

Self Administered Medications 2021 Basics

An Operational Guide

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Agenda and Objectives

Objectives

Participant will be able to:

- State what a Self Administered Medication (SAD) is
- Demonstrate understanding of how is determined to be SAD
- Be able to select the correct revenue code based on setting and administration
- Understand the requirements of billing SAD to Medicare Part B and D
- OIG Safe harbor ruling on waiver of SAD charges

Agenda

1. Cover the basics of Self Administered Medications
2. Cover some complexities involved with charging
3. Review what is available (or was available) on SAD facts from Medicare
4. To charge or not to charge that is the question

What Does SAD Stand For ?

Self Administered Medication

A forgotten source of revenue



Overview of SAD

Source Authority

Medical And Other Health Services

(s) The term “medical and other health services” means any of the following items or services:

(1) physicians’ services;

(2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician’s professional service, of kinds which are commonly furnished in physicians’ offices and are commonly either rendered without charge or included in the physicians’ bills (or would have been so included but for the application of section 1847B);

(B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians’ services rendered to outpatients and partial hospitalization services incident to such services;

Medicare Benefit Policy Manual

- Chapter 15, Section 50.2

- <http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>

Coverage Before Reimbursement

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Items-and-Services-Not-Covered-Under-Medicare-Booklet-ICN906765.pdf>

- In order to expect reimbursement from Medicare the service, supply or medication must meet one of the 4 following benefit categories as detailed by the Social Security Act and 42 CFR. These are:
 - Part A (inpatient)
 - Part B (outpatient / professional)
 - Part C (Medicare Advantage)
 - Part D (Pharmaceutical Benefit)
- Since SAD medications are statutorily excluded from benefit there is no expectation of reimbursement from the payor

Overview of Medicare SAD

The Medicare program covers medications in different fashions based on the Medicare plan:

- Part A (aka – inpatient) – covered benefit
- Part B – only those medications that are **not integral** to a procedure and are **not determined to be SAD** are covered benefits
- Part D – based on the plan, formulary and fee schedules

In all of these Parts there is one rule that must be understood

- ***The service, procedure or medication must be a covered service and be medically necessary***
 - ***Therefore cannot be excluded from coverage***

Overview of SAD

The issue with the SAD medications is that they are **excluded by statute** and therefore, not covered by the program (“Statutorily Excluded”)

- Remember **coverage before payment** (reimbursement)



In order for a drug to be covered under Part B it must meet certain requirements as stated in the Benefit Policy Manual

Benefit Policy Manual CH 15 § 50 - Coverage

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals (see §50.1);
- They are of the type that are not usually self-administered. (see §50.2);
- They meet all the general requirements for coverage of items as incident to a physician's services (see §§50.1 and 50.3);
- 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 (see §50.4);
- They are not excluded as noncovered immunizations (see §50.4.4.2); and
- They have not been determined by the FDA to be less than effective. (See §§50.4.4).

Incident To Criteria – BPM 15, § 50.3

50.3 - Incident To Requirements

(Rev. 1, 10-01-03)

B3-2049.3

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:

- • Be of a form that is not usually self-administered;
- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

What Constitutes Self Administered:

Usually:

- “usually self administered” = >50% of the Medicare beneficiaries can administer the drug by themselves

Evidence:

- Absent evidence to the contrary all drugs delivered intravenously are **NOT** usually self administered
- Absent evidence to the contrary presume all drugs delivered intramuscularly are **NOT** usually self administered
- Absent evidence to the contrary presume drugs delivered subcutaneously **ARE** self administered
- [BPM Ch 15, § 50.2]
- Based on this all oral, inhalation, rectal, topical, SQ, intradermal are SAD

Self Administered Definition

1.Administered: (How the drug enters the body)

- Generally **only injectable drugs are eligible for coverage** under the incident to benefit
- If there is more than one use for the drug then the Medicare **contractor must determine** whether the drug is self administered or non-self administered for each use
 - Ex: Med has both injectable and oral forms
 - Must weigh each indication

Determining Other Factors

Contractors (MACs) are instructed to consider factors that result in the Self Administered Exclusions List:

- **Acute Condition**

- Long term use – more likely to be SAD (Insulin)
- Short term/emergent use – less likely to be SAD

- **Frequency of Administration**

- More frequent – more likely to be SAD (Insulin)
- Less frequent / one time use – less likely to be SAD

Integral

“Certain drugs are so integral to a treatment or procedure that the treatment or procedure could not be performed without them. Because 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 within the APC payment for the procedure or treatment of which they are an integral part.

- [A-02-129 p. 30]

If the facility CDM requires a line for cost accounting purposes then it needs to be assigned to the packaged revenue center of 0250 so that all charges do roll into the procedure. These are considered integral supplies to the procedure

- Some examples are on the next page

Integral – CMS 100.02, Ch 15, § 50.2(M)

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.

Medicare Beneficiaries Have Received Notice

The fact that self administered medications are excluded from service and patient liability is within the yearly Medicare handbook – *Medicare and You*

- <https://www.medicare.gov/Pubs/pdf/10050-Medicare-and-You.pdf>

If the covered drugs you get in a hospital outpatient setting are part of your outpatient services, you pay a copayment for the services. However, Part B doesn't cover other types of drugs in a hospital outpatient setting (sometimes called "self-administered drugs" or drugs you'd normally take on your own). What you pay depends on whether you have Medicare drug coverage or other drug coverage, whether your drug plan covers the drug, and whether the hospital's pharmacy is in your drug plan's network. Contact your drug plan to find out what you pay for drugs you get in a hospital outpatient setting that Part B doesn't cover.

Other than the examples above, you pay 100% for most drugs, unless you have Medicare drug coverage or other drug coverage. See pages 75–86 for more information about Medicare drug coverage.

CMS Benefit Policy Manual Ch15, § 50.2

A “Voluntary” ABN could be issued for SAD

Voluntary ABNs are provided when the service is statutorily excluded

- However, voluntary ABN *is not required but good business to ensure customer satisfaction*

Payment Condition 1 on following slides

If a beneficiary’s claim for a particular drug is denied because the drug is subject to the “self-administered drug” exclusion, the beneficiary may appeal the denial. Because it is a “benefit category” denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A “benefit category” denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug.

CMS Scenarios

SCENARIO	PAYMENT CONDITION #1	PAYMENT CONDITION #2	PAYMENT CONDITION #3
DESCRIPTION	Items and services being billed are statutorily excluded from Original Medicare coverage , meaning it is not defined as a specific Medicare benefit defined in the Act; therefore, it is never paid.	Items and services being billed are either a reduction or termination of Medicare coverage, or are otherwise expected to be denied, leaving financial liability for a beneficiary or provider .	Items or service is presumed to be a Medicare benefit and can be paid.
NOTIFICATION (PRIOR TO BILLING)	Liability notices are voluntary (i.e., ABN); for statutory exclusions, there are no required Medicare notices.	Liability notices are required (i.e., expedited determination notice, ABN).	Liability notices, mandatory or voluntary, are never used in advance of such billing.
BILLING	Items and services may be billed as non-covered on Medicare claims.	Billing of such items and services can vary, and can depend on the ability to segregate its covered and non-covered portions (if both exist).	Items and services are billed as covered

CMS Scenarios

SCENARIO	PAYMENT CONDITION #1	PAYMENT CONDITION #2	PAYMENT CONDITION #3
LIABILITY (displayed on MSNs or remittances)	Always denied in Medicare claims processing; beneficiaries are liable for these denials unless providers code their claims to transfer liability to themselves.	For any services that are not paid by Medicare itself, properly notified beneficiaries are usually liable for resulting denials.	If Medicare doesn't pay itself as expected, the specific reason for rejection or denial will determine liability according to established Medicare policy.
NOTE: Only one of these conditions can apply to a given item or service, or to a given line of a claim.			

Benefits to Providing a Voluntary ABN

- Notifies the patient that they will receive a patient statement and be liable for the charges personally
- Outlines the potential amounts that they will be responsible for
- Can act as a source of education for the patient
- Decreases the “sticker shock” the patient gets when they get the bill for the SADs
- Include with the ABN a selection from the “Medicare and You” handbook - use CMS as the authority and not have the patient feel it is their facility or provider doing this
- USE THE ABN TO PROMOTE CUSTOMER SATISFACTION

Steps to Determine SAD


1) Determine that the medication either oral, topical, inhalation or if an injection it IS on the exclusions list from you FI / MAC

- “The CMS issued the *Self-Administered Drug Exclusion* Program Memorandum, Change Request 2200, on August 1, 2002. The directive instructed each Medicare carrier to establish a process, modeled along CMS guidelines, to determine the **exclusion** from Medicare coverage of those drugs, which were deemed usually self-administered, even though they may have been previously covered under “incident to” provisions”
- Each MAC/FI/Carrier must determine which medications could be considered to be excluded and non covered
- <http://www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AgAAAAAAAAAAAA&>

MAC SAD Information

Louisiana – Novitas A

- <https://www.novitas-solutions.com/policy/drug-self.html>



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Drugs & Biologicals: Self-Administered Drug Exclusions

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Self-Administered Drugs

Medicare provides only 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 administered by the patients who take them. Each Medicare Administrative Contractor (MAC) as well as fiscal intermediary and carrier must make its own determinations for determining which drugs will be excluded from coverage. The detailed process for this determination is available in the:

- [Medicare Benefit Policy Manual Internet-Only Manual \(IOM\) Publication \(Pub.\) 100-02 Chapter 15, Section 50.2](#) *

Definitions

In making these determinations, Novitas Solutions used the following definitions:

Self administered—administered by the patient to him or herself. This does NOT include administration by spouses, nursing aides, allied health professionals, or physicians. Therefore, oral medications are considered self administered drugs. However, payment for an oral drug is made as a rare exception when the drug is an oral anti-cancer drug or an oral antiemetic that is given with chemotherapy treatments (See IOM 100-02, Chapter 15, Section 50.5.3 and 50.5.4).

Usually self administered—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 other words this determination is made by evaluating beneficiaries as a collective whole rather than basing it on an individual drug or individual beneficiary.

Acute condition—any condition that the expected course of treatment is less than two weeks

Steps to Determine SAD

2) Determine that the medication either oral, topical, inhalation or if an injection it IS on the exclusions list from you FI / MAC

Coding Table Information

CPT/HCPCS Codes - Table Format

Code	Descriptor Generic Name	Descriptor Brand Name
J0135	INJECTION, ADALIMUMAB, 20 MG	Humira
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)	Caverject, Edex, Provistin VR
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
J0630	INJECTION, CALCITONIN SALMON, UP TO 400 UNITS	Miacalcin, Fortical, Calcimar
J1324	INJECTION, ENFUVIRTIDE, 1 MG	Fuzeon
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
J1595	INJECTION, GLATIRAMER ACETATE, 20 MG	Copaxone

Steps to Determine SAD

Step 2) (continued)

- If on the exclusions list or can be administered by more than 50% of Medicare beneficiaries (oral, inhalation, topical, suppository, SQ) and
- Not integral to a procedure thereby constituting a supply
- Use Revenue Code 0637 and any applicable HCPCS code
- Note Medicaid in some states wants 259 as the alternative but all commercial payors will follow their contract (either 250 or 637)

Billing Self Administered Medications

Revenue Code

025x is utilized for general pharmacy items

- Must be provided by a licensed pharmacist
- Covered revenue center
- Generally constitutes a packaged revenue center
- Usually used for SAD that are integral and function as supplies

343 – Diagnostic Radiopharmaceutical

- Policy packaged – requires HCPCS

0637 is utilized for all Self Administered Medications

- Designated by National Uniform Billing Committee (NUBC)

Revenue Codes by Setting

The setting and circumstance determines which revenue code to utilize

- Inpatient – 025x (0250)
 - SAD is not a concept utilized with **inpatient** services
- Self Administered Medication – **Outpatient** – 0637
- Self Administered Medication – **Observation** – 0637
- **Outpatient but integral** to a procedure – 025x (0250) or 343 (Dx. Radiopharms)

NDC Determines HCPCS

- When submitting claims it is essential that whenever possible and required the HCPCS code is present
- The NDC label or barcode gives such information and can be cross mapped to the HCPCS code in Vitalware solutions
- NDC numbers can be either 10 digit or 11 digit (more recent formats)
- What is a National Drug Code (NDC)?
 - “Each listed drug product listed is assigned a unique 10-digit, 3-segment number. This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies package sizes and types. Both the product and package codes are assigned by the firm. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.”
 - [www.fda.gov]

VitalKnowledge Makes NDC to HCPCS Lookup Easy

ZINPLAVA 1000MG/40ML Solution	00006302501	J0565	Injection, bezlotoxumab, 10 mg	MERCK SHARP & D
EMEND 150MG Solution Reconstituted	00006306100	J1453	Injection, fosaprepitant, 1 mg	MERCK SHARP & DOHME
EMEND 150MG Solution Reconstituted	00006306101	J1453	Injection, fosaprepitant, 1 mg	MERCK SHARP & DOHME
EMEND 150MG Solution Reconstituted	00006306102	J1453	Injection, fosaprepitant, 1 mg	MERCK SHARP & D
EMEND 150MG Solution Reconstituted	00006306103	J1453	Injection, fosaprepitant, 1 mg	MERCK SHARP & D
EMEND 150MG Solution Reconstituted	00006306104	J1453	Injection, fosaprepitant, 1 mg	MERCK SHARP & DOHME
EMEND 150MG Solution Reconstituted	00006306105	J1453	Injection, fosaprepitant, 1 mg	MERCK SHARP & DOHME
PRIMAXIN IV 500MG Solution Reconstituted	00006351659	J0743	Injection, cilastatin sodium; imipenem, per	MERCK SHARP & DOHME

Are HCPCS Codes Required ?

HCPCS codes must be reported with any medication for which a code exists

- CMS has stated within the OPPS guidelines that they expect these to be reported
 - CMS 1504-P (Display Copy) Pg. 146 (7/2/10)

Most SAD's are oral, topical or inhalation and the majority of these do not have a HCPCS code nor would we expect a CPT code

Should Part B or Part D Be Billed ?

There is confusion within the facilities that have Part D pharmacies on site as to whether the medication is an SAD under Part B or should it be billed as Part D

- *Facilities, at this time, are not required to bill for medications provided as part of a Part B service to any other Medicare programs*
- SAD's will remain the responsibility of the patient

Customer service is another matter – clients do want the information so they can submit it to their Part D provider (in or out of network)

Chargemasters should be updated to include the NDC number whenever possible

Should Part B or Part D Be Billed ?

The client statement generally contains a line stating “Pharmacy” and then a rolled up price

In order to bill Part D the client / patient would require at a minimum:

- NPI number of prescribing physician
- Facility NPI
- NDC number
- Total Dispensed
- Other items may be required and the facility should work with a retail pharmacy to ensure that the client receives the information required to submit it to their Part D carrier

CMS Publishes a Guide for Medicare Beneficiaries

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



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-administered 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.

Charges are Key

Most complaints arise from the disparity between hospital pricing and that which can be obtained at a local retail pharmacy

■ Ex:

- Tylenol 500 mg in the hospital is \$5.00 but you can buy a bottle of 50 tabs at the local pharmacy.
- Bacitracin is \$10.00 per large tube at the local pharmacy but \$5.00 per small packet in the hospital
- Disparities in pricing between retail and hospital pharmacy, especially with SAD is a large cause of patient dissatisfaction in charging practices.

Patient Education

SAD's are one of the most prevalent customer complaints

Whenever possible written materials should be provided

Some possibilities would include:

- Discharge personnel reviewing the SAD potential charges with the patient at time of discharge
- Provide written brochures / pamphlet regarding SAD responsibilities to Medicare outpatients in clinics, ED and ambulatory surgery areas
 - Use as many documents with the CMS logo as possible to demonstrate it is not the facility stating this but CMS
 - This tends to be the biggest problem in the ED and the Ambulatory Surgery areas

Can We Waive the Charges for SAD's ?

PRIOR TO OIG Statement:

A facility may not waive the charges for the SAD's and not bill them and make attempts to collect them from the patient

Beneficiary Inducement Statute provides for civil monetary penalties for inducement or offering an item of value that will induce a beneficiary to use the provider

CMS has also indicated that waiver of SAD charges is not consistent with the regulations

Take Away Point:

- *Waiver of SAD charges can represent a compliance risk and be considered as an inducement*
- *Check with your legal counsel for further information*

OIG Statement on Waiving SAD charges

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

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.

GY Modifier

- SAD medications utilize the “GY modifier” to indicate a statutory exclusion or categorical exclusion.
- If a voluntary ABN was provided would also add the “GX” modifier
- By placing this modifier on the charge line the patient becomes liable for the charge associated with the SAD provided
- Facilities differ on whether to “hardcode” the GY modifier on SAD medications – most do not hard code for secondary payer billing

GY Modifier

- Some patient accounting systems will allow for differing HCPCS codes based on the payer, but others will not. This ability is a limiting factor in whether hardcoding is an option.
- GY is not required if the claim is entirely non-covered. Only required when the claim includes covered services as well as non-covered SAD items.

GY Modifier (cont'd)

GY modifiers require a HCPCS code.

- If it does not have a HCPCS code, and many SAD's do not then a Non Covered HCPCS (A9270) code must be utilized.
- GY is used on a line to indicate statutorily excluded item for the purpose of secondary insurance billing

In most cases it is clearer to bill all non-covered services on a non-covered claim utilizing the appropriate condition code for automatic denial for the purpose of secondary billing.

National Government Services

GY Modifier

GY modifier

"Item or service statutorily excluded or does not meet the definition of any Medicare benefit."

Description	When to use the GY modifier	Examples of its use	What happens if you use the GY modifier?	What happens if you don't use the GY modifier?
<p>These are the so- called "statutory exclusions" or "categorical exclusions" and the "technical denials. "</p> <p>ABNs are not an issue for these services.</p> <p>There are no advance beneficiary notice (ABN) requirements for statutory exclusions.</p> <p>There are no ABN requirements for technical denials (except three types of DMEPOS denials, and they are listed under modifiers GZ & GA).</p>	<p>1) When you think a claim will be denied because it is not a Medicare benefit or because Medicare law specifically excludes it.</p> <p>2) When you think a claim will be denied because the service does not meet all the requirements of the definition of a benefit in Medicare law.</p> <p>3) When you submit a claim to obtain a Medicare denial for secondary payer purposes.</p>	<p>1) Routine physicals, laboratory tests in absence of signs or symptoms, hearing aids, air conditioners, services in a foreign country, services to a family member.</p> <p>2) Surgery performed by a physician not legally authorized to perform surgery in the state.</p>	<p>The claim will be denied by Medicare. The carrier may "auto-deny" claims with the GY modifier. This action may be quicker than if you do not use a GY modifier.</p> <p>The beneficiary will be liable for all charges, whether personally or through other insurance.</p> <p>If Medicare pays the claim, the GY modifier is irrelevant.</p>	<p>The claim will be reviewed by Medicare and probably will be denied. This action may be slower than if you had used a GY modifier.</p> <p>If the claim is denied as an excluded service or for failure to meet the definition of a benefit, the beneficiary will be liable for all charges, whether personally or through other insurance.</p>

GX Modifier – R1921CP

- A new modifier, -GX, has been created with the definition “Notice of Liability Issued, Voluntary Under Payer Policy.”
- This modifier is to be used to report **when a voluntary ABN was issued** for a service. Providers may use the –GX modifier to provide beneficiaries with voluntary notice of liability regarding services excluded from Medicare coverage by statute. In these cases, the –GX modifier may be reported on the same line as certain other liability-related modifiers. The –GX modifier must be submitted with non-covered charges only and will be denied by the Medicare contractor as a beneficiary liability.
- This is to be placed on a wholly covered claim on the line item for which the charge appears.

Building the CDM for SAD's

The Required Team

The team that will be required to determine how to manage SAD's within the toolkit and your CDM

- Pharmacy / Pharmacist:
- Will need to go through the formulary for the purpose of:
 - Identifying those normally SAD items that could be considered integral (0250) or diag. radiopharms (0343)
 - Identify those outpatient SAD's (RCC 0637) that would need to be placed in RCC 0250 if provided to inpatients
 - Identify those items that are only offered to outpatients and would be considered SAD (0637)
 - Assign the NDC number to each chargemaster line item
 - Maintain NDC numbers within the CDM if there is a change

The Required Team

The team that will be required to determine how to manage SAD's within the toolkit and your CDM

- Pharmacy / Pharmacist:
- Will need to work with either retail pharmacy or determine the requirements for submitting the medication for those that have Part D.
 - Note the facility will not be responsible for this only offering the information on a client statement so that they might pursue this for their Part D
 - May assist in educational materials to assist clients in understanding how to submit to Part D

The Required Team

The team that will be required to determine how to manage SAD's within the toolkit and your CDM

- CDM Analyst
 - Ensure that for each SAD the NDC is present
 - Look up the NDC / HCPCS cross map in the toolkit
 - Work with Billing Office / Patient Financial Services in determining whether to hard code the “GY” modifier
 - Note – hardcoding this modifier is not the preferred approach but should at least be considered
 - Develop a process for each addition to the formulary and CDM to ensure equitable treatment of the medication in determining how the SAD should be represented

The Required Team

The team that will be required to determine how to manage SAD's within your CDM

- Billing Office / Patient Financial Services:
 - Will need to randomly review claims to ensure that the SAD's appear in the non-covered columns
 - Work with your local FI / MAC to determine if they want the SAD represented with 0637 alone or do they require the A9270 HCPCS code in addition
 - Follow guidelines on billing for SAD's
- CFO / Compliance:
 - Ensure there is policy / procedure for the billing of SAD and ensure that the charges are not waived creating inducement concerns

Representations within the CDM

CDM #	CDM Description	Revenue Code	HCPCS Code	Patient Charge
11000	Supply: Mydriatic Drop	0250		\$20.00
11001	Erythromycin 500 mg oral tablet	0637	A9270	\$8.00
11002	Pediculosis Cream / topical	0637	A9180	\$10.00
11003	Riboflavin per oral dose	0637	A9152GY	\$40.00

Developing Customer Support Strategies

Key to Successful Implementation

- Beneficiary knowledge is the key to client success and satisfaction
- Create pricing consistent with your end objective
- Produce informational packets that include CMS logo items
- Present informational information early in the episode of care
- *Remember you may provide exceptional care but they might only remember the charges they did not expect*



Customer Support

SAD are a predominant source of customer complaints and require the attention of the business office to answer

Customer support begins with education

- Start early and repeat through discharge - Provide SAD education at time of registration
 - Pamphlet describing SAD policy of Medicare
 - Provide a copy of the Medicare SAD Brochure demonstrating this is a Medicare requirement
 - Use the voluntary ABN to provide estimate of drug costs
 - Difficult in ASU and ED
 - For further information on Limitation on Liability / ABN consult: <http://www.cms.gov/manuals/downloads/clm104c30.pdf>

Customer Support

Emergency Services

- Educational materials should be given BEFORE discharge during the discharge process
- Copies of the SAD Medicare document should be considered as an essential element of the discharge
- Nursing must be trained to explain the SAD during the discharge process
- Remember the ED doesn't require medical necessity and the patient may think all their services are covered

Clinic Services

- Same as ED but do education during the visit or at registration

Customer Support

Anaesthesia / Pre-Op clearance

- Use this time to provide educational materials about SAD drugs provided in the outpatient ASU episode of care
 - Examples are oral agents such as oral Zofran, Percocet, Darvocet and Vicodin
 - Insulin provided during operative episode of care
- Work with billing to give the patient itemized statements that they can submit to Part D.

Customer Support

Observation

- Most likely the highest number of complaints occur because of observation
- Nursing is poorly informed in general of the inpatient and outpatient billing difference
- Patient think they are “in the hospital” so why is it not covered ?
- Little or no understanding of SAD within the concept of observation.

Customer Support

Observation

- Facilities will need to identify the best place in the episode of care to educate the patient regarding SAD
- Nursing will need to be educated
- Published materials will need to be provided
- Consider putting a short “educational spot” on the TV system for the facility (many have their own educational stations)

Customer Support

Goal:

- Maximize education
- Provide evidence that this is not a hospital concept but a Medicare requirement
- Provide published materials
- Provide itemized billing with the data that will allow the beneficiary to submit to Part D or secondary insurance

Summary

Summary

- SAD drugs are defined in the Benefit Policy Manual
- CMS notifies the beneficiary in advance that these are not covered services
- OIG has created guidance on how to decide to waive or not waive charges for SAD
- Most facilities are pricing SAD similar to retail pharmacy charges and billing them to the patient
- Many commercial payors will package them in the case rate or service
- Have to charge all patients the same – if you charge BCBS for an SAD you have to charge all patients for the SAD to prevent cost shifting
- Education of the patient can reduce the surprise when they receive their statement



Questions?

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Thank you!