

Usually Self-Administered Drugs (Part B)

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished “incident to” a physician’s service provided the drugs are not usually self-administered by the patients who take them. On May 15, 2002, the Centers for Medicare & Medicaid Services (CMS) issued Program Memorandum AB-02-072/Change Request 2200, which contains guidelines to be used by contractors to determine whether a drug or biological is usually self-administered and excluded from payment. 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.

The following guidelines are to be used for the process of determining whether a drug is usually self-administered:

Evidentiary Criteria

Only evidence of the following types will be considered: peer reviewed medical literature, standards of medical practice, evidence based practice guidelines, FDA approved labeling information and package inserts.

Presumptions

Because reliable statistical information on the extent of self-administration by the patient may not always be available, the following considerations will be used:

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

Additional consideration will be given to whether the condition being treated by the drug is acute or chronic and the frequency of administration.

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.

The list of drugs identified below have been determined, following the above guidelines, to be usually self-administered by the patients who use them and are excluded from payment. Publication on this list begins a 45 day notice period whereby existing medical review and payment procedures will remain in effect. After the 45-day notice period ends, payment will be denied. The list will be reviewed periodically and updated as further determinations are made. Therefore, the absence of any particular drug on the exclusion list does not mean, at some later date, the drug might be deemed excluded based on the guidelines listed above.

HCPCS	Descriptor	Notice Date	Effective Date of Exclusion	Exclusion End Date	Comments
J0135	Adalimumab, 20 mg	12/17/2007	02/01/2008		
J0270	Alprostadil injection, 1.25 mcg	12/17/2007	02/01/2008		
J0275	Alprostadil urethral suppository	12/17/2007	02/01/2008		
J3590	Anakinra, 1mg	12/17/2007	02/01/2008		
J0630	Calcitonin-Salmon, up to 400 units	12/17/2007	02/01/2008		
J3590	Efalizumab, 150 mg	12/17/2007	02/01/2008		
J1324	Enfuvirtide, 1 mg	12/17/2007	02/01/2008		
J1438	Etanercept, 25 mg	12/17/2007	02/01/2008		
J3590	Exenatide, 5 mcg	09/01/2008	10/16/2008		
J1595	Glatiramer, 20 mg	12/17/2007	02/01/2008		
J1675	Histreltin, 10 mcg	12/17/2007	02/01/2008		
J1562	Immune globulin subcutaneous, 100 mg (Vivaglobin)	12/17/2007	02/01/2008		
J1815	Insulin, per 5 units	12/17/2007	02/01/2008		
J1817	Insulin for administration through DME, per 50 units	12/17/2007	02/01/2008		
J9212	Interferon alfacon-1, 1 mcg	12/17/2007	02/01/2008		
J1830	Interferon beta-1b, 0.25 mg	12/17/2007	02/01/2008		
J9216	Interferon gamma-1b, 3 million units	12/17/2007	02/01/2008		
J9218	Leuprolide, 1 mg	12/17/2007	02/01/2008		
J2170	Mecasermin, 1 mg	12/17/2007	02/01/2008		
J2354	Octreotide, non-depot form, 25 mcg	12/17/2007	02/01/2008		
J2440	Papaverine, up to 60 mg	12/17/2007	02/01/2008		
J3590	Peginterferon alfa-2a	12/17/2007	02/01/2008		

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J3590	Peginterferon alfa-2b	12/17/2007	02/01/2008		
J3590	Pegvisomant 10 mg	12/17/2007	02/01/2008		
J3490	Pramlintide 3 mg	12/17/2007	02/01/2008		
Q0515	Sermorelin, 1 mcg	09/01/2008	10/16/08		
J2941	Somatropin, 1 mg	12/17/2007	02/01/2008		
J2940	Somatrem, 1 mg	12/17/2007	02/01/2008		
J3030	Sumatriptan, 6mg	12/17/2007	02/01/2008		
J3150	Testosterone propionate, up to 100 mg	12/17/2007	02/01/2008		
J3140	Testosterone suspension, up to 50 mg	12/17/2007	02/01/2008		
J3110	Teriparatide, 10 mcg	12/17/2007	02/01/2008		
J3355	Urofollitropin, 75 IU	12/17/2007	02/01/2008		