Drugs & Biologicals: Self-Administered Drug Exclusions

Self-Administered Drugs

[Self-Administered Drug Exclusion List (A53127)](https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53127&ver=143&bc=0) (Currently in Effect)

[Self-Administered Drug Exclusion List (A53127)](https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53127&ver=148&bc=0) (Effective 6/30/2024)

Medicare provides only 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 administered by the patients who take them. Each MAC (Medicare Administrative Contractor) as well as fiscal intermediary and carrier must make its own determinations for determining which drugs will be excluded from coverage. The detailed process for this determination is available in the:

* [Medicare Benefit Policy Manual Internet-Only Manual (IOM) Publication (Pub.) 100-02 Chapter 15, Section 50.2](http://www.cms.gov/manuals/Downloads/bp102c15.pdf#page=51) \*

Definitions

In making these determinations, Novitas Solutions used the following definitions:

* Self-administered—administered by the patient to him or herself. This does NOT include administration by spouses, nursing aides, allied health professionals, or physicians. Therefore, oral medications are considered self-administered drugs. However, payment for an oral drug is made as a rare exception when the drug is an oral anti-cancer drug or an oral antiemetic that is given with chemotherapy treatments (See IOM 100-02, Chapter 15, Section 50.5.3 and 50.5.4).
* Usually self-administered—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 the contractor may not make any Medicare payment for it. In other words, this determination is made by evaluating beneficiaries as a collective whole rather than basing it on an individual drug or individual beneficiary.
* Acute condition—any condition that the expected course of treatment is less than two weeks
* Chronic condition—any condition that requires treatment for more than two weeks.

Process of Determination

In making these determinations, Novitas Solutions uses the process prescribed by CMS. The process is summarized as follows.

Statistical information is used to make the required decisions. However, when this data is not available the following factors are considered: route of administration, status of the condition, frequency of drug administration.

* Route of Administration:
* Drugs delivered intravenously are presumed to be NOT usually self-administered
* Drugs injected intramuscularly are presumed to be NOT usually self-administered, although depth and nature of the drug may be considered.
* Drugs administered subcutaneously are considered to be usually self-administered.
* Status of the Condition
* Acute: any condition that the expected course of treatment is less than two weeks
* Chronic condition: any condition that requires treatment for more than two weeks.
* Frequency of Administration
* Infrequent injection: drug given less than once per week
* Frequent injections: drug given one or more times per week

Novitas Solutions arrived at a single determination for each drug by reviewing each indication and route of administration for that indication. The relative contribution for each indication to the total use of that drug (i.e., weighted average) was obtained to determine the overall status of administration. For example, if a drug has three indications where the first indication makes up 40% of its use and is usually self-administered, the second and third indications make up 60% of its use and the drug is not usually self-administered for these indications, then the overall determination of that drug is that it is not usually self-administered. Conversely, if the first indication makes up 60% of its use and the drug is usually self-administered, and the second indication makes up 40% of its use and the drug is not usually self-administered, the overall determination made is that the drug is usually self-administered. After the route of administration is determined, the status of the condition and the frequency of administration are assessed. The drug is determined to be not usually self-administered if the condition is acute or if the drug is given less frequently than one time per week.

For certain injectable drugs, it is apparent that due to the nature of the condition(s) for which they are self-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. For these drugs, the rationale for the determination is “apparent on its face value.”

Drugs and Biologicals furnished Incident to a Physician’s service are subject to the Medicare Self-Administration Drug Exclusion

This list will be continuously updated as soon as new determinations are made available. This list contains only those drugs and biologicals that are determined to be “usually self-administered by the patients” and therefore not eligible for Medicare coverage.

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 ABN (Advance Beneficiary Notice) 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 Section 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 Chapter 29 of the Medicare Claims Processing Manual.

For complete information on Medicare Regulations regarding Drugs and Biologicals, please see the [CMS IOM (Internet Only Manual) Pub. 100-02, Chapter 15, Section 50](http://www.cms.gov/manuals/Downloads/bp102c15.pdf#page=49).