HCPro, Inc., presents

Understanding the Complexity Around Self-Administered Drugs: It’s a SAD State of Affairs

A 90-minute interactive audio conference

Thursday, September 5, 2013

1:00 p.m.–2:30 p.m. (Eastern)
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Dear Program Participant,

Thank you for participating in our “Understanding the Complexity Around Self-Administered Drugs: It’s a SAD State of Affairs” audio conference, featuring speakers Debbie Mackaman, RHIA, CHCO, and Valerie A. Rinkle, MPA, and moderated by Todd Hutlock.

Our team is excited about the opportunity to interact with you directly. We encourage you to ask our experts your questions during the program. If you would like to submit a question before the audio conference, please send it to the producer, Todd Hutlock, at thutlock@hcpro.com and provide the program date in the subject line. We cannot guarantee that your question will be answered during the program, but we will do our best to include a good cross section of questions.

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Sincerely,

Elizabeth Petersen
Vice President
HCPro, Inc.
Understanding the Complexity Around Self-Administered Drugs: It’s a SAD State of Affairs

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Agenda

I. Medicare's coverage of drugs in general
   A. Coverage under different “parts” of Medicare
      • Part A
      • Part B
      • Part C
      • Part D

II. Definition and identification of self-administered drugs (SAD)
   A. Guidelines MACs use to identify SADs, including oral, topical, suppositories, certain injections
   B. Identify MAC-specific list of SADs

III. Understand when drugs are considered integral to outpatient services
   A. CMS rules, followed by two case studies
   B. Review lack of clarification from CMS

IV. Understand when and how to bill SADs
   A. Revenue codes
   B. Modifiers
   C. Associated impact on related drug administration
   D. Operational ideas

V. Identify compliance risks and resolutions
   A. Part A – B clarification
   B. Three-day payment window
   C. Discounting and pricing
   D. Reimbursement issues

VI. Live Q&A
Speaker Profiles

**Debbie Mackaman, RHIA, CHCO**

Debbie Mackaman is an instructor for HCPro’s Medicare Boot Camp®—Hospital Version and Medicare Boot Camp®—Critical Access Hospital Version. She is a former hospital compliance officer and HIM director with more than 18 years of experience in the healthcare industry, including both inpatient and outpatient prospective payment systems as well as critical access hospital coding and reimbursement issues.

**Valerie A. Rinkle, MPA**

Valerie A. Rinkle, MPA, is associate director of healthcare at Navigant. She has more than 20 years of healthcare reimbursement experience including, 10 years as revenue cycle director for Asante Health System in Medford, Ore. and 11 years in nationwide consulting to hospitals and physicians regarding Medicare and Medicaid payment systems and compliance. She is the author of numerous articles on OPPS and hospital-based clinics.
Exhibit A

Presentation by Debbie Mackaman, RHIA, CHCO, and Valerie A. Rinkle, MPA
Understanding the Complexity Around Self-Administered Drugs: It’s a SAD State of Affairs

An HCPro audio conference presented on September 5, 2013

Speakers

- Debbie Mackaman, RHIA, CHCO
  - Regulatory Specialist
  - HCPro, Inc.
- Valerie A. Rinkle, MPA
  - Associate Director, Healthcare
  - Navigant Consulting
Agenda

- Medicare’s coverage of drugs in general
- Definition and identification of self-administered drugs (SAD)
- SADs as supplies integral to outpatient procedures
- Correct billing of SADs – revenue codes & modifiers
- Hospital collection of non-covered SAD & waivers

Agenda (cont.)

- Safety/operational considerations of patients bringing their own medications to the hospital
- Implications for Medicare Advantage plans
- Implications of drug manufacturer indigent programs
- Implications for 340b hospitals
Coverage of Drugs by Medicare

- Medicare’s coverage of drugs depends on which “part” is paying for the drug:
  - Part A covers most drugs
  - Part B covers only selected drugs
  - Part C covers drugs as specified by the plan
  - Part D covers drugs from enrolled pharmacies

Part A Coverage

- Medicare covers drugs under Part A for hospital inpatients if:
  - (1) They represent a cost to the hospital or CAH;
  - (2) They are ordinarily furnished by the hospital or CAH for the care and treatment of inpatients; &
  - (3) They are furnished to an inpatient for use in the hospital or CAH
Part B Coverage

- Medicare covers drugs under Part B for hospital outpatients if:
  - “Incident to” a physician’s service AND not usually self-administered;
  - Self-administered but required in the performance of diagnostic services;
  - Self-administered but covered by statute; or
  - Self-administered but are integral to a procedure
    - Could not be performed without the drug
    - Not patient specific

Part B Coverage: Incident To

- Soc. Sec. Act § 1861 (s)(2)(B)
  - Provides for Part B coverage of hospital outpatient services provided incident to a physician’s service, including drugs and biologicals that are not usually self-administered by the patient
Part B Coverage: Usually Self-Administered

- CMS allows the MAC to make its own determination whether a drug is or is not usually self-administered
- MAC must post to its website:
  - Process it uses to make “usually self-administered” determinations
  - List of injectable drugs it considers self-administrable
  - [Link to CMS website for SAD exclusion list](http://www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAA)
- Over-the-counter drugs are usually self-administered

Part B Coverage: Usually Self-Administered

- Rules for MAC determination that a drug is “self-administered”
  - “Usually” – 50% of beneficiaries or indications
  - Determination is drug specific – not beneficiary specific
  - Made based on all Medicare beneficiaries – not the particular beneficiary receiving the drug
Part B Coverage: Usually Self-Administered

- Suppositories, oral, topical, and inhalation drugs are considered to be usually self-administered
  - CMS indicates there are exceptions – doesn’t name any
- SubQ injections are presumed to be self-administered
- IM injections and IV infusions are presumed to be not usually self-administered
  - May also include IA
  - Unless determined to be self-administered
  - Route of administration must be medically necessary compared to a self-administered route

Part B Coverage: Diagnostic Services

- 42 CFR 410.29 allows coverage of self-administered drugs as specified in 410.28(a) for outpatient diagnostic services

- 42 CFR 410.28(a) allows coverage of drugs required in the performance of diagnostic services, even if they are self-administered
Part B Coverage: Per Statute

- Immunosuppressive drugs and drugs used in conjunction with the immunosuppressive drug as part of a therapeutic regimen
  - Must be FDA approved
  - *Benefit Policy Manual*, Chapter 15 § 50.5.1

- EPO for treatment of anemia in dialysis patients
  - *Benefit Policy Manual*, Chapter 15 § 50.5.2

Part B Coverage: Per Statute

- Oral anti-cancer drugs and anti-emetics used with them when a high likelihood of vomiting exists
  - *Benefit Policy Manual*, Chapter 15 § § 50.5.3, 50.5.4

- Blood clotting factors for hemophilia
  - *Benefit Policy Manual*, Chapter 15 § 50.5.6
Part B Coverage: Integral Drugs

- SADs are covered when they are *integral to a procedure*
  - Directly related to:
    - Eye drops for cataract surgery
  - Facilitate the performance of:
    - Oral contrast media for MRI/CT

Part B Coverage: Integral Drugs

- SADs are covered when they are *integral to a procedure*
  - Recovery from:
    - Antibiotic ointment for wounds
  - **Not covered** if the drug is the treatment itself
    - Pain medication given to patient presenting with pain
    - Insulin for high blood sugar
    - High blood pressure medication prior to procedure
Evolution of Integral Drugs

CMS authority on the coverage of drugs integral to a procedure has evolved over time:

- 1998 – CMS takes the position that self-administered drugs were billable to the patient even if they were related to a procedure:
  
  63 Fed. Reg. 47563: “... drugs that can be self-administered are not covered under Part B of Medicare ... This presents problems in the outpatient hospital setting because even a pain killer given to a groggy patient postoperatively would not be covered. The only way such drugs can be paid for is for the hospital to bill the beneficiary.”

Evolution of Integral Drugs

- 2000 – Regulations adopted at the inception of OPPS and still in existence indicated drugs “directly related and integral” to a procedure are covered:

  42 CFR 419.2 (b): “The prospective payment system (OPPS) established a national payment rate ... that includes operating ... costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis ... These costs include ... (4) anesthesia, certain drugs, biologicals and other pharmaceuticals ...”

  - CMS was silent if this included self-administered drugs
Evolution of Integral Drugs

- 2001 – CMS issued a clarification indicating that “most drugs” were considered integral:

  A-01-133: “Under OPPS, packaged services are items and services that are considered to be an integral part of another service that is paid under OPPS ... For example, routine supplies, anesthesia, recovery, and most drugs are considered to be an integral part of a surgical procedure so payment for these items is packaged into the APC payment for the surgical procedure.”

  Unfortunately, it still did not directly address the self-administered drug issue under OPPS

Evolution of Integral Drugs

- 2002 – When asked about the 1998 statements, CMS changed course and indicated it was not finalizing the 1998 policy statement, saying:

  67 Fed. Reg. 66776: “Contractors must determine whether the drug meets all program requirements for coverage ... and whether it is excluded from payment because it is usually self-administered.

  Certain drugs are so integral to a procedure or treatment that the procedure or treatment 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.”
Evolution of Integral Drugs

- CMS specifically included in a list of packaged drugs, self-administered drugs that are integral to procedures, reiterating language from the Fed. Reg.:
  
  A-02-129 (see attached): Certain drugs are so integral to a treatment or procedure that the treatment or procedure could not be performed without them ... 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.”

Evolution of Integral Drugs

- A-02-129 (cont.)
  - “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 solutions for photodynamic therapy, local anesthetics, and antibiotic ointments are also listed
Evolution of Integral Drugs

- 2011 – CMS indicated that the policy of coverage of self-administered drugs integral to procedures:
  - Is a “very limited policy”
  - The “overwhelming majority” of self-administered drugs are non-covered
  - List of items in A-02-129 should be used as examples to determine whether other drugs might be covered under the policy
  - Ask the local contractor

Evolution of Integral Drugs

- 2012 – CMS provided further clarification in the Benefit Policy Manual, Chapter 15 § 50.2:
  - Covered when “integral component of a procedure” OR “directly related to it”
    - Directly related: “facilitate the performance of or recovery from a particular procedure”
    - Also removed local anesthetics from the list of examples of covered drugs
  - See attached
Evolution of Integral Drugs

- If the “drug itself is the treatment instead of being integral or directly related to the procedure”

- Added example focusing on the drug as treatment of the patient’s presenting problem:
  - Fentanyl patch patient presenting with pain

- Appears to supersede A-02-129 that included drugs integral to “a treatment or procedure”

Evolution of Integral Drugs (cont.)

- CY 2014 OPPS Proposed Rule

  78 Fed. Reg. 43560: “We also are proposing to package all drugs provided to the beneficiary as part of the delivery of the comprehensive service except for those drugs separately paid through a transitional pass through payment .... We note that, in defining these packaged drugs, we are applying both our existing definitions of self-administered drugs (SADs) and our existing definition of drugs as supplies to the situation where the OPD service is a comprehensive service. We are proposing that all medications provided by the hospital for delivery during a comprehensive service pursuant to a physician order, regardless of the route of administration, would be considered to be adjunctive supplies and therefore packaged as part of the comprehensive APC. We believe that the physician order demonstrates that the delivery of the medication by the hospital is necessary to avoid possible complications during the delivery of the comprehensive service, to ensure patient safety, and to ensure that the comprehensive service delivery is not compromised, and therefore the medication should be considered an adjunctive supply.”
Part B Coverage: Integral Drugs

- So where does that leave us?
  - CMS appeared to be getting more strict with SADs in 2011
  - Since then, CMS policies to increase bundling and packaging has opened the door to more liberal “integral” and “supportive” interpretations to bill SADs and any administration services as covered

Part B Coverage: Drug Administration

- What about the administration?
  - If the drug is covered as packaged, Medicare will generally cover the administration of the drug BUT ...
  - Significant bundling policies may affect whether they are separately reportable on the claim
    - *Coding Clinic* has stated that drug administration services “specific to the patient,” although not part of the “regular routine” for a procedure, are integral and not reported if due to the procedure
Part B Coverage: Drug Administration

- What about the administration?
  - If the drug isn’t covered – presumably, neither is the administration
    - Even if it would otherwise be bundled into the procedure
    - Both the drug and the administration should be billed to the patient
  - See attached flowchart

Part B Coverage: Integral Drugs

- Hospital should have policies on SADs:
  - Support policy with applicable guidance; may need to seek further guidance on particular situations from FI/MAC
- Self-administered drugs that are not integral, or covered by regulation/statute, are non-covered under Part B and the patient’s responsibility to pay
  - Do I need to give the patient an ABN to bill them?
  - What about coverage under their Part D plan?
Is an ABN Required?

- An ABN is required if the patient would be protected by the LOL statute without such notice of non-coverage
  - LOL only protects the patient in specific situations, not including categorical and technical denials
- An ABN is not required if non-coverage is based on a categorical or technical denial
  - CMS lists self-administered drugs specifically in the list of technical denials (*MCPM*, Ch. 30 § 20.2.2)
    - But seems to fit categorical denial because no benefit category for self-administered drugs

Can I Give an ABN Anyway?

- Hospitals may choose to voluntarily provide an ABN to patients to give them notice
  - Hospitals may still bill the beneficiary if a voluntary ABN is not given in a particular case
    - The patient is not protected under LOL
  - This may cause confusion with beneficiaries if provided in some settings and not others
What About Other Notices?

- Hospitals may also choose to give Medicare’s notice on self-administered drugs (attached)
  - Confusing on why drugs might be covered differently based on circumstances
  - Does a good job of explaining Part D coverage
- Hospital could also choose to give a notice it developed itself
  - Could incorporate explanation of Part D coverage
  - Why some drugs are covered sometimes and not others
  - Notify patients on particular non-covered drugs

Part D Coverage

- Part D coverage is normally limited to network pharmacies
  - Hospitals could enroll in the Part D network similar to a retail pharmacy
- Part D coverage can be afforded out of network for drugs received in hospital outpatient departments
  - 70 Fed. Reg. 4268: We therefore clarify that we expect that Part D plans guarantee out-of-network access to covered Part D drugs in cases in which an enrollee is provided covered Part D drugs dispensed by an out-of-network institution-based pharmacy while a patient in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting.
Part D Coverage

- Patient must submit an out-of-network claim
  - Upon request, hospital must provide the beneficiary the NDC, quantity, and charge
- Part D plan pays/reimburses in-network rates if:
  - Drug is on the Part D plan formulary
  - Drug is not routinely obtained out of network
  - Drug couldn’t have been reasonably obtained in network
  - Patient provided receipts and documentation, including reason for the hospital visit
- Patient makes up the difference

Correct Billing of SADs

Billing of SADs when covered
- Appropriate revenue code (e.g., 0250, 0343)
- Options for HCPCS code
  - HCPCS code specific to drug, if one exists (recommended)
  - May be billed without HCPCS code
- Charge in the covered column of the UB-04
  - Tip: If SAD is provided on same date as HCPCS for comprehensive service or significant service, the SAD could be billed as 0250 covered and integral drug
Correct Billing of SADs

Billing of SADs when not covered

- Revenue code 0637
- Options for HCPCS code
  - HCPCS code specific to drug, if one exists
  - HCPCS code A9270 (“Non-covered item or service”)
  - May be billed without HCPCS code – OCE bypasses edit requiring HCPCS code for revenue code 0637
- Modifier GY for statutory exclusion
- Charge in the non-covered column of the UB-04

Correct Billing of SADs – 3-Day Window

- Non-covered self-administered drugs (SADs) provided in 3-day window must be separately billed
- Key is to determine whether the SADs are covered
- Hospital pharmacy item masters and Patient Accounting System charge masters typically list a specific SAD once, regardless of how it is used
  - Example: Antibiotic ointment – used as part of a wound care clinic treatment versus dispensed to an observation patient for use on a skin lesion
Implications for 340b

- Are you a 340b hospital?
- All SADs to Medicare outpatients can be claimed under 340b
- Caution for Medicaid outpatients – program requirements are that these should be excluded from 340b virtual inventories
- What if GPO price is better than 340b price?

Are SADs Anachronistic?

- Outpatient hospital services were rare in 1965, the beginning of the Medicare program
- Patients were rarely impacted by this coverage exclusion
- Outpatient hospital and observation services have expanded greatly over the past 15–20 years
- More beneficiaries are impacted by this benefit exclusion
- Increased OPPS packaging & bundling allows for increased coverage of SADs
**Hospital Collection Practices**

- “Currently, drugs that can be self-administered are not covered under Part B of Medicare ... This presents problems in the outpatient hospital setting because even a pain killer given to a groggy patient postoperatively would not be covered. The only way such drugs can be paid for is for the hospital to bill the beneficiary. In many cases, the hospital does not, both because keeping track of such small charges for billing purposes is burdensome and because beneficiaries would not understand why they are being asked to pay for, for example, pain medication that was clearly related to the procedure they had undergone.” [63 FR 47563 Sept 8, 1998]

**Hospital Collection Practices**

- Hospitals bill beneficiaries non-covered charges after Medicare denial and write-off balances for patients who complain
- Hospitals do not bill beneficiaries non-covered charges after Medicare denial
- Hospitals do not bill Medicare at all for non-covered charges
- Conflicting practices between hospitals, communities, and regions of the country
Compliance Considerations of Routinely Writing Off SADs

- “Neither the OPPS nor other Medicare reimbursement rules regulate the provision or billing by hospitals of non-covered drugs to Medicare beneficiaries. Accordingly, it would be inappropriate to include the statement in the 1998 rule. However, in some circumstances, such practices potentially implicate 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.” [67 FR 66776 Nov. 1, 2002]

Strategies to Mitigate Negative Consequences of Beneficiary Billing

- Pricing of SADs
- Reducing incidence of SADs
- Informing patients
- Patients bringing own medications to the hospital
- CMS tip sheet:
Pricing of SADs

- In an attempt to diminish patient complaints, hospitals may identify SADs for significantly lower pricing.
- Particularly true for over-the-counter drugs recognizable by name (e.g., aspirin, acetaminophen).
- Consider identifying over-the-counter drugs with the non-covered revenue code 0253 so that staff know they do not need to provide NDCs for these drugs because no Part D coverage for OTC drugs.

Reducing Incidence of SADs

- **Review use of drugs:** Are they in support of a diagnostic test? Then the drugs are covered.
- **Review use of drugs:** Are they integral to the performance of a test, procedure, or service? Then covered as OPPS service (e.g., solutions used during wound care).
- **Medical necessity of drug:** Review vitamins and other supplements used during short observation stays. Are they critical to patient outcomes?
Patients Bring Own Meds From Home?

- Most hospitals have policies prohibiting this practice
  - CoPs updated to allow more flexibility: 42 CFR 482.23(c)(6)
- If allowed, requires patient’s physician to order
- Medications must be in original prescription bottle
- Pharmacist must validate drugs in their bottles
- Cost of validation is higher than cost for hospital to dispense drugs under routine process
- Risk of medication administration errors increases
- Reevaluate value of this for transitional & coordinated care reasons

Medicare Advantage Plans

- Negotiate coverage of SADs in contract negotiations
- Point out that if they advertise they cover medications, then they need to cover and pay for SADs
Questions?

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Exhibit B

Program Memorandum, Transmittal A-02-129
CHANGE REQUEST 2503

SUBJECT: 2003 Update of the Hospital Outpatient Prospective Payment System (OPPS)

This Program Memorandum (PM) outlines changes in the OPPS for calendar year 2003. These changes were discussed in the OPPS final rule for 2003, which was published in the Federal Register on November 1, 2002. Unless otherwise noted, all changes discussed in this PM are effective for services furnished on or after January 1, 2003.

The PM addresses the following subjects:

I. Limitations on Beneficiary Co-payment
II. Outlier Payments
III. Outpatient billing for Dialysis
IV. Partial Hospitalization Program (PHP)
V. Billing and Payment Requirements for Observation Services
VI. Payment Policy When a Surgical Procedure on the Inpatient List Is Performed on an Emergency Basis or When a Patient Whose Status is Outpatient Dies
VII. New G Codes Under HCPCS and Status Under OPPS
VIII. Billing Instructions for the G code for Ear Wax Removal
IX. Billing for Prostate Brachytherapy
X. Billing for Stereotactic Breast Biopsy
XI. Billing for Radiologic or Ultrasound Guidance
XII. Billing for Active Wound Care Procedures
XIII. Sacroiliac Joint Injections
XIV. Drug Eluting Stents
XV. Outpatient Services Under Clinical Trials
XVI. Placement of Occlusive Device
XVII. Radiopharmaceutical Biodistribution of Zevalin
XVIII. Renal and Iliac Angiography Performed with Cardiac Angiography
XIX. Arthroscopic Procedures of the Knee
XX. Billing for Radiation Therapy (CPT Codes 77401 through 77416)
XXI. Hospital OPPS Modifiers
XXII. Pass-Through Devices
XXIII. Changes to Pass-Through Drugs, Biologicals and Radiopharmaceuticals
XXIV. Non-Pass-through Drugs Under OPPS
XXV. Changes to the OPPS PRICER Logic
XXVI. Processing of CCI Edits for OPPS Claims
XXVII. Provider Notification
XXVIII. Provider Education and Training
Payment will be based on the provider type. Hospitals (bill type 13X), and HHAs (bill type 34X) will be paid based on reasonable cost for the vaccines and their administration. CORFs (bill type 75X) will be paid based on the lower of the charges or 95 percent of the average wholesale price (AWP) for the vaccine and on Medicare the Physician Fee schedule for the administration.

A new status indicator (SI) of “L” (L – Paid reasonable cost; not subject to deductible or coinsurance) will be assigned to influenza and PPV vaccines and their administration in the Outpatient Code Editor (OCE). The applicable HCPCS codes are 90657, 90658, 90659, 90732, G0008 and G0009.

As a result of this payment change, the Standard System Maintainers are required upon receipt of the SI “L” from the OCE to make the appropriate payment determination (reasonable cost or AWP) based on the type of bill submitted.

Although the effective date of the change to payment for influenza and PPV vaccines and their administration is January 1, 2003, due to the need for shared systems changes, the change will not be implemented by the standard system maintainers (SSMs) in January. As a result, if you receive claims with dates of service January 1, 2003, through June 30, 2003, containing any of the HCPCS for the influenza and PPV vaccines and their administration, hold the claims and do not release them for processing until your SSM has implemented the July release. Advise your hospitals, CORFs, and HHAs that claims containing these HCPCS will be held and not processed until the system change is completed.

For vaccines furnished during the period January 1, 2003, through June 30, 2003, if a hospital, CORF or HHA furnishes additional services that would be reported on the same claim as the vaccines, they may wish to remove the vaccine and administration charges from the claim in order to receive payment for the remaining services. In this instance an adjustment bill would need to be submitted to include the vaccine and administration charges after the SSM implements the July release.

When releasing the held claims for payment, apply applicable interest and enter condition code 15 to indicate the claims are clean claims in which payment was delayed due to a CMS processing delay and are therefore not subject to contractor performance evaluation for claims processing timeliness.

Note: Payment to all other providers for these vaccines will remain the same. In addition, payment for hepatitis B vaccine will also remain the same.

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.

3. OPPS Policy on Payment for the Unused Portion of a Drug

Once a drug is reconstituted in the hospital’s pharmacy, it may have a limited shelf life. Since an individual patient may receive less than the fully reconstituted amount, hospitals are encouraged to schedule patients in such a way that the hospital can use the drug most efficiently. However, if the hospital must discard the remainder of a vial after administering part of it to a Medicare patient, the provider may bill for the amount of drug discarded along with the amount administered. In the event that a drug is ordered and reconstituted by the hospital’s pharmacy, but not administered to the patient, payment may not be made under OPPS.

Example 1: Drug X is available only in a 100-unit size. A hospital schedules three Medicare patients to receive drug X on the same day within the designated shelf life of the product. An appropriate hospital staff member administers 30 units to each patient. The remaining 10 units are billed to OPPS on the account of the last patient. Therefore, 30 units are billed on behalf of
the first patient seen and 30 units are billed on behalf of the second patient seen. Forty units are billed on behalf of the last patient seen because the hospital had to discard 10 units at that point.

Example 2: An appropriate hospital staff must administer 30 units of drug X to a Medicare patient, and it is not practical to schedule another patient who requires the same drug. For example, the hospital has only one patient who requires drug X, or the hospital sees the patient for the first time and does not know the patient’s condition. The hospital bills for 100 units on behalf of the patient, and OPPS pays for 100 units.

4. Hospital Billing Instructions for Drugs with Status Indicator “K” or “N”

In order to receive separate payment for any drug having a status indicator of “K”, hospitals must bill for the drug using revenue code 636 “Drugs requiring detail coding” and report the appropriate HCPCS code for the drug.

Hospitals should bill for drugs with status indicator “N” using any of the drug revenue codes that are packaged revenue codes under OPPS: 250, 251, 252, 254, 255, 257, 258, 259, 631, 632, 633, or under revenue code 636. Hospitals may but are not required to use HCPCS codes when billing for packaged drugs. (Note, however, that revenue code 636 does require HCPCS coding) Although hospitals are not required to report the HCPCS codes for these drugs, it is essential that hospitals bill charges for packaged drugs by including the charge for packaged drugs in the charge for the procedure or service for which the drug is used or as a separate drug charge. This is critical because the costs of the packaged drugs are used for calculating the hospital’s outlier and transitional corridor payments and used in the annual update of APC payments rates for the procedures and services with which the drugs are furnished.

XXV. Changes to the OPPS PRICER Logic

The following list contains a description of all OPPS PRICER logic changes that are effective beginning January 1, 2003.

A. New OPPS wage indexes will be effective January 1, 2003. These are the same wage indexes that were implemented on October 1, 2002 for inpatient hospitals. Some corrections have been made since the publication of the inpatient rule and we are using the corrected wage indexes where applicable.

B. Inpatient hospitals considered reclassified on October 1, 2002, will be considered reclassified for OPPS on January 1, 2003.

C. Section 401 designations and floor MSA designations will be considered effective for OPPS on January 1, 2003.

D. New payment rates and coinsurance amounts will be effective for OPPS on January 1, 2003. Some APCs have coinsurance amounts limited to 55 percent of the payment rate effective January 1, 2003. Some APCs have a coinsurance limit equal to the inpatient deductible of $840 effective January 1, 2003.

E. If a claim has more than 1 service with a status indicator (SI) of T (SI of S has been removed from this rule) and any lines with SI T have less than $1.01 as charges, charges for all T lines will be summed and the charges will then be divided up proportionately to the payment rate for each T line. The new charge amount will be used in place of the submitted charge amount in the line item outlier calculation.

<table>
<thead>
<tr>
<th>e.g., SI</th>
<th>Charges</th>
<th>Payment Rate</th>
<th>New Charges Amount</th>
</tr>
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<tbody>
<tr>
<td>T</td>
<td>$19,999</td>
<td>$6,000</td>
<td>$12,000</td>
</tr>
</tbody>
</table>
50.2 - Determining Self-Administration of Drug or Biological  
(Rev. 157, Issued: 06-08-12, Effective: 07-01-12, Implementation: 07-02-12)

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). Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the “incident to” benefit. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are 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.)
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.

F. Evidentiary Criteria

Contractors are only required to consider the following types of evidence: peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA approved label, and package inserts. Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Contractors should also use these evidentiary criteria when reviewing requests for making a determination as to whether a drug is usually self-administered, and requests for reconsideration of a pending or published determination.

Note that prior to August 1, 2002, one of the principal factors used to determine whether a drug was subject to the self-administered exclusion was whether the FDA label contained instructions for self-administration. However, CMS notes that under the new standard, the fact that the FDA label includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to this exclusion.

G. Provider Notice of Noncovered Drugs

Contractors must describe on their Web site the process they will use to determine whether a drug is usually self-administered and thus does not meet the “incident to” benefit category. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their Web site, including the data and rationale that led to the determination. Contractors will report the workload associated with developing new coverage statements in CAFM 21208.

Contractors must provide notice 45 days prior to the date that these drugs will not be covered. During the 45-day time period, contractors will maintain existing medical review and payment procedures. After the 45-day notice, contractors may deny payment for the drugs subject to the notice.

Contractors must not develop local coverage determinations (LCDs) for this purpose because further elaboration to describe drugs that do not meet the ‘incident to’ and the
‘not usually self-administered’ provisions of the statute are unnecessary. Current LCDs based solely on these provisions must be withdrawn. LCDs that address the self-administered exclusion and other information may be reissued absent the self-administered drug exclusion material. Contractors will report this workload in CAFM 21206. However, contractors may continue to use and write LCDs to describe reasonable and necessary uses of drugs that are not usually self-administered.

H. Conferences Between Contractors

Contractors’ Medical Directors may meet and discuss whether a drug is usually self-administered without reaching a formal consensus. Each contractor uses its discretion as to whether or not it will participate in such discussions. Each contractor must make its own individual determinations, except that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion.

I. Beneficiary Appeals

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.

J. Provider and Physician Appeals

A physician accepting assignment may appeal a denial under the provisions found in Pub. 100-04, Medicare Claims Processing Manual, chapter 29.

K. Reasonable and Necessary

Contractors will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient’s condition. Contractors will continue to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Contractors will also continue to make the determination as to whether a physician’s office visit was reasonable and necessary. However, contractors should not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician’s office or outpatient hospital setting. That is, while a physician’s office visit may not be reasonable and necessary in a specific situation, in such a case an injection service would be payable.

L. Reporting Requirements
Each carrier, intermediary and Medicare Administrative Contractor (MAC) must report to CMS its complete list of injectable drugs that the contractor has determined are excluded when furnished incident to a physician’s service on the basis that the drug is usually self-administered. The CMS expects that contractors will review injectable drugs on a rolling basis and update their list of excluded drugs as it is developed and no less frequently than annually. For example, contractors should not wait to publish this list until every drug has been reviewed. Contractors must enter their self-administered drug exclusion list to the Medicare Coverage Database (MCD). This database can be accessed at www.cms.hhs.gov/mcd. See Pub.100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3, “Policies and Guidelines Applied During Review”, for instructions on submitting these lists to the MCD.

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 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.

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.

The charge, if any, for the drug or biological must be included in the physician’s bill, and the cost of the drug or biological must represent an expense to the physician. Drugs and biologicals furnished by other health professionals may also meet these requirements. (See §§170, 180, 190 and 200 for specific instructions.)

Whole blood is a biological, which cannot be self-administered and is covered when furnished incident to a physician’s services. Payment may also be made for blood fractions if all coverage requirements are satisfied and the blood deductible has been met.
Exhibit D

SAD flow chart
Determining When Self-Administered Drugs Are Covered Packaged Supplies

Was there a Procedure During the Encounter?

YES

Is the Drug Treating a Condition Unrelated to the Procedure?

NO

YES

Is Drug Directly Related to the Procedure, i.e. Facilitated Performance of or Recovery From the Procedure?

(See list of examples in BPM Ch. 15 § 50.2M)

NO

YES

Self-Admin Drug IS COVERED as Packaged Drug

Self-Admin Drug NOT COVERED as Packaged Drug

Is the Administration Bundled to the Procedure per Coding Guidelines?

NO

YES

Bill Drug to Medicare

Bill Administration Separately to Medicare

Do Not Report Administration Separately (Report without Code or Include Costs in Procedure)

Bill Drug and Administration to Patient

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Exhibit E

CMS SAD tip sheet
Information Partners Can Use on:

Medicare Drug Coverage under Medicare Part A, Part B, and Part D

This tip sheet provides an overview of drug coverage under Medicare Part A (Hospital Insurance), Medicare Part B (Medical Insurance), and Medicare Part D (Medicare prescription drug coverage).

Does Medicare cover drugs under Part A?

Generally, Part A doesn’t pay for outpatient prescription drugs. However, people with Medicare may get drugs as part of their inpatient treatment during a covered stay in a hospital or skilled nursing facility (SNF). Part A payments made to the hospital or SNF generally cover all drugs provided during a covered stay.

Note: Some hospital services are provided in an outpatient setting, like an emergency department or hospital observation unit. See page 3 for information about Medicare drug coverage in these settings.

Does Medicare cover drugs under Part B?

Yes, but Part B only covers limited types of drugs. Generally, Part B covers drugs that usually aren’t self-administered and are given as part of a doctor’s service. Coverage usually is limited to drugs that are given by infusion or injection. If the injection usually is self-administered or isn’t given as part of a doctor’s service, Part B generally won’t cover it.

In most cases, these drugs are subject to the yearly Part B deductible. This means that people with Medicare may have to pay the Part B deductible amount before Medicare pays its share.

Part B also covers:

• Shots (vaccinations):
  – Flu shot: In general, 1 flu shot per flu season. Flu shots are usually given before the start of the flu season, in the late summer, fall, or winter, but some people may get the shot in the spring. This means people with Medicare can sometimes get this preventive shot twice in the same calendar year.
  – Pneumococcal shot: A shot to help prevent pneumococcal infections (like certain types of pneumonia). Most people only need this shot once in their lifetime.
  – Hepatitis B shots: A series of 3 shots covered only for people at high or medium risk for Hepatitis B. A person’s risk for Hepatitis B increases if the person has hemophilia, End-Stage Renal Disease (ESRD—permanent kidney failure requiring dialysis or a kidney transplant), or certain conditions that increase the person’s risk for infection. Other factors may also increase a person’s risk for Hepatitis B. To determine if he or she is eligible for coverage, a person with Medicare should check with his or her doctor to see if he or she is at high or medium risk for Hepatitis B.
  – Other shots: Some other vaccines when they’re directly related to the treatment of an injury or illness (like a tetanus shot after stepping on a nail).
Does Medicare cover drugs under Part B? (continued)

- **Durable Medical Equipment (DME) supply drugs:** Some drugs used with DME, like infusion pumps and nebulizers, if considered reasonable and necessary.
- **Injectable drugs:** Most injectable drugs given by a licensed medical provider if the drug is considered reasonable and necessary for treatment and usually isn’t self-administered.
- **Osteoporosis drugs:** An injectable drug for women with osteoporosis who meet the criteria for the Medicare home health benefit and have a bone fracture that a doctor certifies was related to post-menopausal osteoporosis. A doctor must certify that the woman is unable to learn how to or unable to give herself the drug by injection. The home health nurse or aide won’t be covered to provide the injection unless family and/or caregivers are unable or unwilling to give the woman the drug by injection.
- **Some antigens:** If they’re prepared by a doctor and given by a properly-instructed person (who could be the patient) under doctor supervision.
- **Erythropoiesis-stimulating agents:** For people undergoing dialysis and, if given as part of a doctor’s service, for certain other conditions.
- **Blood Clotting factors:** For people with hemophilia who give themselves the drug by injection.
- **Immunosuppressive drugs:** Drug therapy for transplant patients if the transplant meets Medicare coverage requirements, the patient has Part A at the time of the transplant, and the patient has Part B at the time the drugs are dispensed.
- **Oral anti-cancer drugs:** Some oral anti-cancer drugs if the same drug is available in injectable form for the same use and covered under Part B. As new oral anti-cancer drugs become available, Part B may cover them.
- **Oral anti-nausea drugs:** Used as part of an anti-cancer chemotherapeutic regimen. The drugs must be administered immediately before, at, or within 48 hours after the administration of the chemotherapy drug and must be used as a full therapeutic replacement for the intravenous anti-nausea drugs that would otherwise be given.
- **Oral End-Stage Renal Disease (ESRD) drugs:** Some oral ESRD drugs if the same drug is available in injectable form and covered under the Part B ESRD benefit.
- **Parenteral and enteral nutrition (intravenous and tube feeding):** Certain nutrients for people who can’t absorb nutrition through their intestinal tracts or can’t take food by mouth.
- **Intravenous Immune Globulin (IVIG) provided in the home:** For people with a diagnosis of primary immune deficiency disease. A doctor must decide that it’s medically appropriate for the IVIG to be given in the patient’s home. Part B covers the IVIG itself, but Part B doesn’t pay for other items and services related to the patient getting the IVIG in his or her home.
Does Part B cover self-administered drugs given in an outpatient setting, like an emergency department or hospital observation unit?

Generally, Part B doesn’t cover self-administered drugs a person gets in outpatient settings. A person’s Medicare drug plan (Part D) may cover these drugs under certain circumstances. A person might need to pay out-of-pocket for these drugs and submit a claim to his or her Part D plan for a refund. He or she should call the plan for more information.

For more information, visit www.medicare.gov/publications to view the fact sheet, “How Medicare Covers Self Administered Drugs Given in Hospital Outpatient Settings (CMS Product No. 11333).” You can also call 1-800-MEDICARE (1-800-633-4227) to find out if a copy can be mailed to you. TTY users should call 1-877-486-2048.

Which drugs does Part D cover?

Medicare offers comprehensive prescription drug coverage to people with Medicare under Part D. In general, a Part D-covered drug must meet all of these conditions:

- The drug is available only by prescription
- The drug is approved by the Food and Drug Administration (FDA)
- The drug is used and sold in the U.S.
- The drug is used for a medically-accepted indication, as defined under the Social Security Act
- The drug isn’t covered under Part A or Part B
- The drug is covered by the person’s Part D plan or coverage is obtained through the exceptions or appeals process

Does Part D cover shots (vaccinations)?

Yes. All Medicare drug plans must include all commercially available vaccines (like the shingles vaccine) on their drug formularies (except vaccines that are covered under Part B, like the flu or pneumococcal shot). The plan member or provider can contact the Medicare drug plan for more information about coverage.
Are there certain drugs that Part D doesn’t cover?
Yes. By law, Part D can’t pay for drugs when they would be covered under Part A or Part B. In addition, the following drugs can’t be included in basic Part D coverage:

- Benzodiazepines
- Barbiturates
- Drugs for weight loss or gain
- Drugs when used for treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the FDA
- Drugs for relief of cough and colds
- Non-prescription drugs
- Drugs used for cosmetic purposes or hair growth
- Drugs used to promote fertility
- Prescription vitamins and minerals, except prenatal vitamins and fluoride preparation products

Some Medicare drug plans may choose to cover these drugs as part of the plan’s supplemental benefits. However, any amount spent for these drugs isn’t counted toward the person’s share of the costs, like the deductible or out-of-pocket limit.

Can people appeal a drug coverage decision?
Yes. People with Medicare have certain guaranteed rights. One of these is the right to a fair process to appeal decisions about coverage or payment of health care services. How people file an appeal will depend on the type of Medicare plan they have. People with Medicare should review their coverage decision notices carefully for instructions on how to file an appeal.

Where can people get more information or help?

- Visit www.medicare.gov.
  - Look for more information on appeals in the “Help & Support” section. Select “Filing a Complaint or Grievance.”
  - Look for more information on Medicare drug coverage by selecting “Health & Drug Plans.”
- Call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.
- Contact your State Health Insurance Assistance Program (SHIP) to get free personalized health insurance counseling. To get the phone number, visit www.medicare.gov/contacts, or call 1-800-MEDICARE.
Exhibit F

List of useful industry acronyms

Source: HCPro, Inc.
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAPC</td>
<td>American Academy of Professional Coders</td>
</tr>
<tr>
<td>ABN</td>
<td>Advance beneficiary notice</td>
</tr>
<tr>
<td>ACDIS</td>
<td>Association of Clinical Documentation Improvement Specialists</td>
</tr>
<tr>
<td>ADR</td>
<td>Additional documentation request</td>
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<td>AHA</td>
<td>American Hospital Association</td>
</tr>
<tr>
<td>AHIMA</td>
<td>American Health Information Management Association</td>
</tr>
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<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>AMI</td>
<td>Acute myocardial infarction</td>
</tr>
<tr>
<td>AOA</td>
<td>American Osteopathic Association</td>
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<td>APCs</td>
<td>Ambulatory payment classifications</td>
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<td>ARRA</td>
<td>American Recovery and Reinvestment Act of 2009</td>
</tr>
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<td>ASC</td>
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<td>Average sales price</td>
</tr>
<tr>
<td>AWP</td>
<td>Average wholesale price</td>
</tr>
<tr>
<td>CAH</td>
<td>Critical access hospital</td>
</tr>
<tr>
<td>CC</td>
<td>Complication and comorbidity</td>
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<tr>
<td>CCHIT</td>
<td>Certification Commission for Health Information Technology</td>
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<td>CCR</td>
<td>Continuity of care record/Cost-to-charge ratio</td>
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<tr>
<td>CDI</td>
<td>Clinical documentation improvement</td>
</tr>
<tr>
<td>CDM</td>
<td>Charge description master</td>
</tr>
<tr>
<td>CERT</td>
<td>Comprehensive Error Rate Testing</td>
</tr>
<tr>
<td>CPI</td>
<td>Consumer price index</td>
</tr>
<tr>
<td>CMI</td>
<td>Case-mix index</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
</tr>
<tr>
<td>CMSA</td>
<td>Consolidated Metropolitan Statistical Area</td>
</tr>
<tr>
<td>CPI</td>
<td>Consumer price index</td>
</tr>
<tr>
<td>CPT</td>
<td>Current procedural terminology</td>
</tr>
<tr>
<td>CRNA</td>
<td>Certified registered nurse anesthetist</td>
</tr>
<tr>
<td>CT</td>
<td>Computed tomography</td>
</tr>
<tr>
<td>CY</td>
<td>Calendar year</td>
</tr>
<tr>
<td>DED</td>
<td>Dedicated emergency department</td>
</tr>
<tr>
<td>DRG</td>
<td>Diagnosis-related group</td>
</tr>
<tr>
<td>DSH</td>
<td>Disproportionate share hospital</td>
</tr>
<tr>
<td>ED</td>
<td>Emergency department</td>
</tr>
<tr>
<td>EDMS</td>
<td>Electronic Document Management System</td>
</tr>
<tr>
<td>EHR</td>
<td>Electronic health records</td>
</tr>
<tr>
<td>E/M</td>
<td>Evaluation and management</td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic medical records</td>
</tr>
<tr>
<td>EOB</td>
<td>Explanation of benefits</td>
</tr>
<tr>
<td>ePHI</td>
<td>Electronic protected health information</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
</tr>
<tr>
<td>FFY</td>
<td>Federal fiscal year</td>
</tr>
<tr>
<td>FI</td>
<td>Fiscal intermediary</td>
</tr>
</tbody>
</table>
### HIM Acronyms to Know

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>FY</td>
<td>Fiscal year</td>
</tr>
<tr>
<td>GAF</td>
<td>Geographic adjustment factor</td>
</tr>
<tr>
<td>GME</td>
<td>Graduate medical education</td>
</tr>
<tr>
<td>H&amp;P</td>
<td>History and physical</td>
</tr>
<tr>
<td>HAC</td>
<td>Hospital-acquired condition</td>
</tr>
<tr>
<td>HCCA</td>
<td>Health Care Compliance Association</td>
</tr>
<tr>
<td>HCFA</td>
<td>Health Care Financing Administration</td>
</tr>
<tr>
<td>HCPCS</td>
<td>Healthcare Common Procedure Coding System</td>
</tr>
<tr>
<td>HCRIS</td>
<td>Hospital Cost Report Information System</td>
</tr>
<tr>
<td>HHA</td>
<td>Home health agency</td>
</tr>
<tr>
<td>HHS</td>
<td>U.S. Department of Health and Human Services</td>
</tr>
<tr>
<td>HIC</td>
<td>Health insurance card</td>
</tr>
<tr>
<td>HIMSS</td>
<td>Healthcare Information and Management Systems Society</td>
</tr>
<tr>
<td>HINN</td>
<td>Hospital-Issued Notice of Non-Coverage</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act of 1996</td>
</tr>
<tr>
<td>HIS</td>
<td>Health information system/services</td>
</tr>
<tr>
<td>HIT</td>
<td>Healthcare information technology</td>
</tr>
<tr>
<td>HITECH Act</td>
<td>Health Information Technology for Economic and Clinical Health Act</td>
</tr>
<tr>
<td>HMO</td>
<td>Health maintenance organization</td>
</tr>
<tr>
<td>HSA</td>
<td>Health savings account</td>
</tr>
<tr>
<td>HSRVcc</td>
<td>Hospital-specific relative value cost center</td>
</tr>
<tr>
<td>HQA</td>
<td>Hospital Quality Alliance</td>
</tr>
<tr>
<td>HQI</td>
<td>Hospital quality initiative</td>
</tr>
<tr>
<td>ICD-9-CM</td>
<td>International Classification of Diseases, 9th Revision, Clinical Modifications</td>
</tr>
<tr>
<td>ICD-10-PCS</td>
<td>International Classification of Diseases, 10th Revision, Procedure Coding System</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive care unit</td>
</tr>
<tr>
<td>IHS</td>
<td>Indian Health Service</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
</tr>
<tr>
<td>IPF</td>
<td>Inpatient psychiatric facility</td>
</tr>
<tr>
<td>IPPS</td>
<td>Inpatient prospective payment system</td>
</tr>
<tr>
<td>IRF</td>
<td>Inpatient rehabilitation facility</td>
</tr>
<tr>
<td>IT</td>
<td>Information technology</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
</tr>
<tr>
<td>LCD</td>
<td>Local coverage determination</td>
</tr>
<tr>
<td>LTC-DRG</td>
<td>Long-term care diagnosis-related group</td>
</tr>
<tr>
<td>LTCH</td>
<td>Long-term care hospital</td>
</tr>
<tr>
<td>MAC</td>
<td>Medicare Administrative Contractors</td>
</tr>
<tr>
<td>MCC</td>
<td>Major complication and comorbidity</td>
</tr>
<tr>
<td>MCO</td>
<td>Managed care organization</td>
</tr>
<tr>
<td>MCV</td>
<td>Major cardiovascular</td>
</tr>
<tr>
<td>MDC</td>
<td>Major diagnostic category</td>
</tr>
<tr>
<td>MDH</td>
<td>Medicare dependent hospital (small rural)</td>
</tr>
<tr>
<td>MedPAC</td>
<td>Medicare Payment Advisory Commission</td>
</tr>
<tr>
<td>MedPAR</td>
<td>Medicare Provider Analysis and Review</td>
</tr>
</tbody>
</table>
### HIM Acronyms to Know

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>MIC</td>
<td>Medicaid Integrity Contractors</td>
</tr>
<tr>
<td>MRHFP</td>
<td>Medicare Rural Hospital Flexibility Program</td>
</tr>
<tr>
<td>MS-DRG</td>
<td>Medicare Severity DRG</td>
</tr>
<tr>
<td>NAHIT</td>
<td>National Alliance for Health Information Technology</td>
</tr>
<tr>
<td>NCCI</td>
<td>National Correct Coding Initiative</td>
</tr>
<tr>
<td>NCD</td>
<td>National coverage determination</td>
</tr>
<tr>
<td>NCHS</td>
<td>National Center for Health Statistics</td>
</tr>
<tr>
<td>NCQA</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>NCVHS</td>
<td>National Committee on Vital and Health Statistics</td>
</tr>
<tr>
<td>NHIN</td>
<td>National Health Information Network</td>
</tr>
<tr>
<td>NICU</td>
<td>Neonatal intensive care unit</td>
</tr>
<tr>
<td>NPI</td>
<td>National Provider Identifier</td>
</tr>
<tr>
<td>NQF</td>
<td>National Quality Forum</td>
</tr>
<tr>
<td>NVHRI</td>
<td>National Voluntary Hospital Reporting Initiative</td>
</tr>
<tr>
<td>OCE</td>
<td>Outpatient code editor</td>
</tr>
<tr>
<td>OCR</td>
<td>Office for Civil Rights</td>
</tr>
<tr>
<td>OES</td>
<td>Occupational employment statistics</td>
</tr>
<tr>
<td>OIG</td>
<td>Office of Inspector General</td>
</tr>
<tr>
<td>OMB</td>
<td>Office of Management and Budget</td>
</tr>
<tr>
<td>OPPS</td>
<td>Outpatient prospective payment system</td>
</tr>
<tr>
<td>OR</td>
<td>Operating room</td>
</tr>
<tr>
<td>OSCAR</td>
<td>Online Survey Certification and Reporting (System)</td>
</tr>
<tr>
<td>PHR</td>
<td>Personal health record</td>
</tr>
<tr>
<td>PO</td>
<td>By mouth</td>
</tr>
<tr>
<td>POA</td>
<td>Present on admission</td>
</tr>
<tr>
<td>PPI</td>
<td>Producer price index</td>
</tr>
<tr>
<td>PPS</td>
<td>Prospective payment system</td>
</tr>
<tr>
<td>PRA</td>
<td>Per resident amount</td>
</tr>
<tr>
<td>PRM</td>
<td>Provider Reimbursement Manual</td>
</tr>
<tr>
<td>PRRB</td>
<td>Provider Reimbursement Review Board</td>
</tr>
<tr>
<td>PS&amp;R</td>
<td>Provider Statistical and Reimbursement (System)</td>
</tr>
<tr>
<td>QIO</td>
<td>Quality Improvement Organization</td>
</tr>
<tr>
<td>RA</td>
<td>Remittance advice</td>
</tr>
<tr>
<td>RAC</td>
<td>Recovery Audit Contractor</td>
</tr>
<tr>
<td>RBC</td>
<td>Red blood cell</td>
</tr>
<tr>
<td>RC</td>
<td>Revenue code</td>
</tr>
<tr>
<td>RHC</td>
<td>Rural health clinic</td>
</tr>
<tr>
<td>RHIO</td>
<td>Regional health information organization</td>
</tr>
<tr>
<td>ROI</td>
<td>Release of information (OR return on investment)</td>
</tr>
<tr>
<td>RY</td>
<td>Rate year</td>
</tr>
<tr>
<td>SAF</td>
<td>Standard analytic file</td>
</tr>
<tr>
<td>SCH</td>
<td>Sole community hospital</td>
</tr>
</tbody>
</table>
### HIM Acronyms to Know

<table>
<thead>
<tr>
<th>Acronym</th>
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</thead>
<tbody>
<tr>
<td>SNF</td>
<td>Skilled nursing facility</td>
</tr>
<tr>
<td>SOC</td>
<td>Standard occupational classifications</td>
</tr>
<tr>
<td>SSA</td>
<td>Social Security Administration</td>
</tr>
<tr>
<td>SSI</td>
<td>Supplemental Security Income</td>
</tr>
<tr>
<td>ST</td>
<td>Status indicator</td>
</tr>
<tr>
<td>TAG</td>
<td>Technical Advisory Group</td>
</tr>
<tr>
<td>UHDDS</td>
<td>Uniform Hospital Discharge Data Set</td>
</tr>
<tr>
<td>WBC</td>
<td>White blood cell</td>
</tr>
<tr>
<td>ZPIC</td>
<td>Zone Program Integrity Contractor</td>
</tr>
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<th>Order code</th>
<th>Quantity</th>
<th>Total</th>
</tr>
</thead>
</table>

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Sales tax (see below)**
Grand total

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  - Long-term care
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