The Facts about Reimbursement for Self-administered Drugs
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Introduction

In our visits to hospitals around the United States we have observed much uncertainty about how self-administered drugs should be handled in Medicare and Medicaid claims. Generally, self-administered drugs are not reimbursable. But there are some notable exceptions. Hospitals should familiarize themselves with those exceptions, so that they do not pass up reimbursement to which they are legitimately entitled.

Background

Self-administered drugs (SADs) are a Part B (outpatient) traditional fee-for-service Medicare concept. This concept does not apply to Part A or Part D Medicare. SAD medications are generally excluded by the Social Security Act from coverage and therefore from reimbursement.

Coverage

Self-administered drugs are detailed in the Medicare Benefit Policy Manual beginning with Chapter 15 §50.2. The introduction states "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:

1. They meet the definition of drugs or biologicals
2. They are of the type that are not usually self-administered
3. They meet all the general requirements for coverage of items as incident to a physician’s services
4. 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.
5. They are not excluded as non-covered immunizations; and
6. They have not been determined by the FDA to be less than effective.

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or that are used for self-injection. There are a few exceptions to this coverage guideline. 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. Oral cancer drugs are defined in Claims Processing Manual, Chapter 17, Section 80.2.1.1.
Definition of “Self-administered”

Contractors are responsible for determining the exclusions according to the Medicare Benefit Policy Manual, Chapter 15 §50.2. There are several considerations in this determination:

“Administration”
The term “administered” refers only to the physical process by which a drug enters the body. It does not refer to whether the process is supervised by a medical professional. Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the “incident to” benefit and are therefore not considered self-administered. With limited exceptions, drugs taken via other routes of administration, including – but not limited to – oral drugs, suppositories, and topical medications, are considered to be usually self-administered by the patient.

“Usually”
The Medicare program provides limited benefits for drugs that “are not usually self-administered by the patients who take them.” The term “usually” means more than 50 percent of the time for all Medicare beneficiaries who use the drug. In other words, if the drug is self-administered by more than 50 percent of Medicare beneficiaries, then the drug is excluded from coverage. The contractor cannot make any payment for an excluded drug. The contractor is responsible for making separate determinations for each indication of a drug as to whether that drug is usually self-administered.

“Absent Evidence to the Contrary”
CMS offers the following guidance for each contractor’s consideration in making the determination, in the absence of statistical information, on the “extent of self-administration” by the patient. In essence, if the contractor cannot tell if it is administered by more than 50 percent of the Medicare population then this guidance is used.

- “Absent evidence to the contrary” presumes that drugs delivered intravenously are not usually self-administered by the patient.
- “Absent evidence to the contrary” presumes that drugs delivered by intramuscular injection are not usually self-administered by the patient.
- “Absent evidence to the contrary” presumes that drugs delivered by subcutaneous injection are usually self-administered by the patient.

CMS has offered further guidance to the contractor to assist in the determination of self-administered status.

- Acute Condition – “Is the condition for which the drug is used an acute condition? If so, is it 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.”
- 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.”
After weighing all these considerations the contractor must publish a “Provider Notice of Noncovered Drugs.” The contractor must describe on their website the process they will use to determine whether a drug is usually self-administered and therefore would be moved from the benefit category of “incident to” to a non-covered benefit or self-administered medication. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their website, including the rationale that led to the determination.

**SADs that are Integral to a Procedure**

According to Medicare Program Memorandum, Transmittal Number A-02-129, January 3, 2003, page 30, “Drugs treated as Supplies,” some drugs are so integral to the procedure that they constitute a supply. “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 Hospital Outpatient Prospective Payment System (OPPS) into the Ambulatory Payment Classification (APC) for the procedure or treatment. Consequently, payment for them is included in the APC payment for the procedure 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. They are considered 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. They 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 solutions used with photodynamic therapy furnished at the hospital to treat non-hyperkeratotic actinic keratosis lesions of the face or scalp.

- Local anesthetics such as Marcare® or lidocaine.

- Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of the procedure.

Hospitals may not separately bill beneficiaries for items whose costs are packaged into the APC payment for the procedure. Drugs that are treated as supplies (including those meeting self-administered definitions) should be reported under the revenue code associated with the cost center under which the hospital accumulates costs for the drugs. Generally, this would be revenue code 0250. [Transmittal A-02-129, page 30]
Advanced Beneficiary Notice (ABN) and Self-administered Drugs

Self-administered drugs, by their definition, are statutorily excluded items. Therefore, a mandatory ABN would not be required. However, with the changes in April 2010 a hospital may consider providing a “voluntary ABN” to the patient. Although they are not required to provide them, many hospitals and physicians are beginning to use the “voluntary ABN” more extensively to prevent future patient complaints. For further discussion of the use of the voluntary ABN see the Medicare Claims Processing Manual, Chapter 30, “Financial Liability Protections” and www.cms.gov/bni.

Billing and Claims Submissions for Self-administered Drugs

Revenue Codes

Based upon the actual clinical situation one of two revenue codes would be required when billing for self-administered drugs. The following details the specifics:

- **Outpatient SAD.** Use revenue code 0637.
- **Observation SAD.** Use revenue code 0637 (observation is an outpatient status).
- **Outpatient SAD but integral to a procedure.** Use revenue code 0250.
- **SAD provided to inpatient.** SAD is not an inpatient concept, so the facility should use the general billing requirements for inpatient pharmacy. Use revenue code 0250.

HCPCS Codes

CMS has stated within the OPPS guidelines that they expect that a HCPCS code be reported if one exists. [CMS 1504-P (display copy), page 146 (July 2, 2010)] However, most self-administered drugs do not have a HCPCS code and should be billed with just revenue code 0637 on a wholly non-covered claim.

If the claim contains covered items, then the HCPCS code will need to be modified to demonstrate the service as statutorily excluded. Two modifiers are used for this purpose:

- **GY Modifier** – indicates statutory exclusion or categorical exclusion.
- **GX Modifier** – indicates that a voluntary ABN was issued to the patient.

Since most SADs don’t have a HCPCS code, CMS has provided guidance that HCPCS code A9270 (Noncovered item or service) with the appropriate modifier(s) and revenue code 0637 should be used.

Overcoming Patient Concerns

SAD charges to Medicare patients can result in significant customer complaints to the billing office or the patient financial services department. Patients frequently do not understand that Medicare does not cover these medications; there is “sticker shock” when they receive a patient statement showing their personal liability. The most successful method of overcoming these concerns is to provide targeted patient education.
Patient Education

The “Medicare and You 2010” beneficiary manual provides the patient with CMS guidance on self-administered drugs. Specifically it states: “In most cases the prescription drugs you get in an outpatient setting like an emergency department (sometimes called “self-administered drugs”) aren’t covered by Part B. … You will likely need to pay out-of-pocket for these drugs and submit a claim to your drug plan for a refund.” Additionally CMS has provided a document with their logo on self-administered drugs which can be found at: www.medicare.gov/Publications/Pubs/pdf/11333.pdf.

Craneware recommends that a copy of the “Medicare and You” document with the actual verbiage stated above be available and shared with the patient at time of registration, at some point in pre-operative clearance (ambulatory surgery), when diagnostic testing and therapeutic services such as cardiac catheterization are provided, as well as through pacemaker laboratories and GI laboratories and any other outpatient location where self-administered drugs are likely to be provided to scheduled patients. In situations where there is unscheduled care, such as in the Emergency Department, we recommend that these documents be provided to Medicare patients at the time of discharge so as to not to interfere with any potential Emergency Medical Treatment and Active Labor Act (EMTALA) requirements. The key to reducing patient concerns and complaints is to provide information regarding SADs to them before sending them a patient statement. Additionally, it is important to note that many facilities have some anxiety regarding billing SADs. We recommend that you provide the documents issued by CMS so that the patient is aware that this is not a facility policy but a Medicare regulation.

References

3 http://www.q1medicare.com/pics/ContentPics/MedicareAndYou2010_10050.pdf
4 http://www.medicare.gov/Publications/Pubs/pdf/11333.pdf
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