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 <u>not</u> 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 OPPS 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 unit 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.

<u>Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC)</u> <u>Payment System</u>

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.