

Drug Wastage

TrailBlazerSM will consider payment for the appropriately discarded amount of a single-use drug/biological product after administering what is reasonable and necessary for the patient's condition. This applies to drugs priced through the Average Sales Price (ASP) drug/biological program. CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs/biologicals most efficiently in a clinically appropriate manner. 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/biological to a Medicare patient, the program provides payment for the amount of drug/biological discarded along with the amount administered up to the amount of the drug or biological indicated on the vial or package label. Most manufacturers provide an extra amount of drug in each vial to account for the wastage in syringe hubs. This extra amount must **not** be billed to Medicare since it does not represent an expense to the provider and clearly exceeds the amount on the vial or package label.

Drug wastage must be documented in the patient's medical record with date, time, amount wasted and reason for wastage. 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. The amount billed as "wasted" must not be administered to another patient or billed again to Medicare.

Clinically Appropriate Examples of Avoiding Drug Wastage

TrailBlazer would expect to see the following documented in the medical record when administering/wasting drugs billed to Medicare.

- All doses must be drawn by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.
- All doses from a given vial should be drawn and administered within the time period specified on the package insert.
- Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.
- Any opened vials or filled syringes must be discarded if not used within the specified time frame of the first puncture of the vial. Vials must be labeled to document the time of first entry and maintained at a temperature specified on the package insert during non-use.
- Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.

- Each facility should have in place a process-monitoring (quality assurance) program, which ensures compliance with these policies and procedures. This program should include:
 - Recording data on infections in treated patients.
 - Unannounced practice audits involving quality assurance staff observing performance of reuse techniques.

Failure to comply with these recommendations, particularly re-entry and reuse of similar-use vials of drugs over a longer period of time than recommended or pooling of these medications from multiple vials, represents a potential hazard and must be avoided since it would pose significant health and safety risks to patients.

Scrupulous infection control and aseptic practices should be strictly followed and enforced in entering a vial, and the number of times a vial is entered should be minimized. Consequently, the growth of bacteria, if introduced, would be very low and subsequent adverse events very unlikely if the material in the vial is used over a short period of time.

Billing for Drug Wastage

HCPCS modifier JW is defined as “drug or biological amount discarded/not administered to any patient” and is used on claims to indicate drug wastage when the above measures have been taken. The JW modifier is only to be applied to the amount of drug/biological discarded.

The amount **administered** and the amount **wasted** must be **billed on the same claim**. The amount administered is on a separate detail line from the amount wasted, which is indicated with the modifier JW (when applicable).

The modifier JW would not be used for claim billings when the actual dose of the drug/biological administered is less than the **billing unit** established by HCPCS description.

As a reminder, drug wastage cannot be billed if none of the drug was administered (such as a missed appointment by the patient).

Note: The JW modifier is not used on claims for drugs or biologicals provided under the Competitive Acquisition Program (CAP). For additional discussion on this topic for drugs/biologicals in the CAP, see the *Medicare Claims Processing Manual*, Pub. 100-04, Chapter 17, Subsection 100.2.9.

The following examples apply in determining the correct way of billing drug wastage to Medicare.

Billing Examples Using JW Modifier

Per-Unit Example, Multiple Patients:

A physician schedules three Medicare patients to receive botulinum toxin type A (J0585, botulinum toxin type A, **per unit**) on the same day within the designated shelf life of the product. Currently, Botox[®] is available only in a 100-unit size. Once Botox[®] is reconstituted in the physician's office, it has a shelf life of only four hours. Often, a patient receives less than a 100-unit dose. The physician administers 30 units to each patient. Your claim for these patients would indicate J0585 billed at quantity 30 (to indicate the amount administered to the patient). Billing J0585 JW is not appropriate for these patients.

Your claim for the last patient receiving Botox[®] in those four hours is where the remaining 10 units are to be billed to Medicare. Your last patient's claim would indicate J0585 billed at quantity 30 (to indicate the amount administered to the patient) on one detail line. The next detail line would indicate J0585 JW billed at quantity 10 (to indicate the 10 units wasted from the 100-unit vial).

Per-Unit Example, Single Patient:

A physician must administer 15 units of Botox[®] to a Medicare patient, and it is not practical to schedule another patient who requires Botox[®]. For example, the physician has only one patient who requires Botox[®] or when the physician sees the patient for the first time and did not know the patient's condition.

Your claim for this patient would indicate J0585 billed at quantity 15 (to indicate the amount administered to the patient) on one detail line. The next detail line would indicate J0585 JW billed at quantity 85 (to indicate the 85 units wasted from the 100-unit vial).

Note in both of the above examples the entire 100 units that were an expense to the billing provider are accounted for with the combination of the drug code on one detail line and the JW wastage on the next detail line. The code description for J0585 is billed in this manner because the **billing unit** (HCPCS description) does not indicate an entire 100-unit vial but a breakdown by units of the vial.

Billing Example Without Use of JW Modifier

The modifier JW would not be used for claim billing when the **billing unit** (HCPCS long description) already includes the amount administered along with the amount wasted. A physician must administer 75 mg of meperidine HCl (J2175, meperidine hydrochloride, **per 100 mg**) to a Medicare patient, not scheduled for an injection at this appointment, and no other patient received a meperidine injection. The provider buys the dosette ampules that are 50 mg/ml. Since two ampules will be used to attain the 75 mg injected, the remaining 25 mg will be wasted. HCPCS code J2175 ASP payment allowance is 100 mg. The entire 100-mg expense to the provider is covered with one detail line by billing J2175 (quantity of one) without an additional modifier. The medical record will document the 75 mg injected and the wastage of the remaining 25 mg. If an additional detail line were billed (J2175 JW, quantity of

one), this would indicate 100 mg were injected and 100 mg were wasted, which was not the case and would not be supported by the medical record. This will result in an overpayment.

Reference: Internet-Only Manual (IOM) Pub. 100-04, Chapter 17, Section 40, updated per Change Request (CR) 6711, Transmittal 1962, dated April 30, 2010.