Self Admin Drug Billing and Compliance

We have had a number of Clients continue to question the required billing process for SAD, as a result the following paper recaps the definition of a SAD and the various options hospitals have implemented to address the issue.

To recap the regulation for Self Admin Drugs:

1. A SAD is any drug which is administered by a Patient to themselves in the universal usage of the drug, not just in the hospital
2. There are J code SADs, they are defined by the MAC or FI, to determine your J code SAD, utilize the filter in the PDE
3. SADs are to be billed to the Patient
4. SADs are billable by the Patient to Part D
5. SADs are billed using revenue code 0637 or 0259, MAC/FI defined
6. Several MACs/FIs require the assignment of A9270 HCPCS code to the line
7. If a drug is "integral" to a procedure it is not a SAD

The only Guidance CMS has provided for several of the options in billing SADs is cited below from the 2003 OPPS Final Rule.

http://www.cms.gov/hospitaloutpatientpps/downloads/a02129.pdf

D. Summary of Policy Affecting Payment for Drugs Under the OPPS

1. General

In accordance with section 1861(s)(2)(B) of the Act and related Medicare regulations and program issuances, drugs and biologicals that are not usually self-administered by the patient are payable under the OPPS when furnished incident to a physician service. Under OPPS, Medicare makes separate payment for certain drugs and biologicals and packages payment for others into the procedure with which they are billed.

The fact that a drug has a HCPCS code and a payment rate under the OPPS does not imply that the drug is covered by the Medicare program, but indicates only how the drug may be paid if it is covered by the program. Intermediaries must determine whether the drug meets all program requirements for coverage; for example, that the drug is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment because it is usually self-administered.

Neither the OPPS nor other Medicare payment rules regulate the provision or billing by hospitals of non-covered drugs to Medicare beneficiaries. However, a hospital's decision not to bill the beneficiary for non-covered drugs potentially implicates other statutory and regulatory provisions, including the prohibition on inducements to beneficiaries, section 1128A(a)(5) of the Act, or the anti-kickback statute, section 1128B(b) of the Act.

2. Drugs Treated as Supplies

Certain drugs are so integral to a treatment or procedure that the treatment or procedure could not be performed without them. Because such drugs are so clearly an integral component part of the procedure or treatment, they are packaged as supplies under the OPPS into the APC for the procedure or treatment. Consequently, payment for them is included in the APC payment for the procedure or treatment of which they are an integral part. Examples include:

- Sedatives administered to patients while they are in the preoperative area being prepared for a procedure are supplies that are integral to being able to perform the procedure.
- Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic ointments, and ocular hypotensives that are administered to the patient immediately before, during, or immediately following an ophthalmic procedure are considered an integral part of the procedure without which the procedure could not be performed.
- Barium or low osmolar contrast media are supplies that are integral to a diagnostic imaging procedure.
- Topical solution used with photodynamic therapy furnished at the hospital to treat non-hyperkeratotic actinic keratosis lesions of the face or scalp.
- Local anesthetics such as marcaine, lidocaine (with or without epinephrine).
- Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.

Examples of cases where a drug is not directly related and integral to a procedure or treatment and would not be considered a packaged supply include:

- Cases where drugs are given to a patient for their continued use at home after leaving the hospital.
- In the situation where a patient who is receiving an outpatient chemotherapy treatment develops a headache, any medication given the patient for the headache would not meet the conditions necessary to be treated as a packaged supply.
- In the situation where a patient who is undergoing surgery needs his or her daily insulin or hypertension medication, the medication would not be treated as a packaged supply.

Hospitals may not separately bill beneficiaries for items whose costs are packaged into the APC payment for the procedure with which they are used (except for the copayment that applies to the APC). Note that drugs treated as supplies should be reported under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs.

An excerpt of the regulation and definition of SADs are pasted below

https://apps.para-hcfs.com/pde/documents/bp102c15.pdf

50.2 - Determining Self-Administration of Drug or Biological
(Rev. 91; Issued: 06-20-08; Effective/Implementation Date: 07-21-08)

The Medicare program provides 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 self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act to redefine this exclusion. The prior statutory language referred to those drugs "which cannot be self-administered." Implementation of the BIPA provision requires interpretation of the phrase "not usually self-administered by the patient".

A. Policy

Fiscal intermediaries, carriers and Medicare Administrative Contractors (MACs) are instructed 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.

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.

B. 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.

C. Usually

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 and the contractor may not make any Medicare payment for it. 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 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent 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, CMS offers the following guidance for each contractor's consideration in making this determination in the absence of such data:

1. Absent evidence to the contrary, presume that drugs delivered intravenously are not usually self-administered by the patient.

2. Absent evidence to the contrary, presume that drugs delivered by intramuscular injection are not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self-administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:

3. Absent evidence to the contrary, presume that drugs delivered by subcutaneous injection are self-administered by the patient. However, contractors should examine the use of the particular drug and consider the following factors:

   A. **Acute Condition** - Is the condition for which the drug is used an acute condition? If so, 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.

   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.

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will no longer pay for such doses. In addition, contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

D. Definition of 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 2 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.

E. By the Patient

The term "by the patient" means Medicare beneficiaries as a collective whole. The carrier includes only the patients themselves and not other individuals (that is, spouses, friends, or other care-givers are not considered the patient). The determination is based 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. The carrier ignores all instances when the drug is administered on an inpatient basis.

The carrier makes 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, 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 are not considered. 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.

The URL's for the MACs J code SAD exclusions are pasted below:

Highmark Medicare

https://www.highmarkmedicareservices.com/articles/mac-ab/a47773-r2.html

National Government Services

http://www.ngsmedicare.com/wps/portal/ngsmedicare

WPS Medicare

http://www.wpsmedicare.com/j5macpartb/policy/usad_listing/

Noridian

https://www.noridianmedicare.com/shared/partb/bulletins/2009/253_apr/SAD_Drugs_-_Determination_of_Which_Drugs_are_Usually_Self-Administered_by_the_Patient.htm

An ABN is not required to bill the Patient for the drugs, the coverage is defined in the Medicare Patient manual, a link and except are pasted below.

http://www.medicare.gov/publications/pubs/pdf/10050.pdf

Part B-Covered Services

Physical Therapy	Evaluation and treatment for injuries and diseases that change your ability to function when your doctor certifies your need for it. There may be limits on these services and exceptions to these limits. You pay 20% of the Medicare-approved amount, and the Part B deductible applies.
Pneumococcal Shot	Helps prevent pneumococcal infections (like certain types of pneumonia). Most people only need this shot once in their lifetime. Talk with your doctor. You pay nothing if the doctor or supplier accepts assignment for giving the shot.
Prescription Drugs (limited)	Includes a limited number of drugs such as injections you get in a doctor's office, certain oral cancer drugs, drugs used with some types of durable medical equipment (like a nebulizer or external infusion pump) and under very limited circumstances, certain drugs you get in a hospital outpatient setting. You pay 20% of the Medicare-approved amount for these covered drugs. If the covered drugs you get in a hospital outpatient setting are part of your outpatient services, you pay the copayment for the services. However, if you get other types of drugs in a hospital outpatient setting (sometimes called "self-administered drugs" or drugs you would normally take on your own), what you pay depends on whether you have Part D or other prescription drug coverage, whether your drug plan covers the drug, and whether the hospital's pharmacy is in your drug plan's network. Contact your prescription drug plan to find out what you pay for drugs you get in a hospital outpatient setting that aren't covered under Part B. See page 81 for more information. Other than the examples above, you pay 100% for most prescription drugs, unless you have Part D or other drug coverage.

The link and a sample of the CMS "booklet" on Patient Billing of Self-Administered Drugs Given in a Hospital Outpatient Setting are pasted below.

http://www.medicare.gov/Publications/Pubs/pdf/11333.pdf

CENTERS FOR MEDICARE & MEDICAID SERVICES

How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings

Medicare Part B (Medical Insurance) generally covers care you get in a hospital outpatient setting, like an emergency department, observation unit, surgery center, or pain clinic. Part B only covers certain drugs in these settings, like drugs given through an IV (intravenous infusion).

Sometimes people with Medicare need "self-administered drugs" while in hospital outpatient settings. "Self-administered drugs" are drugs you would normally take on your own. Part B generally doesn't pay for self-administered drugs unless they are required for the hospital outpatient services you're getting.

If you get self-administered drugs that aren't covered by Medicare Part B while in a hospital outpatient setting, the hospital may bill you for the drug. However, if you are enrolled in a Medicare drug plan (Part D), these drugs may be covered.

What you should know about Medicare drug plans (Part D) and self-administered drugs

- Generally, your Medicare drug plan only covers prescription drugs and won't pay for over-the-counter drugs, like Tylenol® or Milk-of-Magnesia®.
- Any drug you get needs to be on your Medicare drug plan's formulary (or covered by an exception).
- You can't get your self-administered drugs in an outpatient or emergency department setting on a regular basis.

Hospitals have implemented several different processes to address the SAD regulations:

1. Ignore or be unaware of the regulation
2. Process SADs as a "standard" drug since there is little reimbursement and negative Patient impact
3. Write the SAD drug charges off the Medicare claim at the time of billing
4. Bill the SADs as non-covered to Medicare and write-off the charges upon receipt of the R/A
5. Bill the SADs as non-covered to Medicare and bill the charges to the Patient

The "compliant" process is to bill the charges as non-covered to Medicare and then bill the charges to the Patient.

The percentage distribution of Hospital's implementing the processes defined above is as follows:

1. Ignore or be unaware of the regulation – 20%
2. Process SADs as a "standard" drug since there is little reimbursement and a negative Patient impact – 30%
3. Write the SAD drug charges off the Medicare claim at the time of billing – 15%
4. Bill the SADs as non-covered to Medicare and write-off charges upon receipt of the R/A – 15%
5. Bill the SADs as non-covered to Medicare and bill the charges to the Patient – 20%

There is very little reimbursement associated with billing the SADs to the Program, the only scenario in which a hospital would receive additional reimbursement from a SAD is with a OPPS Cost Outlier claim.

PARA has never seen or heard of a MAC or FI audit hospitals for compliance to the SAD regulation.

When a hospital bills the SADs to a Patient there is a “negative” patient reaction to the process, it is recommended by PARA that the price for SADs be reduced to better reflect the efficiency and reduced costs of SADs.

Within the PDE PARA has a pricing model in the RX/Supply tab to re-price drugs, which allows a hospital to maintain the required revenue and at the same time, reducing the charge for the SADs.