Medicare
Carriers Manual
Part 3 - Claims Process

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal 1704 **Date: MAY 25, 2001**

These manual sections incorporate instructions previously issued in a memorandum to HCFA Associate Regional Administrators in August of 1996 on Medicare Coverage of and Processing of Claims for Investigational Devices. This action is merely a manualization of these instructions. Coverage of certain investigational devices became effective on November 1, 1995.

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents - Chapter II	2-3 - 2-6 (4 pp.)	2-3 - 2-6 (4 pp.)
2301.1	----	2-109.2 - 2-109.3 (2 pp.)
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Table of Contents - Chapter III	3-1.2 - 3-2 (2 pp.)	3-1.2 - 3-2 (2 pp.)
3313 - 3319	3-85 - 3-85.2 (3 pp.)	3-85 - 3-86 (2 pp.)
Table of Contents - Chapter IV	4-1 - 4-2 (2 pp.)	4-1 - 4-2 (2 pp.)
4121.3 - 4130	4-38.1 - 4.38.3 (3 pp.)	4-38.1 (1 p.)

MANUALIZATION--***EFFECTIVE DATE: Not Applicable***
IMPLEMENTATION DATE: Not Applicable

Section 2303.1, Devices Not Approved by FDA, has been **deleted**.

Section 2484, Coverage Of Medical Devices Under Medicare, outlines coverage of medical devices under Medicare coverage of certain FDA-approved investigational device exemption (IDE) devices and the services related to these devices. It describes the conditions and limits of coverage and payment for specified devices with an FDA approved IDE.

Section 3317, Appeals Process for IDE Categorization Decisions, specifies the procedure that a sponsor (typically, the manufacturer) must follow if the sponsor does not agree with the FDA categorization of its device.

Section 4122, Certain Devices with a Food and Drug Administration (FDA) Investigational Device Exemption (IDE), explains payment and billing procedures and defines devices in HCFA's Master Investigational Device file.

Section 4122.1, Certain Devices with an FDA Investigational Device Exemption, describes the procedures to be used for processing payment of claims for investigational devices.

Section 4122.2, Payment of Certain Investigational Devices, explains the new benefit provided as a result of the revised coverage policy for investigational devices.

Section 4122.3, HCFA's Master File of Investigational Devices, describes what is contained in the master file of investigational devices and what contractors should verify from the master file before processing a claim.

Section 4122.4, Adjudicating the Claim, describes how to process a claim for an investigational device.

Section 4122.5, EOMB Messages, identifies messages specific to the benefit to be placed on EOMBs for investigational devices.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

These instructions should be implemented within your current operating budget.

CHAPTER II
COVERAGE AND LIMITATIONS

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COVERAGE AND LIMITATIONS

Section

Payment for Rural Health Clinic Services

Ambulatory Surgical Center Services

General Exclusions From Coverage

2484. COVERAGE OF MEDICAL DEVICES

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.
- ? Hospital Institutional Review Board (IRB) approved IDE devices.

A. FDA Approval IDEs.--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 HCFA in determining Medicare coverage, the FDA will place all approved IDEs in one of two categories:

1. Category A.--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).

2. Category B.--Non-Experimental/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.

B. Coverage of FDA-Approved IDEs.--Category A devices are not covered under Medicare because they do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary.

Category B devices may be considered reasonable and necessary and, therefore, may be covered if all other applicable Medicare coverage requirements are met.

Refer to §2300.1--Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare.

C. Providers Seeking Reimbursement for Investigational Devices.--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).
See §4122 for complete claims processing information.

D. 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., apply Medicare's long-standing criteria and procedures for making coverage decisions. 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.

? Established national policy as contained in existing manual instructions, e.g., Coverage Issues Manual instructions, etc.

? In the absence of national policy, local policy for similar FDA-approved devices.

? 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:

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

2. 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.

E. Hospital Institutional Review Board (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 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.

F. Payment for IDE Category B Devices.--Payment for a Category B IDE device or an IRB approved device (provided to a nonhospital patient) and related services is limited to or less than what Medicare would have paid for a comparable approved device or services.

G. Services Related to and Required as a Result of Services Which are Not Covered Under Medicare.--This policy does not affect Medicare's coverage of services related to a noncovered device. That is, services related the use of a noncovered device are not covered under Medicare.

H. 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 of the device should cease. Carriers 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 HCFA master file will be updated to reflect withdrawals of FDA IDE approvals.

I. Confidentiality of IDE Information.--You 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, you must take appropriate action to ensure that the confidentiality of the information is protected. Because this information is proprietary in nature, you 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
HCFA 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. You maintain current records on:

? 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.
? The dates of first shipment or first use of investigational devices for all participating institutions.
? 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
HCFA 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 which 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.

? 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,

CHAPTER III
CLAIMS, FILING, JURISDICTION AND DEVELOPMENT PROCEDURES

Section

Jurisdiction of Claims

Parenteral and Enteral Nutrition

Claim Number

Claims Development Procedures and Situations

CHAPTER III
CHAPTER, FILING, JURISDICTION
AND DEVELOPMENT PROCEDURES

3313. PHYSICIAN OR SUPPLIER REFUSAL TO FURNISH AN ITEMIZED BILL TO THE PATIENT

An enrollee's statement or an SSO's report that a physician or supplier refuses to furnish the patient with an itemized bill until it is paid. Contact the physician or supplier or, when necessary, the local medical society or supplier association, in an effort to resolve the problem. If appropriate, suggest that the enrollee make direct contact with the society. You may find it helpful to enlist the assistance of a State or local consumer protection agency or suggest that the enrollee do so.

Once it is clear that such efforts will not induce the physician or supplier to furnish itemization (or other information necessary to evaluate the services or charges on his bill) which should materially affect your coverage and/or payment determination, try to obtain the information from available medical sources (e.g., the records of the hospital or other facility at which the enrollee received treatment, or the statement of another physician involved in the case). The statement of the enrollee fully describing the services received may also be used.

In dealing with these "itemization refusal" cases, commensurate your efforts with the amount of the SMI benefits at issue. Thus, a trip by a carrier representative to a hospital would probably be warranted only if at least $50 in benefits were at stake. Where necessary information can be obtained by a phone call or letter, a smaller benefit amount justifies the effort and expense.

In some situations (e.g., where a new or unusual procedure is involved), obtain the opinion of your medical staff or the local medical society, if it is important for handling of future claims regardless of the amount involved.

Evaluate the information given by the enrollee (or a relative or other person in a position to know). The information should describe the enrollees condition and give details about the services received. Other evidence to be used in determining the nature and reasonable charge for services furnished should also be provided.

Where all reasonable efforts to obtain a reliable list of the services fail, and it becomes necessary either to disallow or substantially reduce benefits, advise the enrollee to consider consulting an attorney, a legal aid society, or a consumer protection society or appropriate state agency. Determine whether an obligation exists under State law to pay a physician's or supplier's bill on which itemization has been refused.

If necessary, consult appropriate state authorities to ascertain whether the refusal is in violation of any state laws.

If the service in question was furnished on or after September 1, 1990, send a letter to the physician or supplier requesting that he/she complete and submit a claim for the case in question, under the authority of 1848(g)(4). If a claim is not filed within one year of the date of service, develop a violation and, if appropriate, refer the case to OIG for monetary penalty and sanction consideration.

3314. PHYSICIAN OR SUPPLIER REFUSES TO SUBMIT MEDICARE CLAIMS

Section 1848(g)(4) of the Social Security Act requires all physicians and suppliers to submit Part B claims processed by Medicare carriers for covered services furnished to program beneficiaries on or after September 1, 1990. Those physicians and suppliers who knowingly, willfully and repeatedly fail to submit a claim are subject to sanctions, including civil monetary penalties of up to $2000 per violation and exclusion from the Medicare program. OIG is responsible for assessing sanctions.

A beneficiary complaint to you, SSA, or HCFA may occur where a physician or supplier fails to adhere to the claim submission requirement. This may happen, for example, when a beneficiary submits a HCFA-1490S claim and your EOMB notice indicates that the physician or supplier should have filed the claim. The beneficiary may indicate that the physician or supplier refused to comply.

Develop such complaints received and make physician or supplier educational contacts, as appropriate. If physician or supplier noncompliance is not corrected (i.e., your monitoring program consistently identifies a service provider as having 11 or more potential violations per month and educational contacts do not resolve the problem), establish controls to develop and refer cases to OIG after the 12 month filing limit is exceeded. (See §7560.)

33l6. PHYSICAL EXAMINATIONS OF BENEFICIARIES BY CARRIERS

You have the authority to obtain an independent medical examination of a beneficiary where your medical personnel conclude that such an examination will assist in properly and effectively complying with your responsibilities. Expenses incurred in connection with obtaining such independent medical examinations are payable administrative costs. It is expected, however, that carrier-initiated examinations will be utilized only after other methods of resolving the issue have been explored and found to be insufficient, and then, only with the express permission of the beneficiary. (Information which may be derived from hospital records and contacts with the beneficiary's attending physician and evaluations of such data by your medical personnel, as well as the appropriate committees of local medical societies, are among the more usual methods available to resolve questionable claims before initiating an examination of the beneficiary.) The only use to make of the medical information derived from an independent examination is to assist you in the claims review process.

3317. APPEALS PROCESS FOR INVESTIGATIONAL DEVICE EXEMPTION (IDE) CATEGORIZATION DECISIONS

The Food and Drug Administration (FDA) assigns an IDE number that corresponds to each IDE application received. Through an interagency agreement HCFA 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). (See §2484).

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 HCFA 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 HCFA 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:

IDE Categorization Review, Office of Clinical Standards and Quality
Coverage and Analysis Group
Health Care Financing Administration
Room S3-25-25
7500 Security Blvd.
Baltimore, MD 21244-1850

HCFA staff will then review this information to determine whether to change the categorization of the device. HCFA 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, HCFA will review only that information submitted to the FDA. Information not submitted to the FDA for its consideration will not be reviewed by HCFA.

To the extent that HCFA 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 HCFA's 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.

3319. DISPOSITION OF CLAIMS WHERE SUPPORTING EVIDENCE IS NEEDED

Make one request for necessary supporting information as soon as possible after the claim is received. When possible, obtain or request the information by telephone. Follow-up telephone requests in writing within 5 days.

Include in both the written request and the follow-up to the beneficiary/provider that the claim will be adjudicated on the basis of the evidence on hand if the requested information is not received within 45 days from the date of the written request and that this might result in a reduction in the payment allowed or a denial. Do not include in written requests, bills or forms that contain a diagnosis. (See §3311.)

CHAPTER IV
CLAIMS REVIEW AND ADJUDICATION PROCEDURES

Section

Line Review - HCFA-l490S

Line Review - Health Insurance Claim Form

Items and Services Having Special Review Considerations

Section

4121.3 Denial Messages.--When you deny the claim, use the following messages:

A. MSN/EOMB.--

21.22/16.58 "Medicare does not pay for this service because it is considered investigational and/or experimental in these circumstances."

B. Remittance Advice.--American National Standard Institute (ANSI) X-12-835 claim adjustment reason code/message B22, "This claim/service is denied/reduced based on the diagnosis."

4122 CERTAIN DEVICES WITH A FOOD AND DRUG ADMINISTRATION (FDA) INVESTIGATIONAL DEVICE EXEMPTION (IDE)

4122.1 Payment for Certain Investigational Devices.--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 HCFA's master file of IDE devices (See §4122.3)

? 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.

? There is no national coverage policy that would otherwise prohibit Medicare coverage.

(See §2484 of the Medicare Carriers Manual for additional coverage instructions for FDA-approved investigational devices.)

4122.2 Billing Requirements for FDA-Approved Investigational Devices.--Providers bill using the appropriate HCPCS code. Instruct billers to identify claims for investigational devices and/or services incident to the use of such devices with the "QA" modifier. Item 23 of the HCFA-1500 is used by billers to enter the investigational device exemption number assigned to the device. For electronic claims, the device number is entered in the DAO field of the national standard format field 14. The ANSI 837 is position 180 Ref segment, REF 01 value of LX and REF 02 for the investigational device exemption number. (Providers must obtain the investigation device exemption number from the manufacturer supplying the device in the clinical trial.) Providers may also provide a copy of their approval letter (See §2030 C and I. Also see §4122.4B) to substantiate their claim for payment, though this is not mandatory.

4122.3 HCFA's Master File of Investigational Devices.--The devices in the master file are only those devices that may be covered if they meet the coverage criteria outlined in §2030 of the Medicare Carriers Manual. Carriers may access HCFA's master file of investigational devices through the network data mover. The file will be updated as appropriate.

HCFA's master file of investigational devices contains the following fields:

? The investigational device exemption (IDE) number.
? HCPCS code(s) (where available).
? Narrative description of the device.
? Start date.
? End date.
? Maintenance date.

Listed below is a brief description of the fields contained in the HCFA's master file of investigational devices.

Investigational Device Exemption Number - The investigational device exemption number is an alphanumeric (one alpha and six numeric) character that is assigned by the FDA to an investigational device and must be used when filing a claim.

HCPCS Codes - HCFA has identified (where possible) HCPCS code(s) that providers may use to bill for these investigational devices. In the master file of investigational devices some have no identified HCPCS code associated with the claim; these may be billed using the appropriate miscellaneous HCPCS code. Carriers are not to deny claims just because they may have HCPCS code(s) other than those in the master file.

HCFA's master file of investigational devices is to be used as a guide. The indications of use for the device shall be used to determine the appropriate HCPCS code. When you identify additional HCPCS Code(s) for billing the investigational device, notify HCFA (See §4122.2).

Narrative Description - HCFA has provided a brief description of the investigational device, e.g., intraocular lens. This information should assist you in identifying whether the provider is billing correctly.

Start Date - The start date field houses the beginning of the approval period for that investigational device. Claims received with dates of service prior to this date should be denied (See§4122.4 B for the appropriate EOMB message).

End Date - The end date field indicates the completion of the clinical trial for that device. Claims received with dates of service after that date should be denied (See §4122.5 for the appropriate EOMB message).

Maintenance Date -- This is an optional field. It may indicate the date on which a field pertaining to an IDE record is changed.

4122.4 Adjudicating the Claim.--

A. FDA Approval.--Investigational devices are only covered when they are used in a clinical trial approval by the FDA. When billing a service with the investigational modifier, the provider is certifying FDA approval of a clinical trial for the device.

B. Editing the Claim Against the Master File of Investigational Devices.--Claims for investigational devices should be edited against the master file. **Deny** claims in instances where the investigation device exemption number is not found in the master file. When providers submit documentation that a device is a Category B device, carriers should confirm this information with HCFA (E-mail destination SHIPPLER or fax (410) 786-6730). Only after an updated master file is received that contains the investigational device exemption number in question is the claim to be processed.

4122.5 MSN/EOMB Messages.--Providers must identify services for an investigational device and/or the services incident to such devices using a two-digit procedure code modifier as specified in §4122.2.

Deny claims for investigational devices that are Category A devices, using the following EOMB message when denying the assigned claim:

"Medicare does not pay for this investigational device(s)."

If the claim for an IDE is denied because the approval period has not begun or has expired, use the appropriate message:

"Medicare cannot pay for this investigational device because the approval period for the investigation device in the FDA clinical trial has not begun."

"Medicare cannot pay for this investigational device because the approval period for the investigational device in the FDA clinical trial has expired."

If an FDA-approved investigational device or service incident to such a device is denied because the implantation, removal or replacement is determined to be not medically necessary or reasonable, use the **appropriate message:**

Message 15.35, 15.28, 15.29 or 15.30.

Assigned or unassigned claims received containing the HCPCS code and the "QA" modifier but lacking the investigation device exemption number should be developed.

4125. EYE REFRACTIONS (ITEM 7C)

The carrier must exclude that part of the total charge made by the physician for services involving eye care that relate to the procedures performed to determine the refractive state of the eyes. It will be necessary for the carrier to undertake appropriate development, wherever necessary, to ascertain whether refractive procedures were performed and to establish the reasonable charge for these procedures.

EXAMPLE: A beneficiary complaining of failing vision and watering of the eyes was examined by an ophthalmologist. In the course of the diagnostic ophthalmological eye examination the physician performed procedures to determine the refractive state of the eyes. The physician's bill showed a single inclusive charge for the entire diagnostic examination. Apart from the refractive procedures, all of the other services furnished by the ophthalmologist to the beneficiary are covered. Since the physician did not show separate charge for the refractive procedures, the carrier must determine what portion of the physician's total charge represents the charge for the procedure performed to determine the refractive state of the eyes.

In other situations, the physician may indicate the charge for procedures to determine the refractive state of the eye by an itemization of the specific charge, or by a statement of a percentage or proportion of the total charge. These values, if stated, should be evaluated by the carrier under the guidelines stated in §52l7.

4130. PORTABLE X-RAY SERVICES (ITEM 7C)

A. Supplier Bills.--Whether a supplier of portable x-ray services completes an SSA-l490 or furnishes an itemized bill, both the supplier and the physician who ordered the services must be shown. In addition, all bills for portable x-ray services involving the sheet must show the reason an x-ray was required. If any of the information is not submitted with the claim, the carrier should obtain it before making payment. Where it is found that the service is not within the scope of the portable x-ray benefit (see §2070.4) or was not ordered by a physician, no payment may be made.

Carriers should assure, before making payment, that services are not routine screening procedures or tests in connection with routine physical examinations.

NEXT PAGE IS 4-39