

TO: ALL PROVIDERS

FROM: CAREFIRST, INC., MEDICARE PART A

DATE: NOVEMBER 21, 2002

SUBJECT: SELF-ADMINISTERED DRUG EXCLUSION

In May 2002, the Centers for Medicare and Medicaid (CMS) issued Program Memorandum (PM) AB 02-072, CR 2200. This PM provided Medicare contractors with information needed to determine whether a drug or biological that is furnished "incident to" a physician's service, including the hospital outpatient setting, is subject to the Medicare program exclusion for drugs that are usually self-administered by the patient.

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."

Fiscal intermediaries and carriers have been instructed to follow instructions in PM AB-02-072, CR 2200 when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor will make its own determination on each drug. Program Memorandum AB 02-139, CR 2311 states that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion. This fiscal intermediary has made the decision to follow the determinations made by the local carrier, TrailBlazer Health Enterprises, in order to provide consistency for the provider community.

Contractors must continue to apply the policy that not only must the drug be medically reasonable and necessary for any individual claim, but also that the route of administration be medically reasonable and necessary. If the 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, and 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. If a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor 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. The following guidance from CMS will be followed in making a 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 evident 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.

PM AB-02-139, CR 2311, provides a clarification of the **definition of "acute."** For the purposes of determining whether a drug is usually self-administered, an acute condition means a condition that begins over a short time period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval. A course of treatment

consisting of scheduled injections lasting less than two weeks, regardless of frequency or route of administration, is considered acute. Evidence to support this may include Food and Drug Administration (FDA) approval language, package inserts, drug compendia, and other information.

Note: In some instances, payment may have been made 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 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 caregivers).

- Determinations will be based 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. Instances when the drug is administered on an inpatient basis will not be included in this consideration.
- Determinations will be made 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.

Apparent on its Face

For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are NOT, usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

Appeals/Comments

If a beneficiary's claim for a particular drug is denied because the drug is subject to the "self-administered drug" exclusion, the beneficiary may appeal the denial. Because it is a "benefit category" denial and not a denial based on medical necessity, an Advance

Beneficiary Notice (ABN) is not required. A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability [under §1879 of the Act]. Therefore, physicians or providers may charge the beneficiary for an excluded drug. A hospital may also appeal a denial under §3781.2 of the Medicare Intermediary Manual.

The Medicare contractors have discretion in applying the criteria in these instructions in determining whether drugs are subject to this exclusion in their local areas.

A list of injectable drugs that are subject to the self-administered exclusion will be maintained on the Maryland Medicare website (<http://www.marylandmedicare.com>). Providers will be given notice 45 days prior to the date that these drugs will not be covered. During the 45-day time period, contractors will maintain existing medical review and payment procedures. After the 45-day notice, contractors may deny payment for the drugs subject to the notice.

Comments in writing may be directed to:

Clifford Amend, Medical Director
CareFirst, INC., Medicare Part A
1946 Greenspring Drive
Timonium MD 21093

References: Transmittal AB 02-072, CR 2200
Transmittal AB 02-139, CR 2311
(Click on this website to view the above references:
http://www.cms.hhs.gov/manuals/memos/comm_date_dsc.asp)

Questions regarding this bulletin should be directed to Trish Neal in Medical Review at (410) 561-4041.

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ISSUED AFTER OCTOBER 1, 1999 ARE AVAILABLE AT NO COST FROM OUR WEBSITE AT www.marylandmedicare.com