list containing the information specified in 2 above.

4 - The current investigator list is to be submitted to the FDA at 6-month intervals (2) CFR 5. You must submit to the FDA, within 2 days of receipt of a request by the FDA, a current list containing the information specified in 2 above.

5 - The reviewing IRB does not require significant changes in the investigational plan or in the informed consent. That is, require any change which may increase the risks to subjects or affect the scientific soundness of the study. (Please note: if a significant change is requested, this change must be submitted to the FDA for review and approval prior to initiating the study at that investigational site). Minor changes requested by the IRB may be made without prior FDA approval. If you agree to these conditions, you may begin an investigation at a new investigational site after the IRB has approved the investigation. No documentation should be submitted for any institution within the approved limit until the investigational site limit is reached or the 6-month current investigator list is due. The FDA assumes that you have agreed to the conditions of this waiver unless you specifically notify us in writing of your disagreement. Please note, however, that you must submit a supplemental IDE application, and receive FDA approval, prior to extending the investigation beyond the limit specified above. Additionally, if you do not agree to these conditions, you must comply with the full requirements for the submissions to the FDA of a supplemental IDE application for new investigational sites not already specifically approved for participating in your study. (See 21 CFR 812.45(b)).

We would like to point out that the FDA approval of your IDE application does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a pre-market approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application entitled Pre-market Approval (PMA) Manual from the Division of Small Manufactures Assistance at its toll-free number.

Future correspondence concerning this application should be identified as an IDE supplement referencing the IDE number above and must be submitted in triplicate to:

_____

We have enclosed the guidance document entitled Sponsor's Responsibilities for a Significant Risk Device Investigation to help you understand the functions and duties of a manufacturer. Also enclosed is the guidance document entitled Investigators Responsibilities for a Significant Risk Device Investigation, which you should provide to participating investigators.

If you have any questions, please contact _____.

Sincerely Yours,

Sample of Conditional Letter

Ms. Penelope Brown
Manager
ADE Medical Corporation
222 2nd Street
Any City, Any State, USA 11111

RE: IDE Number: G_____
Bladder Controller
Indications for Use: Bladder Control
Dated: January 1, 1999
Received: January 8, 1999
CMS Reimbursement Category: B4

Dear Ms. Brown:

The Food and Drug Administration (FDA) has received your investigational device exemption (IDE) application. Your application is conditionally approved, and you may begin your investigation, using a revised informed consent document that corrects deficiency numbers one and two in accordance with the investigational site waiver granted below. Your investigation is limited to a feasibility study at three of the institutions listed in your submission and ten subjects.

This approval is being granted on the condition that, within 45 days from the date of this letter, you must submit information correcting the following deficiencies:

1 - Per 21 CFR 812.5(b), this manufacturer of the IDE shall not represent that the device is effective for the purpose for which is being investigated. Please revise the informed consent form in conformance with the following:

- Remove the statement that the device is in use in over 10,000 patients;
- Remove paragraph two under purpose of the study;
- Remove the statement regarding pregnant women; and
- Remove the statement under anticipated benefits of the study that says, "From the experiences of patients who have received it in other countries."

This information should be identified as an IDE supplement referencing the IDE number above and must be submitted in triplicate to_____.

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application. The FDA will waive those requirements regarding the submission and prior FDA approval of a

supplemental application and receipt of certification of institutional review board (IRB) approval for the addition of investigational sites (21 CFR 812.45(b)) provided:

1 - The total number of investigational sites does not exceed three.

2 - You maintain current records on:

- The names and addresses of all investigational sites;
- The names and addresses of all investigators, identifying those that are currently participating;
- The names, addresses, and chairpersons of all IRBs;
- The dates of the IRB approvals; and,
- The dates of first shipment or first use of investigational devices for all participating institutions.

If you agree to these conditions, you may begin an investigation at a new investigational site after the IRB has approved the investigation. No documentation should be submitted for any institution within the approval limit until the investigational site limit is reached or the 6-month current investigator list is due. The FDA assumes that you have agreed to the conditions of this waiver unless you specifically notify us in writing of your disagreement.

Please note, however, that you must submit a letter to expand the investigation beyond the limit specified above. Additionally, if you do not agree to these conditions, you must comply with the full requirements for the submission to the FDA of a supplemental IDE application for new investigational sites not already specifically approved for participating in your study (21 CFR 812.35 (b)).

We would like to point out that the FDA approval of your IDE application does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a pre-market approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled Pre-market Approval (PMA) Manual from the Division of Small Manufactures Assistance at its toll free number.

We have enclosed the guidance document entitled Sponsor's Responsibilities for a Significant Risk Device Investigation to help you understand the functions and duties of a manufacturer. Also enclosed is the guidance document entitled Investigators Responsibilities for a Significant Risk Device Investigation, which you should provide to participating investigators.

If you have any questions, please contact _____.

Sincerely yours,

110 - Appeals Process for FDA IDE Categorization Decisions

FDA Web site

(Rev. 1, 10-01-03)

The Food and Drug Administration (FDA) assigns an IDE number that corresponds to each IDE application received. Through an interagency agreement CMS and the FDA have developed a process to categorize all FDA-approved IDEs for Medicare coverage and payment purposes. This categorization process differentiates between novel, first-of-a-kind devices for which absolute risk of the device has not been established (Category A), and those devices which are of a device type for which the underlying questions of safety and effectiveness have been resolved (Category B).

Any manufacturer that does not agree with the FDA decision that categorizes its device as Category A-experimental may submit a written request asking the FDA to reevaluate its categorization decision. The sponsor (e.g., a manufacturer) may send a written request to the FDA at any time asking for a reevaluation of its original categorization decision, submitting any additional evidence and information which it believes supports a recategorization. The FDA notifies both CMS and the sponsor (manufacturer) of its re-evaluation decision.

If the FDA reconfirms its original decision on the categorization of the device, the sponsor (e.g., a manufacturer) may seek a review by the CMS Central Office. The device sponsor (e.g., a manufacturer) must submit its request in writing, and must include all materials submitted with its reevaluation request to the FDA. Review requests must be addressed to:

Centers for Medicare & Medicaid Services
IDE Categorization Review, Office of Clinical Standards and Quality
Coverage and Analysis Group
7500 Security Blvd.
Room S3-25-25
Baltimore, MD 21244-1850

The CMS staff will then review this information to determine whether to change the categorization of the device. CMS will then issue a written decision notifying both the device sponsor (e.g., a manufacturer) and the FDA of its decision. In evaluating a manufacturer's request for recategorization, CMS will review only that information submitted to the FDA. Information not submitted to the FDA for its consideration will not be reviewed by CMS.

To the extent that CMS relies on confidential commercial or trade secret information in its review, the Agency will maintain confidentiality of the information in accordance with Federal law.

No reviews of a categorization decision other than those described above are available to a sponsor (e.g., a manufacturer). Neither the FDA original categorization decision or

reevaluation nor CMS' review constitutes an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H or parts 417, 473, or 498 of title 42 of the Code of Federal Regulations.