Medicare
Carriers Manual
Part 3 - Claims Process

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

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CHANGE REQUESTS 2200 & 2311

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
2049 – 2049.3 (Cont.)	2-18.1 - 2-18.5 (5 pp.)	2-18.1 - 2-18.2 (2 pp.)

MANUALIZATION —*EFFECTIVE/IMPLEMENATION DATES: Not Applicable*

Section 2049 – Drugs and Biologicals, is being updated to manualize Program Memorandum (PM) AB-02-072, Change Request 2200, dated May 15, 2002, and PM AB-02-139, Change Request 2311, dated October 11, 2002.

Section 2049.1 - Definition of Drug or Biological, is being updated to manualize PM AB-02-072, Change Request 2200, dated May 15, 2002, and PM AB-02-139, Change Request 2311, dated October 11, 2002.

Section 2049.2 - Determining Self-Administration of Drug or Biological, is being updated to manualizes Change Request 2200, dated May 15, 2002, and PM AB-02-139, Change Request 2311, dated October 11, 2002.

Section 2049.3 - Incident-to Requirements, is being updated to manualize PM AB-02-072, Change Request 2200, dated May 15, 2002, and PM AB-02-139, Change Request 2311, dated October 11, 2002.

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.

2049. DRUGS AND BIOLOGICALS

The Medicare program provides limited benefits for outpatient 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.

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- o They meet the definition of drugs or biologicals (see §2049.1);
- o They are of the type that are not usually self-administered by the patients who take them. (See §2049.2);
- o They meet all the general requirements for coverage of items as incident to a physician's services (see §§2050.1 and 2050.3);
- o They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (see §2049.4);
- o They are not excluded as immunizations (see §2049.4.B); and
- o They have not been determined by the FDA to be less than effective. (See §2049.4 D.)

Drugs that are usually self-administered by the patient, such as those in pill form, or are used for self-injection, are generally not covered by Part B. However, there are a limited number of self-administered drugs that are covered because the Medicare statute explicitly provides coverage. Examples of self-administered drugs that are covered include blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs. (See §§2100.5 and 2130.D for coverage of drugs which are necessary to the effective use of DME or prosthetic devices.)

2049.1 Definition of Drug or Biological.--Drugs and biologicals must be determined to meet the statutory definition. Section 1861(t)(1) provides that the terms "drugs" and "biologicals" ''include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in one of several pharmacopoeias (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.'' One such pharmacopeia is the United States Pharmacopeia, Drug Indications (USP DI). The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological.

2049.2 Determining Self-Administration of Drug or Biological.--Whether a drug or biological is of a type which cannot be self-administered is based on the usual method of administration of the form of that drug or biological as furnished by the physician.

Whole blood is a biological which cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied. (See §2455 on Part B blood deductible.)

Medicare carriers have discretion in applying the criteria in this instruction in determining whether drugs are subject to this exclusion in their local areas. Carriers are 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. (See §2049.4.2)

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.

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 --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.

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. (For example, interferon beta-1a, tradename Avonex, when delivered by intramuscular injection is not usually self administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption.

3. Absent evidence to the contrary, drugs delivered by subcutaneous injection should be presumed to be self-administered by the patient.

In applying these presumptions, contractors should examine the use of the particular drug and consider the following factors:

A. Acute condition.--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.

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.

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 paraplegia or advanced 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. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for "self-administered by the patient" was based; for example, an early onset of dementia.

Evidentiary Criteria --In making a self-administration determination, 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 August 1, 2002, 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 standard in effect after August 1, 2002, 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 applicable. 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. See Chapter XV of the Medicare Carrier Manual for more detail on the appeals process.

Provider and Physician Appeals --A physician accepting assignment may appeal a denial under the provisions found in §12000 of the Medicare Carriers Manual. See Chapter XV of the Medicare Carrier Manual for more detail on the appeals process.

Reporting Requirements --Each carrier must report to CMS, every September 1 and March 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. Below is an example of the Microsoft Excel template that should be submitted to CMS.

Carrier Name	State	Carrier ID #	HCPCS	Descriptor	Effective date of exclusion	End date of exclusion	Comments

2049.3 Incident-to Requirements.--In order for Medicare payment to be made for a drug, the "incident to" requirements are met. "Incident to" a physician's professional service means that the services are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an illness or injury. See §2050.1 for more detail on incident-to requirements.

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must be furnished by a physician and administered by him/her or by auxiliary personnel employed by him/her under his/her personal supervision. The charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the drug or biological must represent an expense to the physician. Drugs and biologicals furnished by other health professionals may also meet these requirements. (See §§2154, 2156, 2158 and 2160 for specific instructions.)

2049.4 Reasonableness and Necessity.--Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. (See §2303.) Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, you may pay for the use of an FDA approved drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

Deny coverage for drugs and biologicals which have not received final marketing approval by the FDA unless you receive instructions from CMS to the contrary. For specific guidelines on coverage of Group C cancer drugs, see the Coverage Issues Manual.

If there is reason to question whether the FDA has approved a drug or biological for marketing, obtain satisfactory evidence of FDA's approval. Acceptable evidence includes a copy of the FDA's letter to the drug's manufacturer approving the new drug application (NDA); or listing of the drug or biological in the FDA's Approved Drug Products or FDA Drug and Device Product Approvals; or a copy of the manufacturer's package insert, approved by the FDA as part of the labeling of the drug, containing its recommended uses and dosage, as well as possible adverse reactions and recommended precautions in using it. When necessary, the RO may be able to help in obtaining information.

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritive medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §2049.4.C.

Determinations as to whether medication is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations (i.e., with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case). The following guidelines identify three categories with specific examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice.

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