Table of Contents

Introduction

Medicare's Self-Administered Drug billing rules are complex and challenging for most hospitals.

Hospitals are required to submit their claim line items for Self Administered Drugs (SADs) in a manner which transfers financial liability to the Medicare beneficiary only when the drugs are non-covered. The same drug may be considered covered in one outpatient setting (i.e. outpatient surgery) and non-covered in others (i.e. the Emergency Department.) Most hospitals find that some manual intervention is required to correctly bill for drugs under the various conditions which apply in different settings.

The Self Administered Drugs Rule

The full text of the Medicare Benefit Policy Manual, Chapter 50.2 is provided in the Regulatory References section of this paper. The following points briefly recap the regulation for Self Administered Drugs:

1. **A SAD is a drug which is most often self-administered** in the overall use of the drug in all settings, not just in the hospital setting.
2. **Under original Medicare, SADs are statutorily excluded from coverage.** SAD drugs must be billed an outpatient claim to Medicare as "non-covered."
3. **Hospitals should report SAD charge lines under revenue code 0637 with HCPCS A9270 (Non-covered item or service) and modifier GY** (Item or service statutorily excluded or does not meet the definition of any Medicare benefit)
4. **Medicare will process outpatient line items for SADs as non-covered charges;** the charge will drop to patient responsibility on the remittance (along with any other coinsurance or deductible that the patient may have for other services billed on the same claim.)
5. **Drugs which have been assigned HCPCS codes, such as insulin (J1815), may be a SAD.** Each MAC or FI provides a list of injectable drugs which are considered SADs that are not covered, whether or not the provider considers the administration to be "incident to" another service. (SAD Exclusion lists for each of the MACs are available on the Medicare Coverage Database.)
6. **Medicare advises patients with Part D coverage to seek reimbursement** for their SADs under their Part D benefit plan. Not all plans will cover pharmacy items dispensed by the hospital, however, therefore this does not provide a solution for the patient expense on a hospital claim.
7. **MACs/FIs may provide specific SAD billing instructions,** such as the assignment of A9270 HCPCS code and/or the -GY modifier to SAD charges.
8. **Medicare will cover** certain SAD drugs conditionally – depending on whether the drug is on the Part A contractor's "exclusion" list with an asterisk(*), or when the drug is provided "integral" to a procedure. (See the section titled: "Integral to" Coverage of SADs.)
9. **Modifier JA or JB may be required,** as certain injectable drugs (those marked with an asterisk (*) on the MAC Self-Administered Drugs Exclusion List) are considered to be self-administered if administered subcutaneously, but not an SAD if administered via IV.

Implications of Non-Compliance

For OPPS hospitals, there is little difference in Medicare reimbursement whether the hospital is in compliance with SAD rules or not. While a hospital is entitled to collect the cost of non-covered SADs provided in the outpatient setting from the Medicare beneficiary, the pursuit of non-covered drug charges from the Medicare-eligible patient is costly and extremely unpopular with patients.

Regulatory agencies are also unrewarded for their enforcement responsibilities arising from these rules. SADs are not an attractive target for the self-funding Recovery Audit Contractors since little (if any) inappropriate reimbursement could be claimed, as most drugs are not separately paid, but "packaged" into the payment for other services under OPPS.

Compliance risks for OPPS hospitals which fail to correctly report Self-Administered Drugs are not easily quantified. The OIG database contains no examination of individual hospital reporting issues, or penalties arising from any noncompliance. Medicare summarized the implications of hospital non-compliance with SAD rules in its Program Memorandum for Intermediaries Transmittal A-02-129 (January 3, 2003):

> http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/a02129.pdf
>
> "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."

CAH facilities, however, are reimbursed on the basis of their costs for every covered line item on an outpatient claim; failure to report SADs correctly as non-covered on CAH claims is a compliance issue. Noncompliance could generate additional reimbursement which would be subject to eventual recoupment, with penalties, by Medicare.

Hospitals are not uniformly in compliance with the Self-Administered Drugs rules. The following provides an informal estimate of the percentage of hospitals in the various states of compliance:

Ignorant or unaware of the regulation	20%
Aware of rules but fail to identify SADs separately from covered drugs	30%
Aware of rules but write off SAD charges prior to or shortly after submitting the claim to Medicare, (thereby failing to pursue patient liability)	30%
File claims with SADs appropriately and pursue patient liability	20%

"Integral to" Coverage of SADs

Each Medicare Administrative Contractor (or Fiscal Intermediary, in some areas) publishes an "exclusion" list of injectable self-administered drugs. These drugs are not covered as they are considered "Self-Administered", even though the drug is injected.

However, sometimes a self-administered drug may be covered by Medicare when provided "integral to" another service. The Medicare Benefits Policy Manual offers the following guidance, as modified in the July 2012 OPPS Update:

> *"…Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and should not separately bill the beneficiary.*
>
> - *Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.*
> - *Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre-and postoperatively.*
> - *Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.*
> - *Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.*
> - *Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.*

This limited guidance from Medicare on "integral to" results in confusion. Hospitals are charged with the difficult task of making judgment calls as to whether to bill a drug as covered under revenue code 250 or 636, or to simply take a conservative approach of billing the SAD to Medicare in a manner that the patient will be held financially liable. Under these difficult circumstances, hospitals can only make a good faith effort.

SAD Exclusion Lists and Modifiers JA and JB

Most injectable drugs are considered covered, not self-administered. However, some drugs which are commonly injected by patients in the home setting are still deemed self-administered, such as insulin.

To clarify whether an injectable drug is covered or a SAD, each MAC is responsible for publishing its SAD Exclusion List, which itemizes drugs which are injectable but which the MAC deems to be Self-Administered Drugs.

The SAD exclusion list for each MAC is available on the Medicare Coverage Database (MCD) Reports page:

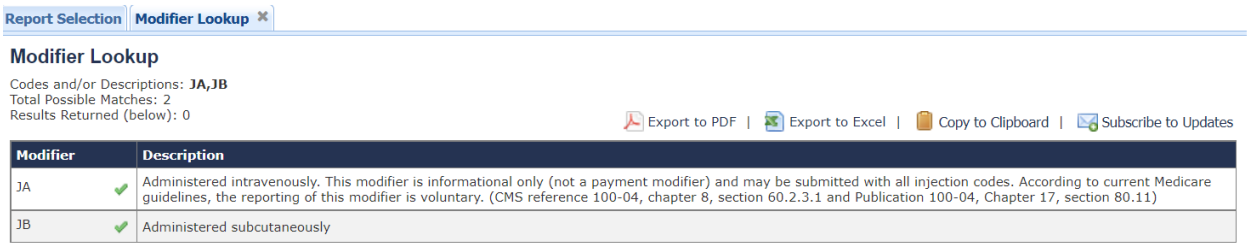
https://www.cms.gov/medicare-coverage-database/new-search/reports/reports.aspx

The SAD Exclusion List became more significant to MACs (and by extension, to providers) when the OIG published an audit criticizing MACs for covering drugs which are sometimes self-administered, as detailed in its report of July 2, 2020:

https://oig.hhs.gov/oei/reports/OEI-BL-20-00100.asp

In response to this criticism, MACs began requiring facilities to append modifier JA or JB to claim lines for drugs that are sometimes self-administered.

The drugs which are conditionally covered are identified in each MAC's "SAD Exclusion Policy" with an asterisk (*), indicating that that particular drug must be billed with modifier JA or JB to indicate the route of administration.


Report Selection | Modifier Lookup

Modifier Lookup

Codes and/or Descriptions: JA,JB
Total Possible Matches: 2
Results Returned (below): 0

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Modifier	Description
JA	Administered intravenously. This modifier is informational only (not a payment modifier) and may be submitted with all injection codes. According to current Medicare guidelines, the reporting of this modifier is voluntary. (CMS reference 100-04, chapter 8, section 60.2.3.1 and Publication 100-04, Chapter 17, section 80.11)
JB	Administered subcutaneously

For example, most MACs list Orencia® (J0129), Benlysta® (J0490), and Sandostatin® (J2354) among the drugs which require a modifier (JA or JB) to identify the route of administration, thereby enabling the MAC to correctly adjudicate the subcutaneous administration of these drugs as self-administered. Each MAC makes its own determination and policy; some MACs also list Actemra® (J3262), and Raptiva® (J3590) as covered only when billed with modifier JA, indicating IV administration.

Orencia is marked with an asterisk in the SAD exclusion policy for the MAC CGS:

Contractor	CPT/ HCPCS Code	CPT/HCPCS Code Description	Drug Brand Name
CGS Administrators, LLC (HHH MAC, MAC - Part A, MAC - Part B)	J0129	Injection, abatacept, 10 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)	Abatacept* Orencia* Orencia Clickjet* Note: If being administered IV use modifier "JA"; if administered subcutaneously use modifier "JB" (subcutaneous injection is considered self-administered)

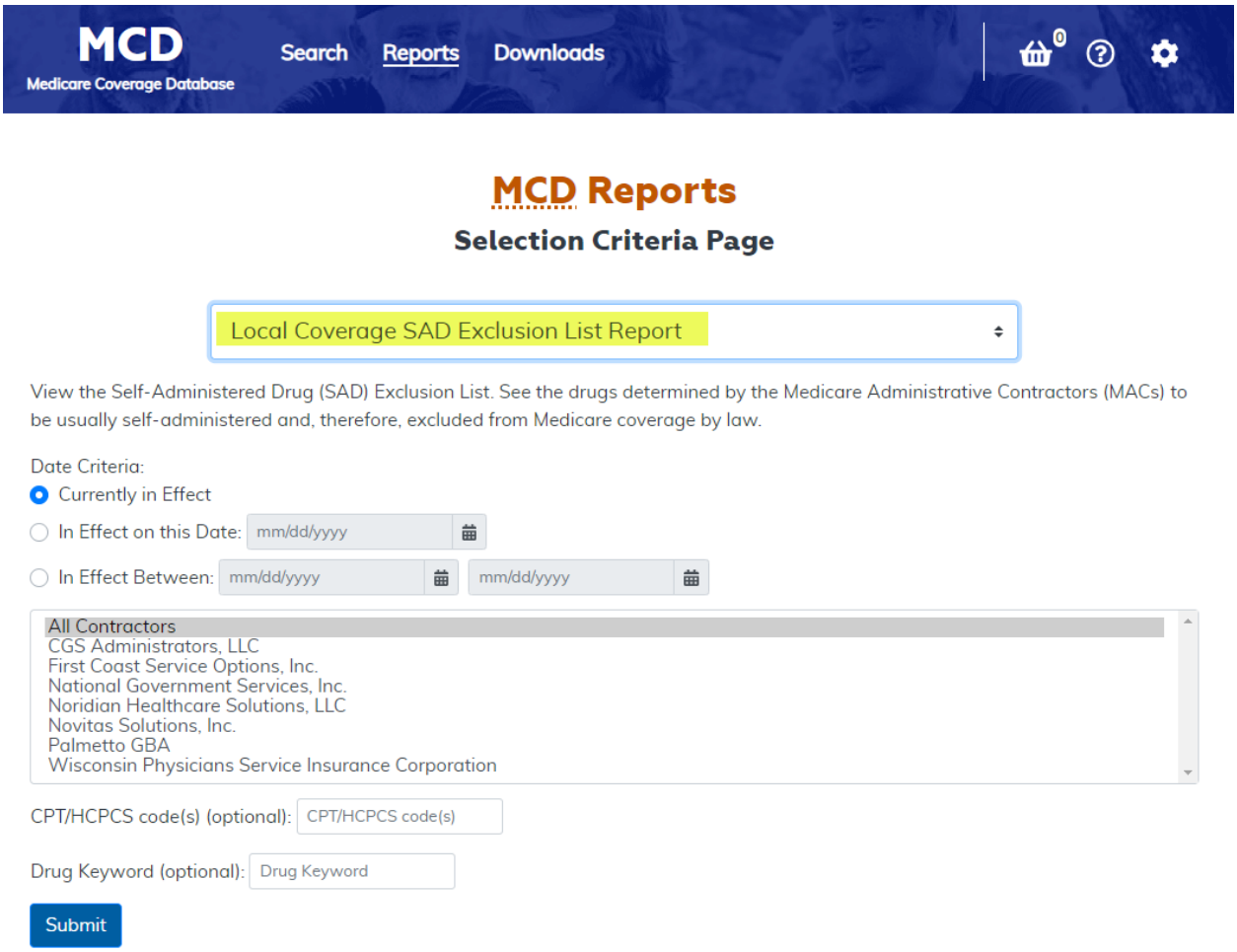
- Claims billed with the JA modifier, indicating an IV therapy route of administration, are generally not considered SADs, and are therefore covered.
- Drugs billed with the JB modifier, indicating a subcutaneous route of administration, are is usually considered self-administered and therefore non-covered.

The MAC will process claims with the JA modifier applying the policy that not only the drug is medically reasonable and necessary, but also that the route of administration is medically reasonable and necessary.

Directions to view each MAC's "SAD Exclusion" list of injectable drugs is provided on the following page.

The Medicare Coverage Database offers access to each MAC's SAD Exclusion List in a format which is searchable by MAC, effective date, CPT®/HCPCS, and/or drug keyword:

https://www.cms.gov/medicare-coverage-database/reports/reports.aspx



Billing the Patient

Hospitals may choose not to pursue the Medicare beneficiary for payment of self-administered drugs provided in the outpatient setting. The OIG issued an opinion in October, 2015 which allows hospitals to discount or waive the patient liability for SADs if certain criteria are met:

https://oig.hhs.gov/compliance/alerts/guidance/policy-10302015.pdf

OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings

"…Ordinarily, routine discounts or waivers of costs owed by Medicare beneficiaries, including cost sharing amounts, potentially implicate the Federal anti-kickback statute,[6] the civil monetary penalty and exclusion laws related to kickbacks,[7] and the Federal civil monetary penalty law prohibiting inducements to beneficiaries.[8]

"Nonetheless, in the limited circumstances described in this Policy Statement, hospitals will not be subject to OIG administrative sanctions if they discount or waive amounts that Medicare beneficiaries owe for Noncovered SADs (including Noncovered SADs that may be covered under Medicare Part D) the beneficiaries receive in outpatient settings, subject to the following conditions:

- This Policy Statement applies only to discounts on, or waivers of, amounts Medicare beneficiaries owe for Noncovered SADs that the beneficiaries receive for ingestion or administration in outpatient settings;[9]
- Hospitals must uniformly apply their policies regarding discounts or waivers on Noncovered SADs (e.g., without regard to a beneficiary's diagnosis or type of treatment);
- Hospitals must not market or advertise the discounts or waivers; and
- Hospitals must not claim the discounted or waived amounts as bad debt or otherwise shift the burden of these costs to the Medicare or Medicaid programs, other payers, or individuals.

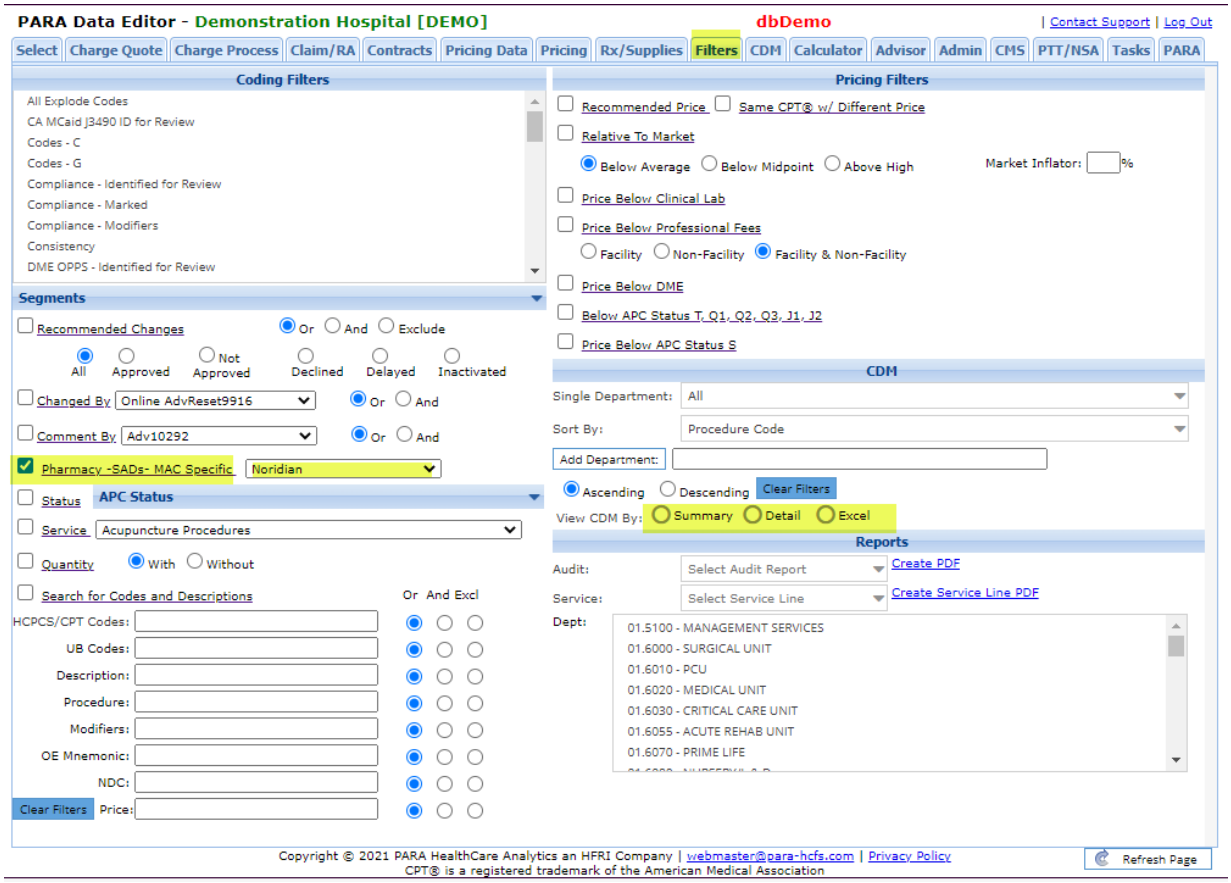
"Nothing in this Policy Statement requires hospitals to discount or waive amounts owed by Medicare beneficiaries for Noncovered SADs that the beneficiaries receive in outpatient settings. …"

Best Practices

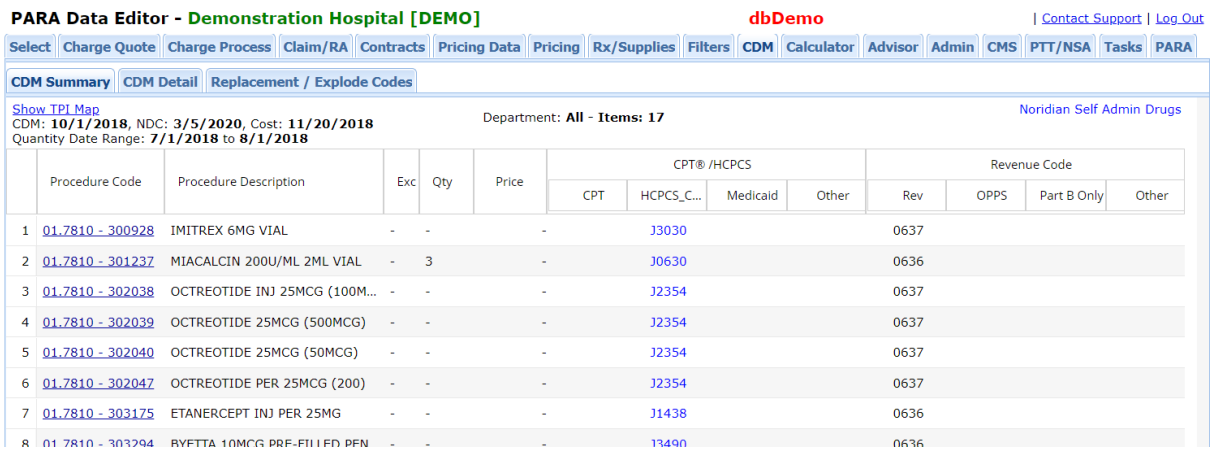
- To comply with Medicare program regulations, hospitals must report SAD charges as non-covered on outpatient claims. To ensure appropriate claims processing, hospitals should bill non-covered SAD drugs used in outpatient claims to Medicare with HCPCS code A9270 (Non-Covered Item or Service) and modifier GY (Statutorily excluded) under revenue code 0637 (Pharmacy - Extension of 025x - Self-Administrable Drugs).
- Each hospital should make its own determination of whether to pursue payment for SADs from the patient, or waive or discount Medicare beneficiary patient liability, in keeping with the OIG policy statement.
- Since the same SAD drug may be covered under some circumstances and non-covered in others, hospitals should use the chargemaster to facilitate compliance with the SAD rule. For instance, some injectible drugs are covered if administered intravenously, but not covered if administered subcutaneously. The hospital chargemaster may offer two separate procedure codes for the same drug to ensure that the appropriate modifier (JA or JB) is appended according to the route of administration when the outpatient claim is submitted to Medicare.
- When a SAD may be covered as "integral to" another procedure, the hospital should consider whether separate chargemaster procedures could be used to distinguish between covered and non-covered use. For example, two charge codes for the same oral anti-emetic could be used, one restricted to covered settings (such as the chemotherapy infusion center), the other for non-covered settings (i.e., the emergency department.)
- Certain oral anti-emetics are covered when used in lieu of IV medication to treat nausea caused by chemotherapy, but are non-covered SADs in any other circumstances. (See PARA paper "Medicare Coverage of Oral Anti-Emetics" for further information.)
- Medicare-beneficiary complaints on SAD charges should be handled with special care and consideration. Patient account representatives should be trained in understanding Medicare's SAD policy, and in communicating the policy to Medicare beneficiaries who question the rule. No Advance Beneficiary Notice is required because the drugs are statutorily excluded from coverage. Refer Medicare beneficiaries to the Medicare and You beneficiary manual (see page 39 on the 2022 edition.)
- Providers should avoid reporting HCPCS A9270 when billing commercial insurance plans unless the plan has a known policy that it will not cover SADs. Most commercial insurers will cover all drugs in the outpatient setting, even SADs. However, if a claim to a commercial carrier reports HCPCS A9270, the commercial carrier will automatically deny the charge because A9270 represents a non-covered service. The denied charge will be adjudicated to patient liability.

Resource: The PARA Data Editor

The Filters tab within the **PARA Data Editor** allows a User to find the injectable SADs defined by their FI/MAC exclusion list and locate the items within the charge master. Select the MAC from the dropdown, check the box on the left, and then click on either Summary, Detail, or Excel radio buttons:



Results returned for the filter above (partial list displayed):



Regulatory References

National CMS instructions related to SADs are found in Medicare Benefit Policy Manual, Chapter 50.2:

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf

The updated language reads:

> ***"…***
> ***M. Drugs Treated as Hospital Outpatient Supplies***
>
> *In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as supplies. This is the case when the drugs provided are an integral component of a procedure or are directly related to it, i.e., when they facilitate the performance of or recovery from a particular procedure. Except for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used. Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and should not separately bill the beneficiary.*
>
> - *Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.*
> - *Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre-and postoperatively.*
> - *Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.*
> - *Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.*
> - *Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.*
>
> *The following are examples of when a drug is not directly related or integral to a procedure, and does not facilitate the performance of or recovery from a procedure. Therefore the drug is not considered a packaged supply. In many of these cases the drug itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance*

(continued next page)

Medicare Benefits Policy Manual - continued

of or recovery from a particular procedure.

- *Drugs given to a patient for his or her continued use at home after leaving the hospital.*
- *Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment.*
- *Daily routine insulin or hypertension medication given preoperatively to a patient.*
- *A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.*
- *A laxative suppository for constipation while the patient waits to receive an unrelated X-ray.*

These two lists of examples may serve to guide hospitals in deciding which drugs are supplies packaged as a part of a procedure, and thus may be billed under Part B. Hospitals should follow CMS' guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs."

Beneficiary Relations and Publications

An Advance Beneficiary Notice is not required to bill the Patient for the drugs, as these are a non-covered supply. Coverage is explained in the "Medicare and You" patient guidebook, a link and excerpt are provided below.

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

Part B-Covered Services

Prescription Drugs (limited)

Medicare covers 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, other types of drugs in a hospital outpatient setting (sometimes called "self-administered drugs" or drugs you would normally take on your own), aren't covered by Part B. 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 94 for more information.

CMS publication "How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings" (Product No. 11333 Revised June 2020):

https://www.medicare.gov/Pubs/pdf/11333-Outpatient-Self-Administered-Drugs.pdf

Revised June 2020

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 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 medications that you would normally take on your own, like medications that you take every day to control blood pressure or diabetes. In most cases, Part B generally doesn't pay for self-adminstered drugs used in the hospital outpatient setting.

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

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 aspirin or laxatives.
- Your Medicare drug plan will only cover prescription drugs that are on its formulary (drug list), unless it's covered by an exception.
- You can't get your self-administered drugs in an outpatient or emergency department setting on a regular basis.