



Medicare Hospital Version

KEY CONCEPTS OUTLINE Module 11: Outpatient Drugs

I. Coverage of Outpatient Drugs

Medicare covers outpatient drugs under three circumstances:

- Statutorily covered drugs
- Drugs incident to a physician's service and NOT usually self-administered
- Drugs integral to a procedure

A. Statutorily Covered Drugs

1. The following drugs are covered by Medicare as specifically authorized by statute:
 - a. Blood clotting factors for hemophilia patients;
 - b. Drugs used in immunosuppressive therapy;
 - c. Erythropoietin for dialysis patients; and
 - d. Certain oral anti-cancer drugs and anti-emetics used in certain situations. <Medicare Benefit Policy Manual, Chapter 15 § 50.5>

B. Drugs Provided Incident to a Physician's Service

1. Medicare covers drugs provided incident to a physician's or NPP's service that are not usually self-administered by the patient. <See Medicare Benefit Policy Manual, Chapter 15 § 50>
2. The local MAC makes the determination a particular drug is usually self-administered or not, applying the following guidelines: <See Medicare Benefit Policy Manual, Chapter 15 § 50.2.A>
 - a. The determination a drug is self-administered is not patient specific. The decision is based on the usual method of administration for all Medicare

beneficiaries who use the drug. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.C>

- b. Drugs administered by any method other than injection and infusion are considered to be usually self-administered, with limited exceptions. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.B>

Self-administered drugs include oral drugs, suppositories, topically applied drugs and inhalation drugs

- c. Drugs administered by subcutaneous injection are presumed to be usually self-administered. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.C.3>
- d. Drugs administered intravenously or by intramuscular injection are presumed to be not usually self-administered. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.C.1 and 2>

3. Each MAC publishes a Self-Administered Drug (SAD) Exclusion List with the injectable drugs the MAC has determined to be usually self-administered and therefore not covered. The MAC SAD Exclusion Lists are posted on the Medicare Coverage Database.

Link: Coverage Database (NCDs, NCAs, LCDs) under Medicare-Related Sites – General

C. Drugs Integral to Procedures

1. Medicare covers certain self-administered drugs if they are an integral component of a procedure or are directly related to it or facilitate the performance of or recovery from the procedure. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.M>

Examples of drugs integral to a procedure:

- Sedatives administered in a preoperative area
- Eye drops and certain other drugs related to eye procedures
- Barium and low osmolar contract media
- Topical solutions used in photodynamic therapy
- Antibiotic ointment such as bacitracin

2. A CMS representative has indicated the “overwhelming majority” of self-administered drugs are non-covered. The representative recommended comparing other items to the list above to determine if they may be covered. <Hospital Open Door Forum, August 23, 2011>

- a. The representative used the example of insulin given to control a patient's blood sugar as a non-covered drug, stating it would not be integral to a procedure because its purpose was to control a patient's blood sugar and not to be used as part of a procedure. <Hospital Open Door Forum, August 23, 2011>

Caution: In the past, there was an exception for insulin when administered in an emergency, but current instructions do not allow payment for a drug administered on an emergency basis if the drug is excluded as usually self-administered.

3. A drug will not be considered covered if the drug itself is the treatment rather than being an integral component of or facilitating the performance of or recovery from a particular procedure. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.M>

Examples of drugs consider a treatment and not integral to a procedure:

- Drugs given to a patient for continued use at home
- Oral pain medication given to an outpatient who develops a headache while receiving a chemotherapy treatment
- Daily routine insulin or hypertension medication given preoperatively
- A fentanyl patch or oral pain medication given to an outpatient presenting with pain
- A laxative for constipation given to a patient waiting for an unrelated x-ray

4. Handout 18 is an algorithm of the coverage of self-administered drugs that are integral to a procedure.

D. Non-covered Self-Administered Drugs

1. Non-covered self-administered drugs may be billed to Medicare for a denial under the revenue code 0637 ("Self-administrable Drugs"), with or without a HCPCS code. <*NUBC Official UB-04 Specifications Manual; IOCE Specifications*, Section 8.2, Edit 48 (Supplement)>
 - a. If no drug HCPCS code is available for the self-administered drug and the provider wishes to bill with a modifier (e.g., -GX indicating a voluntary ABN was provided to the patient), the provider may use HCPCS A9270 ("Non-covered Item or Service"). <*Medicare Claims Processing Manual*, Chapter 1 § 60.4.2>

2. The DHHS Office of Inspector General (OIG) has stated hospitals will not be subject to administrative sanctions if they discount or waive amounts owed for non-covered self-administered drugs, subject to the following conditions:
 - a. The discounts or waivers are for drugs received for ingestion or administration in outpatient settings;
 - b. The policy is uniformly applied without regard to diagnosis or type of treatment;
 - c. The policy is not marketed or advertised; and
 - d. The hospital does not claim the discounted or waived amounts as bad debt or otherwise shift the burden of these costs to the Medicare or Medicaid program, other payers or individuals. <See OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings, dated October 29, 2015>
3. The OIG's policy statement does not affect the OIG's prior guidance on the ability of a hospital to discount or waive any amounts owed by Medicare beneficiaries on the basis of a good-faith, individualized determination of a beneficiary's financial need. <See OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings, dated October 29, 2015>

Case Study 1

Facts: A Medicare patient presents to a hospital outpatient imaging department for an MRI. The patient has longstanding claustrophobia and their treating physician has prescribed 2 tablets of Valium® prior to the procedure to prepare them for the procedure and ensure the MRI can be completed as planned. Is the Valium® a self-administered drug? Is the Valium® a covered drug?

II. Billing for Drugs and Biologicals

A. HCPCS Codes

1. Drugs and biologicals are billed with a HCPCS code, if one exists, and units of service consistent with the HCPCS code description. <Medicare Claims Processing Manual, Chapter 17 § 10, 90.2>

- a. If the provider furnishes a dose of a drug that does not equal a multiple of the units specified in the HCPCS code for the drug, the provider should round to the next highest unit when reporting the drug. <Medicare Claims Processing Manual, Chapter 17 § 10, 40>

Example: A patient is administered 7mgs of a drug. The HCPCS code long descriptor indicates “per 5 mgs”. The hospital should report units of 2 for the drug.

2. If a drug with status indicator G or K is reported without an accompanying administration or procedure code, edit 99 of the IOCE will cause the claim to be returned to the provider. <Medicare Claims Processing Manual, Chapter 4 § 230.2 and Chapter 17 § 10; IOCE Specifications, Section 6.15 and Section 8.2, Edit 99 (Supplement)>
 - a. Exception: Blood clotting factors and certain biological response modifiers may be billed without an accompanying administration or procedure code. <IOCE Specifications, Section 6.15 (Supplement)>
 - b. The codes excluded from IOCE edit 99 are available in the IOCE Quarterly Data Files, Report-Table folder, “Data_HCPCS”, column CV “BYPASS_E99” available on the IOCE homepage. The list is included in the materials behind the outline.

Link: OCE Specifications under Medicare-Related Sites - Hospital

B. Revenue Codes

1. Drugs and biologicals with HCPCS codes should be reported with revenue code 636 “Drugs Requiring Detailed Coding”, except radiopharmaceuticals. Diagnostic radiopharmaceuticals are reported with revenue code 343 and therapeutic radiopharmaceuticals are reported with revenue code 344. <Official UB-04 Data Specifications Manual, Program Memorandum A-02-129>
2. Drugs and biologicals that do not have a HCPCS code should be billed with the appropriate revenue code in the “General Pharmacy” revenue code series 025X, which does not require a HCPCS code for reporting. <Official UB-04 Data Specifications Manual>
3. Self-administered drugs that are covered as packaged supplies should be reported “under the revenue code associated with the cost center under which the hospital accumulates the costs of the drugs”, presumably revenue code 0250. <Medicare Benefit Policy Manual, Chapter 15 § 50.2 M>

- a. Revenue code 0637 “Self-administrable Drugs” should not be reported for covered, packaged self-administered drugs because the OCE identifies it as an excluded revenue code. <IOCE Specifications, Section 8.2, Edit 50 (Supplement)>

C. Modifiers

1. Modifier -JW or -JZ for Drugs in Single-Dose Containers or Single-Use Packages¹

- a. Separately payable drugs and biologicals (i.e., with status indicator “A”, “G”, or “K”) packaged in single-dose containers must be reported with modifier -JW or modifier -JZ. <87 Fed. Reg. 69712 – 69718; see JW/JZ FAQs, Q2, Q12, Q17>
 - i. CMS has published “Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy, Frequently Asked Questions”, referred to in this section as the JW/JZ FAQs, available on OPPS Homepage of the CMS website, and included in the materials behind the outline.
 - ii. CMS has published a “non-exhaustive” list of drug and biological HCPCS codes assigned to single-dose containers and indicated they intend to update the list approximately semi-annually. The list is published on the ASP Billing Resources website, and the current list is included in the materials behind the outline.

Link: ASP Billing Resources under Medicare-Related Sites - General
 - iii. Modifiers -JW and -JZ apply to drugs supplied in “single-dose” containers or “single-use” packages based on the FDA-approved labeling. <See JW/JZ FAQs, Q7>
 - iv. Claims for drugs packaged in single-dose containers submitted without either modifier -JW or -JZ may be returned as un-processable beginning October 1, 2023. <87 Fed. Reg. 69717; see JW/JZ FAQs, Q5, Q11>
 - v. Modifiers -JW and -JZ are not reported on drugs that are packaged for payment purposes (i.e., with status indicator “N”), vaccines, or on drugs reported on inpatient claims. <See JW/JZ FAQs, Q6, Q7, Q21>

b. Modifier -JW

¹ Referred to collectively as “single-dose containers” in the remainder of the outline.

- i. Modifier- JW (“Drug amount discarded/not administered to any patient”) is used to report the discarded amount from a single-dose container if a portion is administered to the patient and the remainder discarded. <Medicare Claims Processing Manual, Chapter 17 § 40>
 - a) The discarded amount of a single-dose container is calculated by subtracting the amount administered from the amount on the label of the purchased container. <87 Fed. Reg. 69718; see JW/JZ FAQs, Q3>
 - 1) The provider is not limited to calculating the discarded amount based on the smallest vial size available for purchase, but rather should use the labeled amount of the product actually purchased. <87 Fed. Reg. 69718>
 - 2) Noridian, the Jurisdiction E and F MAC, continues to have a published policy requiring the billed amount to equal the smallest dose available for purchase from the manufacturer. <Noridian LCA A55932; Noridian LCA A53024>
 - b) Providers must document the amount of the discarded drug or biological in the patient’s medical record. <Medicare Claims Processing Manual, Chapter 17 § 40>
 - 1) The discarded amount can be automatically calculated and documented by software, as long as the wastage is documented accurately. <JW/JZ FAQs, Q16>
 - c) Unused portions of multi-use vials may not be billed to Medicare. <Medicare Claims Processing Manual, Chapter 17 § 40>
 - ii. Report the administered portion and the discarded portion of a single-dose container on separate lines, with modifier JW on the line for the discarded portion. <Medicare Claims Processing Manual, Chapter 17 § 40>
- c. Modifier JZ
- i. Modifier -JZ (“Zero drug amount discarded/not administered to any patient”) is used to report a drug administered from a single-dose container with no wastage (i.e., the full amount of the vial or package is administered). <See JW/JZ FAQs, Q2, Q17>

- a) The policy for modifier -JZ is aligned with modifier -JW and modifier -JZ is required for single dose containers for which the -JW modifier would be required if there were any discarded amount. <87 Fed. Reg. 69712; see JW/JZ FAQs, Q2>

Case Study 2

Facts: A Medicare patient presents to the oncology center of a hospital for an injection of bortezomib (HCPCS code J9041 is reported for 0.1 mg of bortezomib). Bortezomib is supplied in a 3.5 mg vial and must be reconstituted for administration. Bortezomib is packaged in a single use vial that must be used within 8 hours once reconstituted. The patient requires 2.7 mg of bortezomib and the hospital was unable to use the remainder for another patient and had to dispose of it. Will Medicare pay separately for this drug? How should this drug be billed to Medicare?

2. Modifier -JG or -TB for 340B Acquired Drugs
- a. During CY2024, drugs acquired through the 340B drug discount program² may be reported with either modifier -JG or -TB for informational purposes. <88 Fed. Reg. 81792>
- i. Hospitals that have been reporting 340B acquired drugs with modifier -JG may continue to do so until CY2025. <88 Fed. Reg. 81792>
- b. Beginning CY2025, drugs acquired through the 340B drug discount program must be reported with modifier -TB for informational purposes. <88 Fed. Reg. 81792>
- i. CMS has published “Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS), Frequently Asked Questions” updated March 3, 2023, referred to in this section as the 340B FAQs, available on OPPS Homepage of the CMS website.
- Caution: At the time of publishing, the FAQ has not been updated since the CY2024 Final Rule adopted the new requirements for reporting modifier -TB beginning CY2025.
- c. Modifiers -JG and -TB do not apply to drugs not purchased through the 340B program or with status indicators “L”, “M”, or “N”. <340B FAQs, Q9>

² The 340B Program, administered by the Health Resources and Services Administration (HRSA), allows Federal grant recipients, CAHs, and specified Disproportionate Share Hospitals to purchase “covered outpatient drugs” at discounted prices from drug manufacturers.

III. Payment for Drugs and Biologicals

A. Medicare pays for covered drugs and biologicals in three ways:

1. Separate payment under the “pass-through” provisions for new drugs and biologicals <Medicare Claims Processing Manual, Chapter 17 § 90.2 B>; or
2. Separate payment as a “non-pass through” under certain provisions for payment of outpatient drugs and biologicals. <Medicare Claims Processing Manual, Chapter 17 §90.2 C>; or
3. Packaged into payment for other services on the claim.

B. Pass-Through Drugs and Biologicals

1. Under OPPS, “pass-through payment” is made for drugs and biologicals which are new and whose cost is “not insignificant” in relation to the OPPS payment for the procedures or services associated with the new drug or biological. <42 C.F.R. 419.64(a)(4)>
2. The OPPS status indicator for pass-through drugs and biologicals is G. The list of pass-through drugs and biological is updated quarterly in the OPPS Addendum B. <Medicare Claims Processing Manual, Chapter 17 § 90.2 B>
3. Once assigned pass-through status, the drug or biological remains a pass-through for at least 2 years, but no more than 3 years. <Medicare Claims Processing Manual, Chapter 17 § 90.2 B>
4. Although diagnostic radiopharmaceuticals, stress agents, contrast agents and skin substitutes are normally packaged, if they meet the requirements for pass-through status they are paid separately under the pass-through provisions. <80 Fed. Reg. 70430; Medicare Claims Processing Manual Transmittal 3557>
 - a. The list of pass-through radiopharmaceuticals, stress agents, contrasts, and skin substitutes is available in the IOCE Quarterly Data Files, Report-Table folder, “Data_HCPCS”, columns CO “PASSTHROUGH_RADIOPHARM”, CP “PASSTHROUGH_SKIN_PRODUCT”, CQ “PASSTHROUGH_CONTRAST”, and CR “PASSTHROUGH_STRESS_AGENT”. The list is included in the materials behind the outline.
 - b. The payment for pass-through diagnostic radiopharmaceuticals, stress agents, contrast agents and skin substitutes is subject to an offset. <Medicare Claims Processing Manual Transmittal 3557; IOCE Specifications, Section 6.15, 6.15.1 (Supplement)>

- i. The offset is equal to the offset amount for the associated APC with the highest offset reported on the claim with the drug or biological. <77 Fed. Reg. 68370-71; Medicare Claims Processing Manual Transmittal 3557>
- ii. The offset is applied across the entire claim for diagnostic radiopharmaceuticals and by date of service for stress agents, contrast agents and skin substitutes. <IOCE Specifications, Section 6.15, 6.15.1 (Supplement)>
- iii. The offset amount for APCs associated with pass through diagnostic radiopharmaceuticals, stress agents, contrast agents and skin substitutes is available in the IOCE Quarterly Data Files, Report-Table folder, "Offset_APC" available on the IOCE homepage. The list is included in the materials behind the outline.

Case Study 3

Facts: January 15, 2024, a patient presents to the provider-based radiology department for a PET scan (CPT code 78811) for evaluation for suspected Parkinsonian Syndrome (PS). As part of the procedure, the patient is administered 5mCi of the radiopharmaceutical FDOPA (Fluorodopa F18). Code A9602 is used to report 1 mCi of Fluorodopa F18, diagnostic. Assuming a wage index of 1, how much will the hospital be paid for this procedure, including the radiopharmaceutical.

C. Non-Pass-through Drugs and Biologicals

1. Under OPPS, separate "non-pass-through" payment is made for drugs and biologicals that have a mean daily cost of more than \$135 per day. <88 Fed. Reg. 81575>
 - a. The OPPS status indicator for non-pass-through drugs and biologicals is K. The list of non-pass-through drugs and biological is updated quarterly in the OPPS Addendum B. <Medicare Claims Processing Manual, Chapter 17 § 90.2 B, C>
 - b. Regardless of their mean daily cost, diagnostic radiopharmaceuticals, skin substitutes, contrast agents, stress agents, anesthesia and other intraoperative drugs, and drugs used as supplies, that don't qualify for pass through status, are packaged under CMS payment policy and do not qualify for non-pass through payment. <82 Fed. Reg. 59344>

D. Payment Rate for Separately Paid Drugs

1. Status indicator G and K drugs and biologicals are paid based on Average Sales Price (ASP) + 6% to account for acquisition and overhead costs. <88 Fed. Reg. 81804>
2. Status indicator L vaccines are paid on a reasonable cost basis. <OPPS Addendum D1>
3. The payment rate for drugs and biologicals is updated quarterly in the OPSS Addendum B. <Medicare Claims Processing Manual, Chapter 17 § 90.2 B>

E. Packaged Drugs and Biologicals

1. Drugs and biologicals that have a HCPCS code with an OPSS status indicator of N are packaged. <OPPS Addendum D1>
2. Drugs and biologicals that do not have a HCPCS code, but are covered, including self-administered drugs that are integral to a procedure, are also packaged. <See Medicare Benefit Policy Manual, Chapter 15 § 50.2 M>
3. As with all packaged items/services under OPSS, no separate payment is made for packaged drugs and biologicals, however, charges should be billed for packaged drugs and biologicals so that cost of the packaged items can be accumulated for purposes of calculating outlier payments, future rate setting, etc. <Medicare Claims Processing Manual, Chapter 4 § 10.4(A), Chapter 17 § 10>

IV. Biological Skin Substitutes

Biological skin substitute products are billed in one of three ways:

- Billed with a “low cost” skin substitute application procedure HCPCS Level II code (C5271-C5278)
- Billed with a “high cost” skin substitute application procedure CPT code (15271-15278)
- Billed as an implant with a surgical procedure code rather than skin application procedure code.

A. Low Cost Skin Substitutes

1. Low cost skin substitute *products* applied externally must be billed with the low cost skin substitute application *procedure* codes or the claim will be returned to the provider. <78 Fed. Reg. 74934-39; IOCE Specifications, Section 6.16 and Section 8.2, Edit 87 (Supplement)>

- a. Low cost skin substitute *procedure* codes are HCPCS Level II codes C5271-C5278. <78 Fed. Reg. 74934-39>
- b. The list of low cost skin substitute *products* is available in the IOCE Quarterly Data Files, Report-Table folder, “DATA_HCPCS”, column BV “SKIN_SUBSTITUTE_LO” available on the IOCE homepage. The list is included in the materials behind the outline.
 - i. Skin substitute products applied externally are billed with revenue code 0636 (drugs requiring detailed coding). <Medicare Claims Processing Manual Transmittal 4075>

B. High Cost Skin Substitutes

- 1. High cost skin substitute *products* applied externally must be billed with the high cost skin substitute application *procedure* codes or the claim will be returned to the provider. <78 Fed. Reg. 74934-39; IOCE Specifications, Section 6.16 and Section 8.2, Edit 87 (Supplement)>
 - a. High cost skin substitute *procedure* codes are CPT codes 15271-15278. <78 Fed. Reg. 74934-39>
 - b. The list of high cost skin substitute *products* is available in the IOCE Quarterly Data Files, Report-Table folder, “DATA_HCPCS”, column BX “SKIN_SUBSTITUTE_HI” available on the IOCE homepage. The list is included in the materials behind the outline.
 - i. All pass-through skin substitute *products* (designated with status indicator G) are considered high cost skin substitutes. <78 Fed. Reg. 74937; 81 Fed. Reg. 79671>
 - ii. Skin substitute products applied externally are billed with revenue code 0636 (drugs requiring detailed coding). <Medicare Claims Processing Manual Transmittal 4075>

C. Implanted Skin Substitutes

- 1. Implanted skin substitutes are billed with surgical procedure codes outside the skin application procedure code ranges (i.e., they are not reported with 15271-15278 or C5271-5278). <78 Fed. Reg. 74939>
- 2. Implanted skin substitutes are billed with revenue code 0278 (Other Implant). <Medicare Claims Processing Manual Transmittal 4075, 4186>

D. Skin Substitutes that can be Applied or Implanted

1. Some skin substitutes may be used either as an implant, billed with revenue code 0278 (Other Implant), or as an applied skin substitute, billed with revenue code 0636 (drugs requiring detailed coding). <Medicare Claims Processing Manual Transmittal 4075, 4186>
2. CMS has approved the following codes to be billed with either revenue code 0278 or 0636:
 - a. Q4116 (Alloderm, per square centimeter)
 - b. Q4122 (Dermacell, per square centimeter)

Case Study 4

Facts: A Medicare patient undergoes an outpatient orthopedic procedure to repair a tendon in their elbow (CPT code 24341) and receives an injection of 1 cc of Integra flowable wound matrix (Q4114), a biological skin substitute, as an implantable scaffold to support repair of the tendon. Should the hospital report a skin substitute application procedure code in addition to the code for the biological skin substitute? Will the hospital be paid separately for the Integra?

CASE STUDIES WITH ANALYSIS

Case Study 1

Facts: A Medicare patient presents to a hospital outpatient imaging department for an MRI. The patient has longstanding claustrophobia and their treating physician has prescribed 2 tablets of Valium® prior to the procedure to prepare them for the procedure and ensure the MRI can be completed as planned. Is the Valium® a self-administered drug? Is the Valium® a covered drug?

Analysis: As a tablet, the Valium® is presumed to be a self-administered drug. The Valium® is similar to a sedative in a preoperative area. The Valium® is covered as a self-administered drug integral to a procedure because it is directly related to the MRI procedure and provided to facilitate the performance of the procedure. <Medicare Benefit Policy Manual, Chapter 15 § 50.2 M>

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Case Study 2

Facts: A Medicare patient presents to the oncology center of a hospital for an injection of bortezomib (HCPCS code J9041 is reported for 0.1 mg of bortezomib). Bortezomib is supplied in a 3.5 mg vial and must be reconstituted for administration. Bortezomib is packaged in a single use vial that must be used within 8 hours once reconstituted. The patient requires 2.7 mg of bortezomib and the hospital was unable to use the remainder for another patient and had to dispose of it. Will Medicare pay separately for this drug? How should this drug be billed to Medicare?

Analysis: Yes, J9041 has a status indicator of “K” which means it is paid as a non-pass-through drug. The hospital should report J9041 with 27 units and J9041-JW with 8 units. <OPPS Addendum B, *Medicare Claims Processing Manual*, Chapter 17 § 40>

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Case Study 3

Facts: January 15, 2024, a patient presents to the provider-based radiology department for a PET scan (CPT code 78811) for evaluation for suspected Parkinsonian Syndrome (PS). As part of the procedure, the patient is administered 5mCi of the radiopharmaceutical FDOPA (Fluorodopa F18). Code A9602 is used to report 1 mCi of Fluorodopa F18, diagnostic. Assuming a wage index of 1, how much will the hospital be paid for this procedure, including the radiopharmaceutical.

Analysis: The CPT code 78811 has status indicator S and is assigned APC 5593 with a payment rate of \$1,352.93 (see Addendum B). The HCPCS code A9602 has status indicator G and is assigned APC 9053 with a payment rate of \$446.88 (see Addendum B). Because A9602 is a pass-through diagnostic radiopharmaceutical it is subject to an offset of the packaged drug amount already included in APC 5593 (\$364.06) (see the "OFFSET_APC" file in the IOCE Quarterly Data Files, also included behind the outline).

Payment for A9602	= \$446.88 X 5 = \$2,234.40 - \$364.06 =	\$1,870.34
Payment for 78811		<u>\$1,352.93</u>
Total		\$3,223.27

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Case Study 4

Facts: A Medicare patient undergoes an outpatient orthopedic procedure to repair a tendon in their elbow (CPT code 24341) and receives an injection of 1 cc of Integra flowable wound matrix (Q4114), a biological skin substitute, as an implantable scaffold to support repair of the tendon. Should the hospital report a skin substitute application procedure code in addition to the code for the biological skin substitute? Will the hospital be paid separately for the Integra?

Analysis: This skin substitute is an implantable skin substitute and is not on the list of “high cost” or “low cost” skin substitutes in the IOCE Quarterly Data Files. The code Q4114 is not listed as an acceptable code to be reported with a skin substitute application procedure code and reporting Q4114 with the application procedure code would result in the claim being returned to the provider per IOCE edit 87. Code Q4114 should be billed under revenue code 0278 with a surgical procedure code for the tendon repair. Code Q4114 has a status indicator N and will be packaged to the tendon repair procedure. <78 Fed. Reg. 74939, Medicare Claims Processing Manual Transmittal 4075, 4186>

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outs. For example, for specialty 01, the contractor would enter a number of all providers that have a status of opt out as of the close of the quarter.

The CMS will no longer accept faxed, e-mailed or mailed copies of the opt out report.

The report is due in CROWD 30 days after the end of each quarter (e.g., a report for the quarter April 1, 2010, through June 30, 2010, is due July 30, 2010.)

50 - Drugs and Biologicals

(Rev. 1, 10-01-03)

B3-2049, A3-3112.4.B, HO-230.4.B

The Medicare program provides limited benefits for outpatient drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them.

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

- 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).

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs. (See §110.3 for coverage of drugs, which are necessary to the effective use of Durable Medical Equipment (DME) or prosthetic devices.)

50.1 - Definition of Drug or Biological

(Rev. 1, 10-01-03)

B3-2049.1

Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USD-DI), or the American Dental Association (AOA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.



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.) The

contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:



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

A. Acute Condition - Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.

B. Frequency of Administration - How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

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

D. Definition of Acute Condition

For the purposes of determining whether a drug is usually self-administered, an acute condition means a condition that begins over a short time period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval. A course of treatment consisting of scheduled injections lasting less than 2 weeks, regardless of frequency or route of administration, is considered acute. Evidence to support this may include Food and Drug Administration (FDA) approval language, package inserts, drug compendia, and other information.



E. By the Patient

The term “by the patient” means Medicare beneficiaries as a collective whole. The carrier includes only the patients themselves and not other individuals (that is, spouses, friends, or other care-givers are not considered the patient). The determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. The carrier ignores all instances when the drug is administered on an inpatient basis.

The carrier makes this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for “self-administered by the patient” was based; for example, an early onset of dementia.

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.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



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

The purpose of this Policy Statement is to assure hospitals that they will not be subject to Office of Inspector General (OIG) administrative sanctions for discounting or waiving amounts Medicare beneficiaries may owe for self-administered drugs (SADs) they receive in outpatient settings when those drugs are not covered by Medicare Part B, subject to the conditions specified herein. This Policy Statement is designed to address the question whether various guidance documents issued by the Centers for Medicare & Medicaid Services (CMS), including a Program Memorandum outlining changes in the Outpatient Prospective Payment System (OPPS) for calendar year 2003, require hospitals to bill and collect (or make good faith efforts to collect) their usual and customary charges for SADs that are not covered by Medicare Part B (Noncovered SADs) to comply with OIG's fraud and abuse authorities. That Program Memorandum stated that:

[n]either 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 [Social Security] Act, or the anti-kickback statute, section 1128B(b) of the Act.¹

Medicare Part B generally covers care that Medicare beneficiaries receive in hospital outpatient settings such as emergency departments and observation units; however, Medicare Part B covers only certain drugs in these settings. Specifically, Medicare Part B 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.²

Although some or all of the SADs a Medicare beneficiary receives in an outpatient setting may be covered by Medicare Part D, most hospital pharmacies do not participate in Medicare Part D.³ CMS has stated that only hospitals with pharmacies that dispense prescriptions to outpatients and have contracts with Medicare Part D plans should bill the contracted plans directly as in-network pharmacies; otherwise, the hospitals should bill the Medicare beneficiaries for any Noncovered

¹ CMS, "2003 Update of the Hospital Outpatient Prospective Payment System (OPPS)," Program Memorandum Intermediaries, Transmittal A-02-129 (Change Request 2503, January 3, 2003).

² Section 1861(s)(2)(B) of the Social Security Act (the Act); *Medicare Benefit Policy Manual*, CMS, Pub. 100-02, Chapter 15, "Covered Medical and Other Health Services," Sections 50, 50.2.

³ See, e.g., "How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings," CMS Product No. 11333, revised Feb. 2011, available at <https://www.medicare.gov/Pubs/pdf/11333.pdf>.

SADs that the hospitals dispense.⁴ Consequently, Medicare beneficiaries may be billed for Noncovered SADs they received as outpatients—often at amounts much higher than they would have paid at retail pharmacies—even if those drugs are covered under their Medicare Part D plans.⁵

Ordinarily, routine discounts or waivers of costs owed by Medicare beneficiaries, including cost-sharing amounts, potentially implicate the Federal anti-kickback statute,⁶ the civil monetary penalty and exclusion laws related to kickbacks,⁷ and the Federal civil monetary penalty law prohibiting inducements to beneficiaries.⁸ Nonetheless, in the limited circumstances described in this Policy Statement, hospitals will not be subject to OIG administrative sanctions if they discount or waive amounts that Medicare beneficiaries owe for Noncovered SADs (including Noncovered SADs that may be covered under Medicare Part D) the beneficiaries receive in outpatient settings, subject to the following conditions:

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

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

Moreover, nothing in this Policy Statement affects the ability of a hospital to discount or waive any amounts owed by Medicare beneficiaries on the basis of a good-faith, individualized

⁴ See, e.g., “Information Partners Can Use On: Billing for Self-Administered Drugs Given in Outpatient Settings,” CMS Product No. 11331-P, revised Feb. 2011, available at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11331-P.pdf>.

⁵ If a self-administered drug is covered by a Medicare beneficiary’s Part D plan, the beneficiary may submit a paper claim to the Medicare Part D plan for reimbursement; however, the beneficiary typically would remain liable for the difference between what the hospital charged and what the Medicare Part D plan paid. See generally MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2015), available at <http://www.medpac.gov/documents/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>.

⁶ Section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b).

⁷ Sections 1128(b)(7) and 1128A(a)(7) of the Act, 42 U.S.C. §§ 1320a-7(b)(7) and 1320a-7a(a)(7).

⁸ Section 1128A(a)(5) of the Act, 42 U.S.C. § 1320a-7a(a)(5).

⁹ A beneficiary is not considered an outpatient if the only service received from the hospital is the dispensing of a drug for subsequent self-administration.

determination of a beneficiary's financial need. Further, nothing in this Policy Statement affects the operation of CMS's programmatic rules and regulations.

Finally, nothing in this Policy Statement affects a hospital's responsibility to bill only for services performed and to comply with Federal and State billing laws and guidance in effect at the time.

General guidance about the Federal anti-kickback statute and other fraud and abuse authorities is available on OIG's website at <http://oig.hhs.gov/>. This guidance includes the "Special Fraud Alert: Routine Waivers of Copayments or Deductibles Under Medicare Part B;" the "Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries;" safe harbor regulations (and the "preamble" discussions that include explanatory information); compliance program guidance documents for various industry sectors; and OIG advisory opinions.

OIG reserves the right to reconsider the issues raised in this Policy Statement and, where the public interest requires, to rescind, modify, or terminate this Policy Statement.

Questions regarding this Policy Statement may be directed to Jennifer Williams, Senior Counsel, Office of Counsel to the Inspector General, at (202) 401-4133.

/Daniel R. Levinson/

October 29, 2015

Daniel R. Levinson
Inspector General

Date

Version 01/23/2015
Check for Updates

Edit 99 Exclusion List (DATA_HCPCS, Column CV "BYPASS_E99")

HCPCS	DESCRIPTION	BYPASS_E99	LO_VERSION	HI_VERSION
J2506	Inj pegfilgrast ex bio 0.5mg	1	86	94
J7170	Inj., emicizumab-kxwh 0.5 mg	1	92	94
J7175	Inj, factor x, (human), 1iu	1	92	94
J7178	Inj human fibrinogen con nos	1	92	94
J7179	Vonvendi inj 1 iu vwf:rco	1	92	94
J7180	Factor xiii anti-hem factor	1	94	94
J7181	Factor xiii recomb a-subunit	1	94	94
J7182	Factor viii recomb novoeight	1	92	94
J7183	Wilate injection	1	92	94
J7185	Xyntha inj	1	92	94
J7186	Antihemophilic viii/vwf comp	1	92	94
J7187	Humate-p, inj	1	92	94
J7188	Factor viii recomb obizur	1	92	94
J7189	Factor viia recomb novoseven	1	92	94
J7190	Factor viii	1	92	94
J7192	Factor viii recombinant nos	1	92	94
J7193	Factor ix non-recombinant	1	92	94
J7194	Factor ix complex	1	92	94
J7195	Factor ix recombinant nos	1	92	94
J7198	Anti-inhibitor	1	92	94
J7200	Factor ix recombinan rixubis	1	92	94
J7201	Factor ix alprolix recomb	1	92	94
J7202	Factor ix idelvion inj	1	92	94
J7203	Factor ix recomb gly rebinyn	1	92	94
J7204	Inj recombin esperoct per iu	1	92	94
J7205	Factor viii fc fusion recomb	1	92	94
J7207	Factor viii pegylated recomb	1	92	94
J7208	Inj. jivi 1 iu	1	92	94
J7209	Factor viii nuwiq recomb 1iu	1	92	94
J7210	Inj, afstyla, 1 i.u.	1	92	94
J7211	Inj, kovaltry, 1 i.u.	1	92	94
J7212	Factor viia recomb sevenfact	1	92	94
J7214	Altuviio per factor viii iu	1	93	94

Medicare Program
Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently
Asked Questions

Policy: Effective January 1, 2017, providers and suppliers are required to report the JW modifier on all claims that bill for drugs and biologicals (hereafter, drug) separately payable under Medicare Part B with unused and discarded amounts (hereafter, discarded amounts) from single-dose containers or single-use packages (hereafter, single-dose containers). Also, providers and suppliers must document the amount of discarded drugs in Medicare beneficiaries' medical records. Through subsequent rulemaking, we codified the requirement to use the JW modifier for single-dose container drug that are separately payable under Part B. We will use the JW and JZ modifiers to calculate discarded drug refunds effective January 1, 2023.

Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts.

CMS encourages physicians, hospitals and other providers and suppliers to care for and administer drugs and biologicals to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner.

Resources:

2023 Physician Fee Schedule Final Rule ([87 FR 69710 - 69734](#), November 18, 2022)

2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule ([87 FR 71988, 72082 - 72083](#), November 23, 2022)

2024 Physician Fee Schedule Final Rule ([88 FR 79046](#) through [79064](#), November 16, 2023)

MLN Matters <https://www.cms.gov/files/document/mm13056-new-jz-claims-modifier-certain-medicare-part-b-drugs.pdf>; and

Chapter 17 of the CMS Medicare Claims Processing Manual (Section 40) - <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>

Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections - <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-12-35.pdf>

MODIFIER	SHORT DESCRIPTOR (28-character limit)	LONG DESCRIPTOR
JW	Discarded drug not administered	Drug amount discarded/not administered to any patient
JZ	Zero drug wasted	Zero drug amount discarded/not administered to any patient

General

Q1. What is the JW modifier?

A1. The JW modifier is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier required to be reported on a claim to report the amount of drug that is discarded and eligible for payment under the discarded drug policy (explained in the answer to question #3). The modifier should only be used for claims that bill single-dose container drugs.

Q2. What is the JZ modifier?

A2. The JZ modifier is a HCPCS Level II modifier reported on a claim to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for single-dose container drugs.

To align with the JW modifier policy, the JZ modifier is required when there are no discarded amounts of a single-dose container drug for which the JW modifier would be required if there were discarded amounts.

Q3. What is the payment policy for drugs payable under Medicare Part B for which there are discarded amounts?

A3. When a provider must discard an amount of drug from a single-dose container after administering a dose to a Medicare beneficiary, the program provides payment for the discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. The discarded amount is any amount that is not part of the prescribed dose and not intended to have a therapeutic effect in the patient. Even if certain amounts are extracted from the vial or are required to be in the vial to administer the prescribed dose, we do not consider them to be used if they are not intended for therapeutic effect as part of the prescribed dose. Generally, the discarded amount is the labeled amount on the single-dose container (or containers if more than one is required) minus the dose (the dose being the prescribed amount of drug administered to the patient). Also see question #9, which addresses overfill amounts.

Q4. Why did CMS establish a policy for the JW and JZ modifiers (discarded drug policy)?

A4. Prior to January 1, 2017, the discarded drug policy allowed Medicare Administrative Contractors (MACs) to choose whether to require the JW modifier. MACs also were able to issue jurisdiction-specific instructions for the use of the modifier. Effective January 1, 2017, CMS established a consistent policy among all MAC jurisdictions that required the use of the JW modifier for drugs separately payable under Medicare Part B with discarded amounts from single-dose containers.

Subsequently, section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) (hereafter, the Infrastructure Act) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drugs. This provision specifies that discarded amounts of refundable single-dose container or single-use package drugs are to be determined using a mechanism such as the JW modifier or any successor modifier that includes discarded amount data.

To implement section 90004 of the Infrastructure Act, we finalized the use the JW modifier or any successor modifier that includes the same data to determine the total number of billing units of a billing and payment code (such as a HCPCS code) of a refundable single-dose container or single-use package drug, if any, that were discarded for dates of service during a quarter, and we finalized that the JW

modifier identify discarded billing units of a billing and payment code for the purpose of calculating the refund amount as described in section 1847A(h)(3) of the Act.

Because of observed low compliance with JW modifier use (leading to incomplete JW modifier data)¹ and because the discarded drug refund amounts rely on this data, we established that a separate modifier, the JZ modifier, will be required on claims for single-dose container drugs to attest when there are no discarded amounts no later than July 1, 2023.

Q5. Are the JW and JZ modifiers required on claims that bill for single-dose container drugs?

A5. Effective January 1, 2017, the JW modifier must be used to report discarded amounts of a single-dose container drug in order to obtain payment for a discarded amount of drug from single dose or single use packaging.

No later than July 1, 2023, the JZ modifier is required to attest that there were no discarded amounts and no JW modifier amount is reported. (Overfill is discussed in question #9). Starting October 1, 2023, claims for drugs from single-dose containers that do not use the modifiers as appropriate may be returned as un-processable until claims are properly resubmitted.

Q6. In which settings is a billing provider required to use either the JW or JZ modifier?

A6. The JW and JZ modifier policy applies to all providers and suppliers who buy and bill separately payable drugs under Medicare Part B. The JW and JZ modifiers are mostly reported on claims from the physician's office and hospital outpatient settings for beneficiaries who receive drugs incident to physicians' services. The JW and JZ modifier requirements also apply to Critical Access Hospitals (CAHs), since drugs are separately payable in the CAH setting.

The modifiers also may apply to some drugs furnished by suppliers such as pharmacies. However, we believe that those suppliers would likely not have discarded amounts to report on claims. Suppliers who dispense drugs and do not actually administer the drug, or who sell partial vials of sterile products, are not expected to report discarded amounts on claims, as the claim is typically submitted prior to the administration of the drug, and the billing provider is not at the site of administration to measure discarded amounts. Therefore, beginning January 1, 2024, suppliers who dispense but do not actually administer single-dose container drugs that are separately payable under Part B are required to report the JZ modifier on the claim as described in the answer to question #15. Suppliers must report the JZ modifier in these cases to ensure claims can be appropriately processed.

The JW and JZ modifier requirements apply in the case of single-dose drugs administered in an ESRD facility that are not renal dialysis service drugs or biological products provided for the treatment of ESRD. Non-renal dialysis service drugs and biological products are reported on ESRD facility claims with the AY modifier. In such cases, the billing provider should report the AY modifier on a single claim line along with the JZ modifier, or, when there are discarded amounts, on the two claim lines used for the drug (in accordance with billing procedure described in the answer to question #14).

The JW and JZ modifiers do not apply to drugs administered in a Rural Health Clinic (RHC) or a Federally Qualified Health Center (FQHC). Drugs administered in RHCs and FQHCs are generally not separately payable under Part B. Instead, their payment is included in the RHC's all-inclusive rate or the FQHC's prospective payment system rate for the patient's visit.

¹ National Academies of Sciences, Engineering, and Medicine. 2021. Medications in single-dose vials: Implications of discarded drugs. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25911>.

The JW and JZ modifiers are not intended for use on claims for hospital inpatient admissions that are billed under the Inpatient Prospective Payment System. (See question #23 for additional information).

Q7. To which drugs does the policy apply? How can a provider or supplier identify a drug that must be billed using the JW or JZ modifier?

A7. In general, the JW and JZ modifier policy applies to all drugs separately payable under Medicare Part B that are described as being supplied in a “single-dose” container or “single-use” package based on FDA-approved labeling. The use of these modifiers is not appropriate for drugs that are from multipledose containers.

Even if a drug is excluded from the definition of “refundable single-dose container or single-use package drug” (and not subject to the discarded drug refund), for example, multiple source drugs, claims for such drugs furnished from a single-dose container are still required to use the JW and JZ modifiers.

Generally, in the physician office, all drugs paid incident to a physician service are separately payable under Medicare Part B. Therefore, in general, all such drugs that are described as being supplied in a “single-dose” container or “single-use” package are subject to the JW and JZ modifier in the physician office.

In the hospital outpatient department and the Ambulatory Surgical Center (ASC), only the separately payable drugs are subject to the JW and JZ modifier requirement. Please see below under “Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System.”

The JW and JZ modifiers apply to separately payable single-dose drugs administered in the ESRD setting that are not renal dialysis service drugs or biological products provided for the treatment of ESRD. Either the JW or JZ modifier is reported in conjunction with the AY modifier.

The JW and JZ modifier policy does not apply for drugs that are not separately payable, such as packaged OPPS or ASC drugs, or drugs administered in the FQHC or RHC setting.

The JW and JZ modifiers are not required for vaccines described under section 1861(s)(10) of the Act that are furnished from single-dose containers. Since the influenza, pneumococcal, and COVID-19 vaccines, specified in section 1861(s)(10) of the Act, are often roster billed by mass immunizers, and roster billing cannot accommodate modifiers, it would be impractical to require the JW and JZ modifiers for such vaccines. Such a requirement would likely result in substantial operational issues for mass immunizers and impair patient access to these vaccines.

Q8. Which billing and payment codes must be billed using the JW or JZ modifier?

A8. JW or JZ modifiers are required for all billing and payment codes that identify a drug described in FAQ 7. To assist providers and suppliers with identifying codes that must be billed using the JW or JZ modifier, we identified specific billing and payment codes to which only single-dose containers are assigned, and thus may require use of the JW or JZ modifiers depending on the setting of use (see FAQ 7 and FAQs 18 through 22). The identified codes should not be considered an all-inclusive list of codes that are subject to the JW and JZ modifier policy. The list is available on the ASP Billing Resources website and will be updated approximately semi-annually with newly identified codes.

As stated in FAQ7, even if a drug is excluded from the definition of “refundable single-dose container or single-use package drug” (and not subject to the discarded drug refund), claims for such drugs furnished from a single-dose container are still required to use the JW and JZ modifiers even if it is not identified on the list.

Generally, for physician office claims all billing and payment codes on the list are subject to the JW and JZ modifier policy.

See FAQs 18 through 22 for specific additional requirements for JW and JZ modifier for single-dose drugs administered in a hospital outpatient department and ambulatory surgical center settings. For OPSS and ASC payment system claims, the JW and JZ modifier policy applies to codes on this list if they also meet conditions described in such FAQs.

See FAQ 7 for specific additional requirements for JW and JZ single-dose drugs administered in an ESRD facility that are not renal dialysis service drugs or biological products provided for the treatment of ESRD. For ESRD prospective payment system, the JW and JZ modifier policy applies to codes on this list if they also meet conditions described in these FAQs.

Q9. Does the JW modifier apply to drug overfill?

A9. The JW modifier must not be used to report discarded amounts of overfill. Since January 1, 2011, CMS regulations have expressly prohibiting billing for overfill, which is any amount of drug greater than the amount identified on the package or label. Additional information on the overfill policy is available in the Physician Fee Schedule Final Rule published in the November 29, 2010 Federal Register (75 FR 73466-70), which is available at <https://www.federalregister.gov/documents/2010/11/29/2010-27969/medicare-program-payment-policies-under-the-physician-fee-schedule-and-other-revisions-to-partb-for>.

Q10. Is the JW modifier applicable when the dose administered is less than the billing unit?

A10. CMS does not use fractional billing units. Therefore, the JW modifier should not be used when the dose of the drug administered is less than the billing unit. In this situation, the billing provider or supplier would report administering the full billing unit along with the JZ modifier.

Q11. Does a provider or supplier have the option to bill using the JZ modifier now or should they wait until July 1, 2023?

A11. Providers and suppliers may report the JZ modifier prior to July 1, 2023. It is available for use beginning January 1, 2023.

Q12. What happens if a provider or supplier does not use the JW or JZ modifier on claims for drugs provided in single-dose containers?

A12. Claims that bill for drugs with discarded amounts furnished on or after January 1, 2017 through June 30, 2023 that do not use the JW modifier correctly may be subject to review. Claims that bill for drugs furnished on or after July 1, 2023 that do not report the JW or JZ modifier may be subject to provider audits. Claims that do not report the modifiers as appropriate on or after October 1, 2023 may be returned as unprocessable until claims are properly resubmitted.

Q13. Do the JW and JZ modifier requirements apply to single-dose container drugs that are billed using a Not Otherwise Classified (NOC) code?

A13. Although NOC codes do not specifically identify a drug, for consistency with the policy, the JW and JZ modifiers are required to be reported for drugs from single-use containers billed with a NOC code in the physician office. This requirement does not apply to C9399, which has a status indicator of A (see FAQ #18 through 22).

Please see FAQ #10 for modifier use when the dose is less than the billing unit.

Billing, Claims, and Documentation

Q14. What is the appropriate way for providers and suppliers to bill for single-dose container drug with discarded amounts using the JW modifier on claims?

A14. When a provider or supplier administers a separately payable drug under Medicare Part B from a single-dose container and there are discarded amounts, the provider or supplier must file a claim with two lines for the drug.

For the administered amount, one claim line must include the billing and payment code (such as a HCPCS code) describing the given drug, no modifier, and the number of units administered in the units field. For the discarded amount, a second claim line must include the same billing and payment code as used for the administered amount, the JW modifier, and the number of units discarded in the units field.

For example, if a provider or supplier uses a single-dose container that is labeled to contain 100 units of a drug to administer 95 units to the patient and 5 units are discarded. The 95-unit dose is billed on one line, while the discarded 5 units must be billed on another line with the JW modifier. Both line items would be processed for payment.

This manner of billing two claims lines when there are discarded amounts applies even if more than one vial is used for the preparation of the dose. For example, if two vials labeled as containing 50 mg are used to prepare a prescribed dose of 80 mg of a drug (assuming that each billing unit is 1 mg), the claim should be billed on two lines: the first line should include the billing and payment code, no modifier, and 80 billing units and the second line should include the billing and payment code, the JW modifier, and 20 billing units.

Q15: What is the appropriate way for providers and suppliers to bill for single-dose container drugs with no discarded amounts using the JZ modifier on claims?

A15: When a billing provider or supplier administers a separately payable drug under Medicare Part B from a single-dose container and there are no discarded amounts, the provider or supplier must file a claim with one line for the drug.

For the administered amount, the claim line should include the billing and payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the units field.

This manner of billing when there are no discarded amounts applies even if more than one vial is used for the preparation of the dose. For example, if two vials labeled as containing 50 mg are used to prepare a prescribed dose of 100 mg of a drug (assuming that each billing unit is 1 mg), the claim should be billed as 100 billing (on one line) along with the JZ modifier.

Q16. Does CMS have specific requirements regarding documentation for discarded amounts of drugs, such as who is required to document the amount that is discarded, the format for whether

calculated values are acceptable, or where the documentation should be stored? Is there a specific area in the medical record where the administered/discarded amounts should be documented?

A16. Other than the expectation that providers and suppliers will maintain accurate (medical and/or dispensing) records for all beneficiaries as well as accurate purchasing and inventory records for all drugs that were purchased and billed to Medicare², CMS has no specific requirements regarding the method, format, the medical staff responsible for making the record, or location of discarded amount data in a patient's medical record. Providers and suppliers should also check with the MAC that processes their Part B drug claims in case additional information on billing and documentation is available at the local level.

Q17. Will CMS accept an “automatic” calculation of discarded amounts, for example, a calculation done by software, as documentation of discarded amounts within the medical record?

A17. As long as the discarded amount is accurately documented, CMS does not dictate how it is calculated.

Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System

Q18. When billing for services furnished in the hospital outpatient setting, do the JW and JZ modifiers apply to all Part B claims, including Part B inpatient (Type of Bill 12X)? Are eligible and participating 340B providers exempt from the JW and JZ modifier reporting?

A18. The JW and JZ modifier requirement applies to all separately payable drugs from single-dose containers assigned status indicators “G” (Pass-Through Drugs and Biologicals) or “K” (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) under the OPPS for which there is a discarded amount.

The JW and JZ modifier requirement applies to all separately payable drugs from single-dose containers assigned payment indicator “K2” (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) in the ASC for which there is a discarded amount.

340B covered entities are not exempt from reporting the JW and JZ modifiers.

Q19. Are hospitals required to report the JW and JZ modifiers only when the applicable drug is billed with revenue code 636?

A19. The requirements for using the JW and JZ modifiers are independent of revenue codes reporting. Providers should always use the most appropriate revenue code that applies to the service they are reporting.

Q20. Do the JW and JZ modifiers apply to drugs administered in the hospital outpatient department?

A20. The JW and JZ modifier requirements apply to all separately payable drugs from single-dose containers with status indicators “G” (Pass-Through Drugs and Biologicals) or “K” (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) under the OPPS for which there is a discarded amount.

² General guidance on documentation is available in MLN Matters SE 1316 (<https://www.hhs.gov/guidance/sites/default/files/hhs-guidancedocuments/SE1316.pdf>).

Q21. Do the JW and JZ modifiers apply to drugs administered in the ASC setting?

A21. The JW and JZ modifier requirement applies to all separately payable drugs from single-dose containers assigned payment indicator “K2” (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) under the ASC payment system for which there is a discarded amount.

Q22. Do the JW and JZ modifiers apply to OPPS drugs with status indicator “N” and ASC payment system drugs with payment indicator “N1”?

A22. No. The JW and JZ modifiers do not apply to drugs assigned status indicator N (Items and Services Packaged into APC Rates) under the OPPS. Similarly, the JW and JZ modifiers do not apply to drugs assigned payment indicator “N1” (Packaged service/item; no separate payment made) under the ASC payment system. See question #7 for additional information.

Q23. Are hospitals required to transfer the charges related to discarded amounts that the patient incurred when he/she was seen the day before being admitted (3-day or 1-day payment rule) to the inpatient claim?

A23. In circumstances where the 3-day/1-day payment window applies, all hospital outpatient services (and associated charges), including drugs, furnished to a beneficiary during the 3 days/1 day prior to the beneficiary’s inpatient admission are treated as inpatient services and must be included on the claim for the inpatient admission. Since drugs are not separately payable under Part B under the Inpatient Prospective Payment System (IPPS), the JW and JZ modifiers are not required in that situation.

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Medicare Program
Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy
HCPCS Codes

The billing and payment codes (Healthcare Common Procedure Coding System (HCPCS) codes) that have been identified as having only single-dose containers assigned to the code. Therefore, the JW and JZ modifier policy may apply depending on the setting of use. The list is not an all-inclusive list of codes that are subject to the modifier policy and will be updated approximately semi-annually with newly identified codes.

The current list of codes is comprised of all codes with reported discarded amounts based on the JW modifier in the calendar year 2022. Codes with 1 or more multiple-use containers assigned to it are excluded from the list. The range of percentage of discarded amounts from this list for the calendar year 2022 range from 0.2 – 68.5%.

For more information, see the JW Modifier and JZ Modifier Policy FAQ at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>.

HCPCS Code	Descriptor
J0122	Inj., eravacycline, 1 mg
J0172	Inj, aducanumab-avwa, 2 mg
J0202	Injection, alemtuzumab
J0222	Inj., patisiran, 0.1 mg
J0223	Inj givosiran 0.5 mg
J0224	Inj. lumasiran, 0.5 mg
J0291	Inj., plazomicin, 5 mg
J0485	Belatacept injection
J0515	Inj benztropine mesylate
J0565	Inj, bezlotoxumab, 10 mg
J0585	Botulinum toxin a per unit
J0594	Busulfan injection
J0641	Levoleucovorin injection
J0775	Collagenase, clost hist inj
J0883	Argatroban nonesrd use 1mg
J0894	Decitabine injection
J1245	Dipyridamole injection
J1305	Inj, evinacumab-dgnb, 5mg
J1448	Injection, trilaciclib, 1mg
J1451	Fomepizole, 15 mg
J1455	Foscarnet sodium injection
J1602	Golimumab for iv use 1mg
J2186	Inj., meropenem, vaborbactam

J2403	Chloroprocaine hcl ophthalmic, 3% gel
J2425	Palifermin injection
J2562	Plerixafor injection
J2779	Inj, susvimo 0.1 mg
J2786	Injection, reslizumab, 1mg
J2792	Rho(d) immune globulin h, sd
J2795	Ropivacaine hcl injection
J2796	Romiplostim injection
J3101	Tenecteplase injection
J3241	Inj. teprotumumab-trbw 10 mg
J3299	Inj xipere 1 mg
J3300	Triamcinolone A inj PRS-free
J3396	Verteporfin injection
J3430	Vitamin k phytonadione inj
J7194	Factor ix complex
J7315	Ophthalmic mitomycin
J7342	Ciprofloxacin otic susp 6 mg
J9017	Arsenic trioxide
J9021	Inj, aspara, rylaze, 0.1 mg
J9025	Azacitidine injection
J9027	Clofarabine injection
J9032	Injection, belinostat, 10mg
J9037	Inj belantamab mafodot blmf
J9041	Inj., velcade 0.1 mg
J9042	Brentuximab vedotin inj
J9043	Cabazitaxel injection
J9046	Inj, bortezomib, dr. reddy's
J9048	Inj, bortezomib freseniuskab
J9049	Inj, bortezomib, hospira
J9065	Inj cladribine per 1 mg
J9153	Inj daunorubicin, cytarabine
J9178	Inj, epirubicin hcl, 2 mg
J9179	Eribulin mesylate injection
J9203	Gemtuzumab ozogamicin 0.1 mg
J9205	Inj irinotecan liposome 1 mg
J9207	Ixabepilone injection
J9223	Inj. lurbinectedin, 0.1 mg
J9228	Ipilimumab injection
J9229	Inj inotuzumab ozogam 0.1 mg
J9262	Inj, omacetaxine mep, 0.01mg
J9263	Oxaliplatin
J9264	Paclitaxel protein bound
J9269	Inj. tagraxofusp-erzs 10 mcg

J9273	Inj tisotu vedotin-tftv, 1mg
J9274	Inj, tebentafusp-tebn, 1 mcg
J9281	Mitomycin instillation
J9307	Pralatrexate injection
J9309	Inj, polatuzumab vedotin 1mg
J9313	Inj., lumoxiti, 0.01 mg
J9317	Sacituzumab govitecan-hziy
J9318	Inj romidepsin non-lyo 0.1mg
J9319	Inj romidepsin lyophil 0.1mg
J9328	Temozolomide injection
J9330	Temsirolimus injection
J9331	Inj sirolimus prot part 1 mg
J9332	Inj efgartigimod 2mg
J9352	Injection trabectedin 0.1mg
J9355	Trastuzumab
J9358	Inj fam-trastu deru-nxki 1mg
J9359	Loncastuximab-lpyl, 0.1 mg
J9359	Inj lon tesirin-lpyl 0.075mg
J9371	Inj, vincristine sul lip 1mg
J9400	Inj, ziv-aflibercept, 1mg

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Pass-through Radiopharmaceuticals, Skin Substiutes, Contrasts, and Stress Agents
(DATA_HCPCS, Columns CO, CP, CQ, CR)

HCPCS	DESCRIPTION	PASS THROUGH RADIO PHARM	PASS THROUGH SKIN PRODUCT	PASS THROUGH CONTRAST	PASS THROUGH STRESS AGENT	LO_ VERS	HI_ VERS
A9593	Gallium ga-68 psma-11 ucsf	1	0	0	0	84	94
A9594	Gallium ga-68 psma-11, ucla	1	0	0	0	84	94
A9595	Piflu f-18, dia 1 millicurie	1	0	0	0	86	94
A9596	Gallium illuccix 1 millicure	1	0	0	0	88	94
A9601	Flortaucipir inj 1 millicuri	1	0	0	0	94	94
A9602	Fluorodopa f-18 diag per mci	1	0	0	0	89	94
A9608	Flotufolastat f18 diag 1 mci	1	0	0	0	94	94
A9800	Gallium locametz 1 millicuri	1	0	0	0	89	94

There are no pass-through skin substitute products, contrasts, or stress agents for January 2024

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Offset Amounts for Pass-through Radiopharmaceuticals, Skin Substitutes, Contrasts, and Stress Agents
(OFFSET_APC)

APC		AMOUNT	LO_VERSION	HI_VERSION
05591	Radiopharmaceutical	\$60.39	94	94
05592	Radiopharmaceutical	\$115.61	94	94
05593	Radiopharmaceutical	\$364.06	94	94
05594	Radiopharmaceutical	\$245.90	94	94
05054	Skin Substitute	\$770.44	94	94
05055	Skin Substitute	\$442.34	94	94
05571	Contrast	\$39.30	94	94
05572	Contrast	\$63.99	94	94
05573	Contrast	\$124.83	94	94
05593	Stress Agent	\$364.06	94	94
05722	Stress Agent	\$4.30	94	94

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High and Low Cost Skin Substitutes and Skin Substitute Procedures

(DATA_HCPCS, Columns BU, BV, BW, and BX)

HCPCS	DESCRIPTION	SKIN	SKIN	SKIN	SKIN	LO_	HI_
		SUBST	SUBST	SUBST	SUBST		
		PROC	PROC	PROC	PROC	VERS	VERS
		LOW	LOW	LOW	LOW		
C5271	Low cost skin substitute app	1	0	0	0	67	94
C5272	Low cost skin substitute app	1	0	0	0	67	94
C5273	Low cost skin substitute app	1	0	0	0	67	94
C5274	Low cost skin substitute app	1	0	0	0	67	94
C5275	Low cost skin substitute app	1	0	0	0	67	94
C5276	Low cost skin substitute app	1	0	0	0	67	94
C5277	Low cost skin substitute app	1	0	0	0	67	94
C5278	Low cost skin substitute app	1	0	0	0	67	94
A4100	Skin sub fda clrd as dev nos	0	1	0	0	87	94
Q4100	Skin substitute, nos	0	1	0	0	67	94
Q4102	Oasis wound matrix	0	1	0	0	67	94
Q4111	Gammagraft	0	1	0	0	67	94
Q4115	Alloskin	0	1	0	0	67	94
Q4117	Hyalomatrix	0	1	0	0	67	94
Q4124	Oasis tri-layer wound matrix	0	1	0	0	67	94
Q4136	Ezderm	0	1	0	0	67	94
Q4165	Keramatrix, kerasorb sq cm	0	1	0	0	77	94
Q4166	Cytal, per square centimeter	0	1	0	0	67	94
Q4204	Xwrap 1 sq cm	0	1	0	0	74	94
Q4214	Cellesta cord per sq cm	0	1	0	0	77	94
Q4216	Artacent cord per sq cm	0	1	0	0	77	94
Q4220	Bellacell hd, surederm sq cm	0	1	0	0	77	94
Q4224	Hhf10-p per sq cm	0	1	0	0	87	94
Q4225	Amnio or derma tl, per sq cm	0	1	0	0	94	94
Q4236	Carepatch per sq cm	0	1	0	0	90	94
Q4247	Amniotext patch, per sq cm	0	1	0	0	80	94
Q4251	Vim, per square centimeter	0	1	0	0	85	94
Q4252	Vendaje, per square centimet	0	1	0	0	85	94
Q4255	Reguard, topical use per sq	0	1	0	0	81	94
Q4256	Mlg complet, per sq cm	0	1	0	0	87	94
Q4257	Relese, per sq cm	0	1	0	0	87	94
Q4259	Celera per sq cm	0	1	0	0	88	94
Q4260	Signature apatch, per sq cm	0	1	0	0	88	94
Q4261	Tag, per square centimeter	0	1	0	0	88	94
Q4262	Dual layer impax, per sq cm	0	1	0	0	90	94
Q4263	Surgraft tl, per sq cm	0	1	0	0	90	94
Q4264	Cocoon membrane, per sq cm	0	1	0	0	90	94
Q4265	Neostim tl per sq cm	0	1	0	0	91	94

High and Low Cost Skin Substitutes and Skin Substitute Procedures
(DATA_HCPCS, Columns BU, BV, BW, and BX)

HCPCS	DESCRIPTION	SKIN	SKIN	SKIN	SKIN	LO_	HI_
		SUBST	SUBST	SUBST	SUBST		
		PROC	PROC	PROC	PROC	VERS	VERS
		LOW	LOW	LOW	LOW		
Q4266	Neostim per sq cm	0	1	0	0	91	94
Q4267	Neostim dl per sq cm	0	1	0	0	91	94
Q4268	Surgraft ft per sq cm	0	1	0	0	91	94
Q4269	Surgraft xt per sq cm	0	1	0	0	91	94
Q4270	Complete sl per sq cm	0	1	0	0	91	94
Q4271	Complete ft per sq cm	0	1	0	0	91	94
Q4272	Esano a, per sq cm	0	1	0	0	92	94
Q4273	Esano aaa, per sq cm	0	1	0	0	92	94
Q4274	Esano ac, per sq cm	0	1	0	0	92	94
Q4275	Esano aca, per sq cm	0	1	0	0	92	94
Q4276	Orion, per sq cm	0	1	0	0	92	94
Q4277	Woundplus e-grat, per sq cm	0	1	0	0	92	94
Q4279	Vendaje ac, per sq cm	0	1	0	0	94	94
Q4280	Xcell amnio matrix per sq cm	0	1	0	0	92	94
Q4281	Barrera slor dl per sq cm	0	1	0	0	92	94
Q4283	Biovance tri or 3l, sq cm	0	1	0	0	92	94
Q4284	Dermabind sl, per sq cm	0	1	0	0	92	94
Q4285	Nudyn dl or dl mesh pr sq cm	0	1	0	0	93	94
Q4286	Nudyn sl or slw, per sq cm	0	1	0	0	93	94
Q4287	Dermabind dl, per sq cm	0	1	0	0	94	94
Q4288	Dermabind ch, per sq cm	0	1	0	0	94	94
Q4289	Revoshield+ amnio, per sq cm	0	1	0	0	94	94
Q4290	Membrane wrap hydr per sq cm	0	1	0	0	94	94
Q4291	Lamellas xt, per sq cm	0	1	0	0	94	94
Q4292	Lamellas, per sq cm	0	1	0	0	94	94
Q4293	Acesso dl, per sq cm	0	1	0	0	94	94
Q4294	Amnio quad-core, per sq cm	0	1	0	0	94	94
Q4295	Amnio tri-core, per sq cm	0	1	0	0	94	94
Q4296	Rebound matrix, per sq cm	0	1	0	0	94	94
Q4297	Emerge matrix, per sq cm	0	1	0	0	94	94
Q4298	Amnicore pro, per sq cm	0	1	0	0	94	94
Q4299	Amnicore pro+, per sq cm	0	1	0	0	94	94
Q4300	Acesso tl, per sq cm	0	1	0	0	94	94
Q4301	Activate matrix, per sq cm	0	1	0	0	94	94
Q4302	Complete aca, per sq cm	0	1	0	0	94	94
Q4303	Complete aa, per sq cm	0	1	0	0	94	94
Q4304	Grafix plus, per sq cm	0	1	0	0	94	94
15271	Skin sub graft trnk/arm/leg	0	0	1	0	67	94

January 2024 IOCE Quarterly Data Files
 High and Low Cost Skin Substitutes and Skin Substitute Procedures
 (DATA_HCPCS, Columns BU, BV, BW, and BX)

HCPCS	DESCRIPTION	SKIN	SKIN	SKIN	LO_	HI_	
		SUBST	SUBST	SUBST			
		PROC	PROC	PROC	VERS	VERS	
		LOW	LOW	LOW			
15272	Skin sub graft t/a/l add-on	0	0	1	0	67	94
15273	Skin sub grft t/arm/lg child	0	0	1	0	67	94
15274	Skn sub grft t/a/l child add	0	0	1	0	67	94
15275	Skin sub graft face/nk/hf/g	0	0	1	0	67	94
15276	Skin sub graft f/n/hf/g addl	0	0	1	0	67	94
15277	Skn sub grft f/n/hf/g child	0	0	1	0	67	94
15278	Skn sub grft f/n/hf/g ch add	0	0	1	0	67	94
A2001	Innovamatrix ac, per sq cm	0	0	0	1	87	94
A2002	Mirragen adv wnd mat per sq	0	0	0	1	88	94
A2005	Microlyte matrix, per sq cm	0	0	0	1	90	94
A2006	Novosorb synpath per sq cm	0	0	0	1	90	94
A2007	Restrata, per sq cm	0	0	0	1	87	94
A2008	Theragenesis, per sq cm	0	0	0	1	90	94
A2009	Symphony, per sq cm	0	0	0	1	90	94
A2010	Apis, per square centimeter	0	0	0	1	90	94
A2011	Supra sdrm, per sq cm	0	0	0	1	90	94
A2012	Suprathel, per sq cm	0	0	0	1	90	94
A2013	Innovamatrix fs, per sq cm	0	0	0	1	90	94
A2015	Phoenix wnd mtrx, per sq cm	0	0	0	1	90	94
A2016	Permeaderm b, per sq cm	0	0	0	1	90	94
A2017	Permeaderm glove, each	0	0	0	1	90	94
A2018	Permeaderm c, per sq cm	0	0	0	1	90	94
A2019	Kerecis marigen shld sq cm	0	0	0	1	91	94
A2020	Ac5 wound system	0	0	0	1	91	94
A2021	Neomatrix per sq cm	0	0	0	1	91	94
A2022	Innovabrn/innovamatx xl sqcm	0	0	0	1	93	94
A2024	Resolve matrix per sq cm	0	0	0	1	93	94
A2025	Miro3d per cubic cm	0	0	0	1	94	94
C9363	Integra meshed bil wound mat	0	0	0	1	67	94
Q4101	Apligraf	0	0	0	1	67	94
Q4103	Oasis burn matrix	0	0	0	1	67	94
Q4104	Integra bmwd	0	0	0	1	67	94
Q4105	Integra drt or omnigraft	0	0	0	1	67	94
Q4106	Dermagraft	0	0	0	1	67	94
Q4107	Graftjacket	0	0	0	1	67	94
Q4108	Integra matrix	0	0	0	1	67	94
Q4110	Primatrix	0	0	0	1	67	94
Q4116	Alloderm	0	0	0	1	67	94

High and Low Cost Skin Substitutes and Skin Substitute Procedures

(DATA_HCPCS, Columns BU, BV, BW, and BX)

HCPCS	DESCRIPTION	SKIN	SKIN	SKIN	SKIN	LO_	HI_
		SUBST	SUBST	SUBST	SUBST		
		PROC	PROC	PROC	PROC	VERS	VERS
		LOW	LOW	LOW	LOW		
Q4121	Theraskin	0	0	0	1	67	94
Q4122	Dermacell, awm, porous sq cm	0	0	0	1	77	94
Q4123	Alloskin	0	0	0	1	67	94
Q4126	Memoderm/derma/tranz/integup	0	0	0	1	67	94
Q4127	Talymed	0	0	0	1	67	94
Q4128	Flexhd/allopatchhd/sq cm	0	0	0	1	89	94
Q4132	Grafix core, grafixpl core	0	0	0	1	70	94
Q4133	Grafix stravix prime pl sqcm	0	0	0	1	74	94
Q4134	Hmatrix	0	0	0	1	90	94
Q4135	Mediskin	0	0	0	1	94	94
Q4137	Amnioexcel biodexcel 1sq cm	0	0	0	1	74	94
Q4138	Biodfence dryflex, 1cm	0	0	0	1	67	94
Q4140	Biodfence 1cm	0	0	0	1	67	94
Q4141	Alloskin ac, 1 cm	0	0	0	1	67	94
Q4143	Repriza, 1cm	0	0	0	1	67	94
Q4146	Tensix, 1cm	0	0	0	1	67	94
Q4147	Architect ecm px fx 1 sq cm	0	0	0	1	67	94
Q4148	Neox neox rt or clarix cord	0	0	0	1	70	94
Q4150	Allowrap ds or dry 1 sq cm	0	0	0	1	67	94
Q4151	Amnioband, guardian 1 sq cm	0	0	0	1	67	94
Q4152	Dermapure 1 square cm	0	0	0	1	67	94
Q4153	Dermavest, plurivest sq cm	0	0	0	1	67	94
Q4154	Biovance 1 square cm	0	0	0	1	67	94
Q4156	Neox 100 or clarix 100	0	0	0	1	70	94
Q4157	Revitalon 1 square cm	0	0	0	1	67	94
Q4158	Kerecis omega3, per sq cm	0	0	0	1	70	94
Q4159	Affinity1 square cm	0	0	0	1	67	94
Q4160	Nushield 1 square cm	0	0	0	1	67	94
Q4161	Bio-connekt per square cm	0	0	0	1	67	94
Q4163	Woundex, bioskin, per sq cm	0	0	0	1	70	94
Q4164	Helicoll, per square cm	0	0	0	1	67	94
Q4167	Truskin, per sq centimeter	0	0	0	1	82	94
Q4169	Artacent wound, per sq cm	0	0	0	1	67	94
Q4170	Cygnus, per sq cm	0	0	0	1	90	94
Q4173	Palingen or palingen xplus	0	0	0	1	67	94
Q4175	Miroderm	0	0	0	1	67	94
Q4176	Neopatch or therion, 1 sq cm	0	0	0	1	80	94
Q4178	Floweramniopatch, per sq cm	0	0	0	1	72	94

High and Low Cost Skin Substitutes and Skin Substitute Procedures

(DATA_HCPCS, Columns BU, BV, BW, and BX)

HCPCS	DESCRIPTION	SKIN	SKIN	SKIN	SKIN	LO_	HI_
		SUBST	SUBST	SUBST	SUBST		
		PROC	PROC	PROC	PROC	VERS	VERS
		LOW	LOW	LOW	LOW		
Q4179	Flowerderm, per sq cm	0	0	0	1	78	94
Q4180	Revita, per sq cm	0	0	0	1	71	94
Q4181	Amnio wound, per square cm	0	0	0	1	73	94
Q4182	Transcyte, per sq centimeter	0	0	0	1	82	94
Q4183	Surgigraft, 1 sq cm	0	0	0	1	75	94
Q4184	Cellesta or duo per sq cm	0	0	0	1	77	94
Q4186	Epifix 1 sq cm	0	0	0	1	74	94
Q4187	Epicord 1 sq cm	0	0	0	1	74	94
Q4188	Amnioarmor 1 sq cm	0	0	0	1	82	94
Q4190	Artacent ac 1 sq cm	0	0	0	1	82	94
Q4191	Restorigin 1 sq cm	0	0	0	1	90	94
Q4193	Coll-e-derm 1 sq cm	0	0	0	1	82	94
Q4194	Novachor 1 sq cm	0	0	0	1	75	94
Q4195	Puraply 1 sq cm	0	0	0	1	81	94
Q4196	Puraply am 1 sq cm	0	0	0	1	81	94
Q4197	Puraply xt 1 sq cm	0	0	0	1	74	94
Q4198	Genesis amnio membrane 1sqcm	0	0	0	1	82	94
Q4199	Cygnus matrix, per sq cm	0	0	0	1	87	94
Q4200	Skin te 1 sq cm	0	0	0	1	82	94
Q4201	Matrion 1 sq cm	0	0	0	1	84	94
Q4203	Derma-gide, 1 sq cm	0	0	0	1	75	94
Q4205	Membrane graft or wrap sq cm	0	0	0	1	81	94
Q4208	Novafix per sq cm	0	0	0	1	78	94
Q4209	Surgraft per sq cm	0	0	0	1	82	94
Q4210	Axolotl graf dualgraf sq cm	0	0	0	1	90	94
Q4211	Amnion bio or axobio sq cm	0	0	0	1	82	94
Q4217	Woundfix biowound plus xplus	0	0	0	1	90	94
Q4218	Surgicord per sq cm	0	0	0	1	94	94
Q4219	Surgigraft dual per sq cm	0	0	0	1	82	94
Q4221	Amniowrap2 per sq cm	0	0	0	1	94	94
Q4222	Progenamatrix, per sq cm	0	0	0	1	82	94
Q4226	Myown harv prep proc sq cm	0	0	0	1	81	94
Q4227	Amniocore per sq cm	0	0	0	1	82	94
Q4229	Cogenex amnio memb per sq cm	0	0	0	1	88	94
Q4232	Corplex, per sq cm	0	0	0	1	82	94
Q4234	Xcellerate, per sq cm	0	0	0	1	81	94
Q4235	Amniorepair or altiplay sq cm	0	0	0	1	90	94
Q4237	Cryo-cord, per sq cm	0	0	0	1	82	94

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 High and Low Cost Skin Substitutes and Skin Substitute Procedures
 (DATA_HCPCS, Columns BU, BV, BW, and BX)

HCPCS	DESCRIPTION	SKIN	SKIN	SKIN	SKIN	LO_ VERS	HI_ VERS
		SUBST PROC LOW	SUBST SUBST LOW	SUBST PROC LOW	SUBST SUBST LOW		
Q4238	Derm-maxx, per sq cm	0	0	0	1	82	94
Q4239	Amnio-maxx or lite per sq cm	0	0	0	1	82	94
Q4248	Dermacyte amn mem allo sq cm	0	0	0	1	90	94
Q4249	Amniply, per sq cm	0	0	0	1	82	94
Q4250	Amnioamp-mp per sq cm	0	0	0	1	94	94
Q4253	Zenith amniotic membrane psc	0	0	0	1	94	94
Q4254	Novafix dl per sq cm	0	0	0	1	90	94
Q4258	Enverse, per sq cm	0	0	0	1	88	94
Q4278	Epieffect, per sq cm	0	0	0	1	94	94
Q4282	Cygnus dual per sq cm	0	0	0	1	93	94

Version 01/29/2024
 Check for Updates