Program Memorandum Intermediaries/Carriers

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)

Transmittal AB-02-072 **Date: MAY 15, 2002**

CHANGE REQUEST 2200

SUBJECT: Medicare Payment for Drugs and Biologicals Furnished Incident to a Physician's Service

Scope

The purpose of this Program Memorandum (PM) is to furnish you with information needed to determine whether a drug or biological that is furnished incident to a physician's service, including in the hospital outpatient setting, is subject to the Medicare program exclusion for drugs that are usually self-administered by the patient. For purposes of this PM the term "drug" means "drug or biological" as defined in program instructions. This PM provides clarification of section 112 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). This PM supersedes the other program instructions on this subject (PM AB-00-115, Medicare Carriers Manual § 2049.2, Intermediary Manual §§ 3112.4B, 3660.11, and Hospital Manual §§ 230.4, E205 and 422).

Background

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Section 112 of BIPA amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Social Security Act to redefine this exclusion. The prior statutory language referred to those drugs "which cannot . . . be self administered." Implementation of the BIPA provision requires interpretation of the phrase "not usually self-administered by the patient."

Policy

Fiscal intermediaries and carriers are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

Administered

The term "administered" refers only to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Only injectable (including intravenous) drugs are eligible for inclusion under the "incident to" benefit. Other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are all considered to be usually self-administered by the patient.

Usually

For the purposes of applying this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and you may not make any Medicare payment for it.

Reliable statistical information on the extent of self-administration by the patient may not always be available. Consequently, we offer the following guidance for each contractor's consideration in making this determination in the absence of such data:

1. Absent evidence to the contrary, drugs delivered intravenously should be presumed to be not usually self-administered by the patient.
2. Absent evidence to the contrary, drugs delivered by intramuscular injection should be presumed to be not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:
    A. Acute condition.--Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition is longer term, it would be more likely that the patient would self-administer the drug.
    B. Frequency of administration.-- How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

3. Absent evidence to the contrary, drugs delivered by subcutaneous injection should be presumed to be self-administered by the patient. However, contractors should examine the use of the particular drug and consider the following factors:
    A. Acute condition.--Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition is longer term, it would be more likely that the patient would self-administer the drug.
    B. Frequency of administration.-- How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will no longer pay for such doses. In addition, contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

By the patient

The term "by the patient" means Medicare beneficiaries as a collective whole. Include only the patients themselves and not other individuals (that is, do not include spouses, friends, or other care-givers). Base your determination on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. Ignore all instances when the drug is administered on an inpatient basis. Make this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, do not consider individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question. For example, an individual afflicted with dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based.

Implementation

Medicare carriers and intermediaries have discretion in applying the criteria in this instruction in determining whether drugs are subject to this exclusion in their local areas. Medicare carriers and intermediaries should post on their websites the results of their application of the criteria and notify providers at the earliest opportunity available. Additional operational instructions will be forthcoming prior to the implementation date.

Reporting Requirement

Each carrier and intermediary must report to CMS every September 1 and April 1 (i.e., every 6 months) its complete list of injectable drugs that are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered by the patient. E-mail this list along with the contractor's name, Medicare identification number and the State(s) affected by the list to: drugdata@cms.hhs.gov.

The *effective date* for this Program Memorandum (PM) is August 1, 2002.

The *implementation date* for this PM is August 1, 2002.

These instructions should be implemented within your current operating budget.

This PM may be discarded after December 31, 2003.

If you have any questions, contact Angela Mason at 410-786-7452.