Update Your Processes for Reporting Single-Dose Container Waste for 2023

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Since Jan. 1, 2017, the Centers for Medicare & Medicaid Services (CMS) has used a modifier on claims forms across all Medicare jurisdictions to reimburse providers for Medicare Part B drug and biological waste from single-use containers. The agency codified the requirement for all providers to report single-dose container waste with **modifier JW** (drug amount discarded/not administered to any patient) for those paid under Medicare Part B, along with documentation of the waste in the medical record.[1]

What is Meant by Single-Use Container?

It is important for providers to understand that the definition of a single-use container (vial or package) varies based on the context, but the two definitions below are relatable to each other.

- The Centers for Disease Control & Prevention (CDC) defines single-use vials as: "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."[2]
- CMS defines a refundable single-dose container as applying to drugs paid under Medicare Part B (that is, under any payment methodology) that are described as being supplied in a single-dose container or single-use package based on FDA-approved labeling or product information. This definition also includes drugs described in FDA-approved labeling as a 'kit' that is intended for a single dose or single use.[3]

A Change in Policy

While CMS has been paying for the discarded amount from a single-dose container, the Infrastructure Investment and Jobs Act changed this policy.[4] Even though providers do their best to ensure drugs are administered correctly per package inserts, State law, and regulatory guidelines, there are still instances when the remaining portion of a single-dose container must be discarded.

For example, many drugs are dosed based on the patient's body weight or body surface area (BSA). Issues arise when the single- dose container is sized based on an average BSA that is inaccurate because it is years old. The body mass index (BMI) number of the United States population has continued to increase. According to the National Health and Nutrition Examination Survey 2021, adult obesity increased from 30.5 percent to 41.9 percent from 1999 through 2017.[5] If established single-dose containers have not accounted for this increase in the national obesity rate, providers may need to administer the necessary dose from one full container and a portion of another container.

Other single-dose containers are sized more than the average BSA. If a manufacturer were to have a single-dose container that exceeded the directed dosing—or average patient size—it could result in the provider wasting a considerable amount of the drug as required by packaging or regulation, because the sizing does not correlate to the desired population.

According to CMS, 2020 claims data show payments of nearly $720 million for discarded drug amounts billed with **modifier JW**, under Part B, for single-dose vials or single-dose packages. These payment amounts track with the yearly totals in 2017 to 2019, which ranged from approximately $700 million to $750 million each year. Based on these data, CMS questioned if it is the agency's responsibility to make payment for discarded drugs if manufacturer packaging is helping to create these issues.

Section 90004 of the Infrastructure Investment and Jobs Act requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug.[4] The refund amount is the amount of the discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter. CMS clarified that refundable single-dose vials or single-dose packages do not include radiopharmaceuticals, imaging agents, certain drugs requiring filtration, and specifically identified new drugs. With this policy shift, while providers will continue to be paid for the discarded amount as identified on the claim with **modifier JW**, the monies will be paid by manufacturers to CMS who will then pass on payments to providers.

This shift of payment responsibility for discarded drugs from CMS to drug manufacturers has the potential to change the size

of available single-dose containers. If manufacturers are now responsible for paying for discarded drugs, the expectation is that manufacturers will change single-dose containers to more closely reflect appropriate sizing, if they do not already.

It is important that providers appropriately report for waste of single-dose containers with the appropriate modifier. When providers do not report **modifier JW** on the claim form line with the Healthcare Common Procedure Coding System (HCPCS) codes and amount of waste, appropriate payment may not be received (or calculated) and container sizes may not be adjusted.

Billing Scenarios

CMS does specify that the billing for drug waste must coincide with the smallest vial size available. Specifically, it is not appropriate to bill for a larger amount of waste due to the stocking or availability of larger vial sizes when smaller options are available. MLN Matters® SE1316, issued Aug. 1, 2013, states, "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."[6]

An example of proper reporting of **modifier JW** would be the following: Code **J9035** represents Avastin® (bevacizumab),[1] unit per 10 mg. If a patient is given 980 mg from two 400 mg and two 100 mg single use vials (total 1,000 mg), and the remainder of the last vial is discarded (20 mg), the provider should report the following:

- J9035 x 98 units (administered 980 mg)
- J9035-JW x 2 units (wasted 20 mg)

Modifier JW is only applied to the amount of drug or biological discarded. **Modifier JW** would not be reported when the actual dose of the drug or biological administered is less than the billing unit. CMS also states **modifier JW** should not be used "if the billing unit is equal to or greater than the total actual dose and the amount discarded."

For example, in medical oncology, it is common for 25 mg of Benadryl® (diphenhydramine), which is supplied in a 50 mg single dose vial, to be administered prior to chemotherapy. In this scenario, 25 mg is not used and will be wasted; however, as one unit of Benadryl equals 50 mg, no waste would be reported. Since one unit of the code is equal to the total amount administered plus the amount discarded, the provider will bill one unit of code J1200 and the **modifier JW** will not be applied.

In the 2023 Medicare Physician Fee Schedule final rule, CMS indicated that hospital outpatient departments are required to report **modifier JW**, or any successor modifier, to identify discarded drug amounts from single-dose containers described by HCPCS codes assigned status indicator (SI) "K" (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals) or SI "G" (pass-through drugs and biologicals) under the Hospital Outpatient Prospective Payment System (HOPPS).[1] Regardless of whether the drug is assigned pass-through status, **modifier JW** is reported when there is any discarded amount from the single-dose container.

Modifier JW would not be used for drugs that are not separately payable, such as packaged drugs administered in outpatient hospitals or ambulatory surgical centers, federally qualified health centers, or rural health clinics. In addition, CMS has excluded from refund any amount of drug units where payment is packaged into a comprehensive ambulatory payment classification (C-APC) service in an outpatient hospital.

Creating a New Modifier

Concerns about missed reporting when there is drug waste with single-dose containers coupled with the lack of data since **modifier JW** began led CMS to create a new modifier: **modifier JZ**. Providers will use this modifier to attest that there was no discarded amount from the single-dose container paid under Part B. CMS believes that this change will ensure that providers apply a modifier—regardless of whether or not there was drug waste. Use of **modifier JZ** will begin July 1, 2023, to allow providers time to update software and implement processes to ensure appropriate use of the new modifier. Starting in July and for the remainder of 2023, providers should use the following modifiers for single-dose containers not excluded from drug waste reporting:

- **JW:** Drug amount discarded/not administered to any patient
- **JZ:** Zero drug amount discarded/not administered to any patient.

It is important that all providers are aware of these new guidelines regarding reporting of drug waste from single-dose containers. Historically, if a provider did not report **modifier JW** when there was waste from a single-dose container, they were still paid the full amount of the container. Whether it was split or a single-line item on the claim, the total was the same and the amount paid did not vary. Beginning Oct. 1, 2023, Medicare will deny all claims for single-dose containers that do not include **modifier JW** or **modifier JZ**.

CMS has also created a requirement for Medicare Administrative Contractors (MACs) to institute periodic audits of Part B claims to ensure billing and documentation are correct and billed appropriately.

Proactive Steps for Providers

Providers should identify the single-dose containers that are currently part of their treatment regimens and formularies and then audit their documentation and billing to identify any potential compliance issues and areas for improvement. Additionally, education for the staff responsible for coding and billing provider documentation should be conducted to ensure that these staff understand when modifiers are required and when they are excluded.

Drug payment programs and drug pricing have been a focus of CMS and Congress for many years. CMS is likely to adjust single-dose drug waste reporting and payment as these changes are fully implemented and manufacturers begin issuing required refunds. Providers need to understand the key to success and appropriate payment for drugs begins in their court with:

1. Appropriate selection of single-dose containers for treatment and management of patients
2. Accurate documentation

Table 1. CMS Guidelines on Use of Modifiers for Reporting Single-Dose Container Waste in 2023

	PHYSICIAN OFFICE BASED-SETTINGS	OUTPATIENT HOSPITAL-BASED DEPARTMENTS SETTINGS
MODIFIER JW		
Report for single-dose container waste	January 1, 2023	January 1, 2023
Report for waste on single-dose containers with HCPCS codes assigned non-pass-through and pass-through status indicators (SI) "K" or "G"	N/A	January 1, 2023
Drugs supplied via multi-use containers	Excluded	Excluded
Report for single-dose container wast Radiopharmaceuticals, imaging agents, and drugs requiring filtration during the drug preparation process	Excluded	Excluded
New drugs after 11/15/21 and paid less than 18 months	Excluded	Excluded
Packaged drugs in hospital setting	N/A	Excluded
Single-dose containers packaged into comprehensive ambulatory payment classifications (C-APCs), includes SI "K" drugs when administered in conjunction with C-APC	N/A	Excluded
MODIFIER JZ		
Report attesting no discarded amount from single-dose container paid under Medicare Part B and would have required modifier JW if there was waste	July 1, 2023	July 1, 2023
Drugs supplied via multi-use containers	Excluded	Excluded
Radiopharmaceuticals, imaging agents, drugs requiring filtration during the drug preparation process	Excluded	Excluded
New drugs after 11/15/21 and paid less than 18 months	Excluded	Excluded
MODIFIER JW AND JZ		
Claims denied if modifier JW or JZ is missing from single-dose container claims	October 1, 2023	October 1, 2023
Periodic audits by MACs of Part B claims ensure modifiers JW, JZ, discarded drug amounts billed correctly	Included	Included

3. Accurate billing of the HCPCS code for the included single-dose containers.

To assist providers in these efforts, Table 1, above, provides a summary of the CMS guidelines surrounding use of modifiers for reporting single-dose container waste in 2023.

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