Program Memorandum Intermediaries/Carriers

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

Transmittal AB-02-139 **Date: OCTOBER 11, 2002**

CHANGE REQUEST 2311

SUBJECT: Additional Guidance for Applying the Medicare Self-Administered Drug Exclusion

This Program Memorandum (PM) is further guidance, in addition to PM AB-02-072, with respect to determining whether or not an injectable drug, even though furnished incident to a physician's service, is excluded from Medicare payment because it is usually self-administered by the Medicare beneficiaries who use them. For purposes of this PM, the term "drug" means "drug or biological."

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. For example, an injectable drug used to treat migraine headaches is 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.

Presumptions

Per PM AB-02-072, in applying these presumptions two clinical factors are considered. Below is a clarification of the definition of "acute".

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.

Determination of "usually self administered"

In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered.

After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self-administered for the second and third indications, and the first indication makes up 40% of total usage, the second indication makes up 30% of total usage, and the third indication makes up 30% of total usage, then the drug would be considered usually self-administered.

In evaluating whether the beneficiaries as a collective whole self-administer, contractors should note that many individuals afflicted with dementia may have the capacity to self-administer injectable drugs. Such individuals should be included in the population upon which the determination for "self-administered by the patient" was based.

Evidentiary Criteria

Contractors are only required to consider the following types of evidence: peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA approved label, and package inserts. Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Contractors should also use these evidentiary criteria when reviewing requests for making a determination as to whether a drug is usually self-administered, and requests for reconsideration of a pending or published determination.

Please note that prior to the BIPA 2000 amendment, one of the principal factors used to determine whether a drug was subject to the self-administered exclusion was whether the FDA label contained instructions for self-administration. However, we note that under the new standard, the fact that the FDA label includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to this exclusion.

Provider Notice of Non-Covered Drugs

Contractors must describe the process they will use to determine whether a drug is usually self-administered and thus does not meet the "incident to" benefit category. Contractors must place a description of the process on their Web site. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their Web site, including the data and rationale that led to the determination. Contractors will report the workload associated with developing new coverage statements in CAFM 21208.

Contractors must provide 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.

Contractors must not develop local medical review policies (LMRPs) for this purpose because further elaboration to describe drugs that do not meet the 'incident to' and the 'not usually self-administered' provisions of the statute are unnecessary. Current LMRPs based solely on these provisions must be withdrawn. LMRPs that address the self-administered exclusion and other information may be reissued absent the self-administered drug exclusion material. Contractors will report this workload in CAFM 21206. However, contractors may continue to use and write LMRPs to describe reasonable and necessary uses of drugs that are not usually self-administered.

Conferences Between Contractors

Contractors' Medical Directors may meet and discuss whether a drug is usually self-administered without reaching a formal consensus. Each contractor uses its discretion as to whether or not it will participate in such discussions. Each contractor must make its own individual determinations, except that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion.

Beneficiary Appeals

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.

Provider and Physician Appeals

A physician accepting assignment may appeal a denial under the provisions found in §12000 of the Medicare Carriers Manual. A hospital may also appeal a denial under §3781.2 of the Medicare Intermediary Manual.

Reasonable and Necessary

Carriers and fiscal intermediaries will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient's condition. Contractors will continue to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Contractors will also continue to make the determination as to whether a physician's office visit was reasonable and necessary. However, contractors should not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician's office or outpatient hospital setting. That is, while a physician's office visit may not be reasonable and necessary in a specific situation, in such a case an injection service would be payable.

Reporting Requirements

We are correcting an error in PM AB-02-072. Each carrier and intermediary must report to CMS, every September 1 and March 1 (PM AB-02-072 inadvertently stated April 1), its complete list of injectable drugs that the contractor has determined are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered. We anticipate that contractors will review injectable drugs on a rolling basis and publish their list of excluded drugs as it is developed. For example, contractors should not wait to publish this list until every drug has been reviewed. Contractors must send their exclusion list to the following e-mail address: drugdata@cms.hhs.gov using the attached Microsoft Excel template. Any exclusion list not provided in this format will be returned for correction.

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

The *implementation date* for this PM is October 15, 2002.

These instructions should be implemented within your current operating budget.

This PM may be discarded after September 1, 2003.

Attachment

To view the Excel attachment associated with AB-02-139, click here.