

compliance

Wasted, Discarded, and Unused Drugs

BY CINDY PARMAN, CPC, CPC-H, RCC

While providers performing drug administration make every effort to ensure that all drugs are correctly delivered as required by package insert and state law and in compliance with regulatory guidelines, sometimes it is still necessary to discard the remaining drug amount in a vial or package. Billing for discarded drugs has become one of the new battle fronts in the war to reduce fraud, waste, and abuse. Accordingly, while Medicare and other insurers may reimburse for discarded drug amounts, providers must follow billing guidelines to ensure correct payment.

Drug Packaging

The United States Pharmacopeia (USP) defines multi-dose vials (MDVs) as multiple-use containers of liquid medication for parenteral administration (injection or infusion). MDVs contain more than one dose of medication and are labeled as multi-dose by the manufacturer. MDVs usually contain antimicrobial preservatives that help prevent the growth of bacteria.¹

The Centers for Disease Control and Prevention (CDC) defines single-use vials as:²
A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case/procedure/injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.

Medicare Guidelines

The Medicare Claims Processing Manual, Chapter 17, Section 40 states:³

When a physician, hospital or other provider or supplier 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 Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

And, while not required as part of national regulations, local Medicare contractors can require the use of modifier JW to report the discarded drug amount as a separate line item on the UB04 hospital claim or CMS1500 freestanding center or office claim form:

- **JW:** Drug amount discarded or not administered to any patient.

Remember, only waste from single-dose vials (SDVs) can be billed to the Medicare patient; MDVs are not subject to payment for discarded amounts of drug or biological.

While the Centers for Medicare & Medicaid Services (CMS) has published a policy regarding reimbursement for the discarded drug amount in a single-use vial, commercial and managed care payers may have to be contacted to obtain coverage information. Insurers are not required to reimburse for the wasted drug amount in a SDV, so obtaining this

information in writing will ensure coding and billing compliance.

How Does Modifier JW Work?

When CMS implemented this modifier during calendar year 2010, the agency stated that modifier JW was required for all claims that included discarded drug amounts. However, CMS quickly revised this to state that each Medicare contractor can independently decide whether or not to require the modifier.⁴

The JW modifier is only applied to the amount of drug or biological that is discarded. Therefore, the JW modifier would not be reported when the actual dose of the drug or biological administered is less than the billing unit. For example, one billing unit for a specific drug is equal to 10 mg of the drug in a single-use vial. A 7 mg dose is administered to a patient while 3 mg of the remaining drug is discarded. The 7 mg dose is billed using one billing unit that represents 10 mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10 mg of drug administered and discarded.

Billing another unit on a separate line item with the JW modifier for the discarded 3 mg of drug is not permitted because it would result in an overpayment to the provider. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted.

For those Medicare contractors, such as CGS Medicare, that require modifier

When an individual patient is charged for the amount of drug discarded, the patient medical record must include documentation.

JW, the following is an illustration of line items submitted on the same claim:⁵

Claim Line 1:

- HCPCS code for the drug administered
- No modifier
- Number of units administered to the patient
- Calculated price for only the amount of drug administered.

Claim Line 2:

- HCPCS code for discarded drug
- Modifier JW to report wasted drug
- Number of units discarded but billed to patient
- Calculated price for only the discarded drug amount.

For example, if the patient received 316 mg of Avastin from a 400 mg single-use vial, the services would be billed as follows:

- Claim Line 1: **J9035** x 32
- Claim Line 2: **J9035-JW** x 8

The Healthcare Common Procedure Coding System (HCPCS) drug code for Avastin (**J9035**) is billed with 1 unit for every 10 mg administered; therefore, 32 units of this code are reported for the 316 mg administered to the patient. The 84 mg that is wasted is reported with 8 units, since the total number of units billed cannot exceed the 400 mg in the single-use vial. The appropriate charge amounts for the 316 mg administered and 84 mg wasted would be calculated and associated with the correct claim line item.

In addition, there is no charge for drug

overflow included in a vial or package, generally to account for wastage in syringe hubs. This extra amount cannot be billed to Medicare since it does not represent an expense to the provider and exceeds the amount on the vial or package label.⁶

Keep in mind that drug waste cannot be billed if the drug was not administered, such as may occur when the patient misses an infusion appointment.

Documentation for Discarded Drugs

When an individual patient is charged for the amount of drug discarded, the patient medical record must include documentation. Documentation generally includes the date and time, amount of drug administered to the patient, amount of product wasted, and the reason for the waste. According to Novitas Solutions, a Medicare contractor, when a portion of the drug is discarded, the medical record must clearly document the amount administered and the amount wasted.⁷

This medical record notation is typically performed by the nurse, pharmacist, or other individual responsible for charting.

TrailBlazer Health Enterprises requires documentation of drug waste in the patient medical record, and adds:⁸

Upon review, any discrepancy between amount administered to the patient and amount billed will be denied as non-rendered unless the wastage is clearly and acceptably documented.

Some Medicare contractors, such as NHIC, state that the provider of service

is expected to have the most appropriate size vial on hand to minimize the amount of discarded drugs.⁸ For example, if a drug is available in 6 mg and 12 mg single-use packages and the patient requires a 6 mg injection, it would not be appropriate to purchase only the 12 mg packages and bill for 6 mgs of wasted drug for each patient that required this drug. CDC supports this position and adds:²

To prevent unnecessary waste or the temptation to use contents from single-dose or single-use vials for more than one patient, healthcare personnel should select the smallest vial necessary for their needs when making purchasing decisions.

Multi-Dose Audits

Both the Office of the Inspector General (OIG) and certain Recovery Audit Contractors (RACs) have indicated their intent to audit chemotherapy drugs, such as Herceptin, which is available in a multi-dose vial. The Region C RAC states:⁹

Per its package label, Trastuzumab/Herceptin (J9355: Injection, trastuzumab, 10 mg) is supplied from the manufacturer in a 440 mg multi-dose vial. Providers should be billing only units of J9355 associated with the amount of the drug administered to the patient. Drug waste is not paid and should not be billed for drugs supplied in multi-dose vials.

In addition, the 2012 OIG Work Plan includes a statement of intent to review

charges for Herceptin:¹⁰

We will review payments associated with Medicare claims for the drug Herceptin to determine whether they were appropriate. For drug claims involving a single-use vial or package, if a provider must discard the remainder of a single-use vial or package after administering a dose/quantity of the drug or biological, Medicare provides payment for the amount discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label. However, multiuse vials such as those used for supplying Herceptin are not subject to payment for discarded amounts of a drug or biological.

Why Does It Matter?

If Medicare pays for the amount of the drug administered to the patient and the remaining amount of drug in a single-use package that must be discarded, why is the modifier important? In a featured article dated May 15, 2009, Report on Medicare Compliance stated:¹¹


Billing for drug waste is emerging as a compliance and reimbursement issue for hospitals, especially in regions where the Medicare contractor requires documentation of discarded doses. Some hospitals are being audited for drug billing errors that include failure to chart wasted doses, while others sacrifice money unnecessarily by not reporting discarded drugs even though it's OK with CMS, hospital officials and consultants say.

As a result, hospitals and freestanding infusion centers should periodically audit medical records and claim submissions to ensure that the correct drug HCPCS code, modifier JW (if required), and drug units

are billed to insurance. It is also beneficial to review medical record documentation to ensure that the patient chart includes appropriate documentation of administered and wasted drug amounts.

Summary

The following is a brief summary of billing for discarded drug amounts:

- Providers may bill Medicare, and other payers with the same policy, for the amount of drug discarded from single-dose vials or single-use packages.
- Any drug amount discarded from multi-dose vials is not separately charged.
- The provider must make a good faith effort to schedule patients so that the use of drugs is efficient and medically appropriate.
- Any drug amount billed as discarded may not be administered to another patient.
- Coverage may not apply when the provider chooses to purchase larger packages when smaller, more appropriate packaging is available.
- The individual patient medical record must include documentation of the amount of discarded drug billed to that patient.
- Drug waste cannot be billed if none of the drug was administered, such as may occur when the patient misses an administration appointment. 

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