



Self-Administered Drugs

Policy Number: M-0043

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coding Information:

HCPCS Code(s)

Code	Descriptor Generic Name	Descriptor Brand Name	Exclusion Effective Date
90284	IMMUNE GLOBULIN (SCIG), HUMAN, FOR USE IN SUBCUTANEOUS INFUSIONS, 100 MG, EACH	Immune Globulin (SCIg)	05/04/2009
J0135	INJECTION, ADALIMUMAB, 20 MG	Humira [®]	05/04/2009
J0270	INJECTION, ALPROSTADIL, 1.25 MCG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Alprostadil [®] , Caverject [®] , Edex [®] , Prostin VR Pediatric [®]	05/04/2009
J0275	ALPROSTADIL URETHRAL SUPPOSITORY (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Muse [®]	06/01/2010
J0630	INJECTION, CALCITONIN SALMON, UP TO 400 UNITS	Calcimar [®] Miacalcin [®]	05/04/2009
J0718	INJECTION, CERTOLIZUMAB PEGOL, 1 MG	Cimzia [®]	02/01/2010
J1324	INJECTION, ENFUVIRTIDE, 1 MG	Fuzeon [®]	06/01/2010
J1438	INJECTION, ETANERCEPT, 25 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Enbrel [®]	05/04/2009
J1562	INJECTION, IMMUNE GLOBULIN (VIVAGLOBIN), 100 MG	Vivaglobin [®]	05/04/2009
J1595	INJECTION, GLATIRAMER ACETATE, 20 MG	Copaxone [®]	05/04/2009
J1675	INJECTION, HISTRELIN ACETATE, 10 MICROGRAMS	Supprelin [®]	05/04/2009
J1815	INJECTION, INSULIN, PER 5 UNITS	Humulin, Regular, NPH, Lente, Ultralente, etc.	05/04/2009
J1817	INSULIN FOR ADMINISTRATION THROUGH DME (I.E.,	Humalog [®] , etc.	05/04/2009

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	INSULIN PUMP) PER 50 UNITS		
J1830	INJECTION INTERFERON BETA-1B, 0.25 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Betaseron [®]	05/04/2009
J2170	INJECTION, MECASERMIN, 1 MG	Increlex [®] , Iplex [™]	06/01/2010
J2354	INJECTION, OCTREOTIDE, NON-DEPOT FORM FOR SUBCUTANEOUS OR INTRAVENOUS INJECTION, 25 MCG	Sandostatin [®]	05/04/2009
J2940	INJECTION, SOMATREM, 1 MG	Protropin [®]	05/04/2009
J2941	INJECTION, SOMATROPIN, 1 MG	Humatrope [®] , Genotropin, Nutropin [®] , etc.	05/04/2009
J3030	INJECTION, SUMATRIPTAN SUCCINATE, 6 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Imitrex [®]	05/04/2009
J3110	INJECTION, TERIPARATIDE, 10 MCG	Forteo [™]	05/04/2009
J3355	INJECTION, UROFOLLITROPIN, 75 IU	Metrodin [®] , Bravelle [®] , Fertinex [®]	09/01/2011
J3490	UNCLASSIFIED DRUGS	Byetta [®] (Exenatide Injection)	05/04/2009
J3490	UNCLASSIFIED DRUGS	Kineret [®] (Anakinra)	05/04/2009
J3490	UNCLASSIFIED DRUGS	Somavert [®] (Pegvisomant for injection)	06/01/2010
J3490	UNCLASSIFIED DRUGS	Symlin [®] (Pramlintide Acetate Injection)	05/04/2009
J3590	UNCLASSIFIED BIOLOGICS	Raptiva [®] (Efalizumab)	05/04/2009
J3590	UNCLASSIFIED BIOLOGICS	Pegasys [®] (injection, pegylated interferon alfa-2a)	05/04/2009
J3590	UNCLASSIFIED BIOLOGICS	Pegintron [®] (injection, pegylated interferon alfa-2b)	05/04/2009
J3590	UNCLASSIFIED BIOLOGICS	Simponi [®] (Injection, golimumab)	09/01/2011
J9212	INJECTION, INTERFERON ALFACON-1, RECOMBINANT, 1 MICROGRAM	Infergen [®]	05/04/2009

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J9213	INJECTION, INTERFERON, ALFA-2A, RECOMBINANT, 3 MILLION UNITS	Roferon-A [®]	05/04/2009
J9216	INJECTION, INTERFERON, GAMMA 1-B, 3 MILLION UNITS	Actimmune [®]	05/04/2009
J9218	LEUPROLIDE ACETATE, PER 1 MG	Lupron [®]	05/04/2009

Basis for Exclusion:

1. **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. When the drug is used for a condition that is recurrent, identifiable by the patient, given for an immediate effect and provided with self-administration instructions in the drug’s approved package insert, the drug is usually considered 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.

2. **Usual Practice:** For the purposes of applying this exclusion, the term “usually” means more than 50% of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50% of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it.

3. **Presumptions in the absence of objective data specific to the Medicare beneficiary population:** Reliable statistical information on the extent of self-administration by the patient may not always be available. Consequently, CMS offers guidance for considerations in making this determination in the absence of data.
 - A. **Route of administration:** Absent evidence to the contrary, presume:
 - i. Drugs delivered intravenously are not usually self-administered by the patient.
 - ii. Drugs delivered by intramuscular injection are not usually self-administered by the patient. Cahaba GBA may consider the depth and nature of the particular intramuscular injection in applying this presumption. The use of the particular drug, along with the acuity of the condition and frequency of administration, will be considered.
 - iii. Drugs delivered by subcutaneous injection are self-administered by the patient. The use of the particular drug, along with the acuity of the condition and frequency of administration, will be considered.



- B. **Acuity of condition being treated:** If the condition for which the drug is used is an acute condition, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.

- C. **Frequency of administration:** If a 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.

Background:

Cahaba GBA’s Self-Administered Drug Exclusion Lists include those drugs that are determined by this contractor to be ‘usually self-administered’ based upon the instructions provided in the [Medicare Benefit Policy Manual, Chapter 15, Section 50.2](#) .

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

1. Medicare Benefit Policy manual: Chapter 15—Covered Medical and Other Health services. Available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed November 14, 2012.
2. Local Coverage Article for Self-Administered Drug Exclusion List (A48903). Available at: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=48903&ver=39&ContrId=213&ContrVer=1&CtrctrSelected=213*1&Date=01%2f01%2f2012&DocID=A48903&bc=hAAAAAgAAAA&. Accessed November 14, 2012.
3. Cahaba Government Benefit Administrators, LLC. Self Administered Drug (SAD) Exclusion List. Available at: <http://www.cahabagba.com/part-b/medical-review/self-administered-drug-sad-exclusion-list/>. Accessed November 14, 2012.



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