

## Discarded Drugs and Biologicals Policy, Professional

### **IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY**

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage reimbursement policies use Current Procedural Terminology (CPT®\*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms. Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design, and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's Medicare Advantage reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare Medicare Advantage may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare Medicare Advantage enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents\*\*. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare Medicare Advantage due to programming or other constraints; however, UnitedHealthcare Medicare Advantage strives to minimize these variations.

UnitedHealthcare Medicare Advantage may modify this reimbursement policy at any time to comply with changes in CMS policy and other national standard coding guidelines by publishing a new version of the reimbursement policy on this website. However, the information presented in this reimbursement policy is accurate and current as of the date of publication. UnitedHealthcare Medicare Advantage encourages physicians and other health care professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other health care professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. UnitedHealthcare's Medicare Advantage reimbursement policies do not include notations regarding prior authorization requirements.

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*\*\* For more information on a specific enrollee's benefit coverage, please call the customer service number on the back of the member ID card.*

### Application

This reimbursement policy applies to all Medicare Advantage products and for services reported using the 1500 Health Insurance Claim Form (a/k/a CMS 1500) or its electronic equivalent or its successor form. This policy applies to all network physicians and other qualified health care professionals.

### Policy

#### Overview

The Discarded Drugs and Biologicals policy addresses reimbursement guidelines for appropriately reporting wasted drugs and biologicals administered from single use vials, single use packages, and multi-use vials. Physicians and other providers may be reimbursed for discarded drugs and biologicals if appropriately reported based on the policy reimbursement guidelines.

**Reimbursement Guidelines****Drugs and Biologicals**

United Healthcare Medicare Advantage provides limited benefits for outpatient drugs. United Healthcare Medicare Advantage 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; They are of the type that are not usually self-administered. They meet all the general requirements for coverage of items as incident to a physician's services; 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; They are not excluded as noncovered immunizations; and They have not been determined by the FDA to be less than effective. United Healthcare Medicare Advantage 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.

**Discarded Drugs and Biologicals**

CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. However, if a physician, hospital or other provider must discard the remainder of a **single use vial or other single use package** after administering a dose/quantity of the drug or biological to a United Healthcare Medicare Advantage patient, payment may be made for the amount of drug or biological discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label. Medical record documentation must clearly indicate the amount of drug administered and the amount wasted. When billing drugs, units of service must be billed in multiples of the dosage specified in the full HCPCS descriptor. This descriptor does not always match the dose given. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient. The following examples will help illustrate some of these points:

**Example of choice of vial size**

HCPCS for drug A indicates 1 unit = 30 mg.

Drug A doses available from the manufacturer: 60 mg vial and 90 mg vial.

The amount prescribed for the patient is 48 mg. If the provider uses a 90 mg vial to administer the dose, the provider may only bill 2 units (rather than 3 units) as the doses available from the manufacturer allow the prescribed amount to be administered with a 60 mg vial.

Additionally, if after administering the prescribed dosage of any given drug, the provider must discard the remainder of a single-use vial or other package, United Healthcare Medicare Advantage may cover the amount of the drug discarded along with the amount administered.

**Examples of wastage of single use vials:**

Currently, OnabotulinumtoxinA (Botox) is available only in a 100-unit size and has a short shelf life. Often, a patient receives less than a 100-unit dose. Because this is a very expensive drug, physicians are encouraged to schedule patients in such a way that they can use Botox most efficiently. HCPCS code J0585 is defined as per unit.

The physician schedules three United Healthcare Medicare Advantage patients to receive Botox on the same day and administers thirty (30) units to each patient. The remaining ten (10) units are billed to United Healthcare Medicare Advantage on the account of the last patient. Therefore, thirty (30) units are billed on behalf of the first two patients. Forty (40) units are billed on behalf of the last patient seen because the physician had to discard ten (10) units at that point due to the limited shelf life of the drug. The first two patients are billed with J0585, thirty (30) units each. The third patient is billed as J0585, forty (40) units on one line. In the record, the documentation for the last patient should indicate thirty (30) units administered to the patient and ten (10) units wasted. If the ten (10) units wasted are not indicated in the medical record, the physician will only be reimbursed for the thirty (30) units administered to the patient.

If a physician must discard the remainder of a vial after administering it to a United Healthcare Medicare Advantage patient, the program covers the amount of drug discarded along with the amount administered. Per CMS, in order for

the wastage to be covered, the left-over amount must be discarded and not used for another patient. The example below would be illustrative of this situation:

**Per Unit Example, Single Patient:**

A physician must administer 15 units of Onabotulinumtoxin A to a United Healthcare Medicare Advantage patient, and it is not practical to schedule another patient who requires this botulinum toxin, as the physician has only one patient who requires botulinum toxin, or the physician sees the patient for the first time and does not know the patient will be receiving the drug upon scheduling. HCPCS code J0585, per unit, is billed for a total of one hundred (100) units. Again, the record must reflect the wastage.

**Example illustrating the billing of wastage when the waste is included in the units reported:**

"If 2.5 milligrams of Zoledronic Acid is administered, it is appropriate to bill for 3 units, as the HCPCS defines the unit for Zoledronic Acid as 1 milligram." In this example, the wastage is already considered reimbursed in the billing of the 3 units. (2.5 mg given and 0.5mg wasted). The entire 3mg expense to the provider is covered with one detail line by billing the J code multiplied by three. The medical record must document the 2.5 mg injected and the 0.5mg of wastage. As a reminder, drug wastage cannot be billed if none of the drug was administered (such as a missed appointment by the patient).

**NOTE: Multi-use vials are not subject to payment for discarded amounts of drug or biological.**

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This information does not take precedence over CCI edits. Please refer to CCI for correct coding guidelines and specific applicable code combinations prior to billing United Healthcare Medicare Advantage.

- If the "J" code descriptor can be multiplied to reflect the dosage being administered, use the J-code, with the appropriate number of units which reflect the dosage given.
- It is not appropriate to use the "J" code with a multiplier in the units' field, when there is another "J" code, which more closely describes the amount given.
- It is not appropriate to bill for the full amount of a drug when it has been split between two or more patients. Bill only for the amount given to each beneficiary.
- NOC codes should only be reported for those drugs that do not have a valid HCPCS code which describes the drug being administered.
- When appropriate, the NOC code is selected based upon the therapeutic value of the drug (e.g., J8999; J3490).
- When billing with an NOC code, include on the claim, the narrative description reflective of the agent and the dose administered.
- Where the sole purpose of an office visit was for the patient to receive an injection, (CPT codes 96372, 96373, 96374, and 96379) payment may be made only for the injection service (if it is covered).
- Conversely, injection services (CPT codes 96372, 96373, 96374, and 96379) included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time.
- The drug is separately payable. All injection claims must include the specific name of the drug and dosage. Identification of the drug enables proper payment for the services.

**JW Modifier**

CMS guidelines state to report the drug amount administered on one line, and on a separate line you may report the amount of drug NOT administered (wasted) with modifier –JW appended to the associated HCPCS code. Modifier –JW is only applicable to the amount of the drug discarded or wasted, and not the amount administered. Further, the amount wasted and identified by the use of modifier –JW, must be at least equal to one billing unit. The use of JW modifier is not permitted when the billing unit is equal to or greater than the total actual dose and the amount discarded.

For example, if the HCPCS code is reportable in 10mg increments and you administered 7mg of a 10mg SDV, report the entire billing unit (1) without a separate line for the amount wasted. If, on the other hand, a HCPCS code is reportable in 10mg increments, and you administered 70mg from a 100mg SDV, you may report 7 bill units as

administered, and on a separate line report 3 bill units with modifier –JW appended to the HCPCS to indicate the drug amount discarded.

Modifier –JW is not permitted to identify discarded amounts from a multi-dose vial (MDV). In order to ensure you do not receive overpayment, remember to always roll the amount administered **UP** to the next bill unit, then roll **ato** the previous bill unit when reporting the amount of drug discarded. For example, if a HCPCS code is reportable in 10mg increments, and you administered 77mg from a 100mg SDV, you may report 8 bill units as administered, and on a separate line report 2 bill units with modifier –JW appended to the HCPCS to indicate the amount discarded.

**JZ Modifier**

Per CMS published new guidance effective July 1, 2023, the JZ modifier to attest that no amount of drug was discarded. The modifier should only be used for claims that bill for single-dose container drugs. Effective with date of service October 1, 2023, UnitedHealthcare Medicare Advantage will align with the CMS requirement for reporting of new modifier JZ to indicate “no waste”.

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 and the number of units administered in the unit’s field.

As always, United Healthcare Medicare Advantage expects the administration of drugs to be scheduled and performed in an efficient manner, minimizing the amount of drug wastage.

**Documentation Information**

Documentation is expected to be maintained in the patient’s medical record and to be available to United Healthcare Medicare Advantage upon request. Every page of the record is expected to be legible and include both the appropriate patient identification information (e.g., complete name dates of service(s)), and information identifying the physician or non-physician practitioner responsible for and providing the care of the patient. The submitted medical record should support the use of the selected diagnosis code(s). The submitted CPT/HCPCS code should describe the service performed. When a portion of the drug is discarded, the medical record is expected to clearly document the amount administered and the amount wasted.

**Definitions**

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| <b>JW Modifier</b> | Drug amount discarded and not administered to any patient      |
| <b>JZ Modifier</b> | Zero drug amount discarded and not administered to any patient |

**Questions and Answers**

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| <b>1</b> | <p><b>Q:</b> How should medications be billed?</p> <p><b>A:</b> Medications should be billed using the correct Revenue Code and/or Healthcare Common Procedure Coding System (HCPCS) codes for the medication that is being administered and the correct number of units should be entered for the dose that is being administered.</p>  |
| <b>2</b> | <p><b>Q:</b> How should a United Healthcare Medicare Advantage provider correctly bill units for drugs?</p> <p><b>A:</b> The provider should be attentive to the long description of the Healthcare Common Procedure Coding System (HCPCS) code. The definition of the HCPCS code specifies the lowest common denominator of the amount of the dosage. Providers should utilize the unit's field as a multiplier to arrive at the dosage amount. For example, J1756 is 1 mg. For a total dosage of 100 mg, the provider will show (100) in the unit’s field.</p> |
| <b>3</b> | <p><b>Q:</b> Can a provider charge for the 'waste' of a medication when they have used a partial vial of a drug and there is not another patient scheduled who could receive the same drug?</p>  |

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|    | <p><b>A:</b> Providers are encouraged to schedule patients in such a way that the provider can use the drug most efficiently. However, if the provider must discard the remainder of a <b>single use vial</b> after administering part of it to a United Healthcare Medicare Advantage patient, the provider may bill for the amount of drug discarded along with the amount administered.</p> <p><b>To clarify</b>, coverage of discarded drugs applies <b>only to single use vials</b>. Multi-use vials are not subject to payment for discarded amounts of drug. An itemized bill or medication administration records should be submitted with the claim to verify how the drug was supplied.</p> |
| 4  | <p><b>Q:</b> What information is needed in the medical record when billing for medications and/or billing for the 'waste'?</p> <p><b>A:</b> It is expected that the medical record will contain the name of the drug, dosage, route of administration, time and date given. When a portion of the drug is discarded, the medical record must clearly document the amount administered and the amount wasted.</p>  |
| 5. | <p><b>Q:</b> What would be the appropriate way for providers and suppliers to bill single dose container drugs with no discarded amount using JZ modifier?</p> <p><b>A:</b> A single dose container and there is no discarded amount the provider must bill the claim with one line of drug with JZ modifier.</p>   |
| 6. | <p><b>Q:</b> What is the manner of billing when there are no discarded amounts when more than one vial is used for the preparation of dose?</p> <p><b>A:</b> if two vials labeled as 100 mg are used to prepare a prescribed dose of 200 mg of a drug (assume each billing unit is 1 mg), the claim should bill as 200 billing units on one line along with the JZ modifier.</p>  |

### Resources

[www.cms.gov](http://www.cms.gov)

American Medical Association (AMA) Current Procedural Terminology (CPT®)

Centers for Medicare and Medicaid Services, PFS Relative Value Files

CMS Article Number: A53049

CMS Transmittal 1283

Medicare Benefit Policy Manual - Chapter 15 - Covered Medical and Other Health Services Section: 50.1, 50.2, 50.3, 50.4, 50.4.4 and 50.4.4.2

Medicare Claims Processing Manual - Chapter 17 - Drugs and Biologicals Section: 40

The Medicare Learning Network (MLN) MLN Matters: MM7095, MM9603

### History

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| 1/1/2024 | <p>Policy Version Change<br/>         Definition Section: Updated<br/>         Logo: Updated<br/>         Modifier Section: JZ Modifier definition added<br/>         Q&amp;A Section: Updated<br/>         History Section: Entries prior to 1/1/2022 archived</p> |
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| 2/1/2023 | Policy Version Change<br>Resource Section: Updated  |
| 2/1/2022 | Policy Version Change<br>Application Section: Updated<br>Resource Section: Updated<br>History Section: Entries prior to 1/1/2020 archived |
| 1/1/2011 | Policy Approved   |