Medicare Program
JW Modifier: Drug/Biological Amount Discarded/Not Administered To Any Patient
Frequently Asked Questions

Policy: Effective January 1, 2017, providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records.

Resources:

MLN Matters MM9603 https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.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

General

Q1. What is the JW modifier?
A1. The JW modifier is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used on a Medicare Part B drug claim to report the amount of drug or biological (hereafter referred to as drug) that is discarded and eligible for payment under the discarded drug policy. The modifier shall only be used for drugs in single dose or single use packaging.

Q2. What is Medicare Part B's payment policy for discarded drugs?
A2. As described in Chapter 17, Section 40.1 of the Medicare Claims Processing Manual, in addition to paying for the amount of drug that has been administered to a beneficiary, Medicare Part B also pays for the amount of drug that has been discarded, up to the amount that is indicated on the vial or package label. The discarded drug amount is the amount of a single use vial or other single use package that remains after administering a dose/quantity of the drug to a Medicare beneficiary.

Q3. Why did CMS establish a national policy for the JW modifier?
A3. CMS is establishing a consistent policy among all MAC jurisdictions for the use of the JW modifier for discarded drugs that are associated with separately paid Part B drug claims. Prior policy allowed the MACs to choose whether to require the JW modifier. MACs were also able to issue jurisdiction-specific instructions for the use of the modifier.

Q4. Is the JW modifier required on claims for single-dose drugs and biologicals?
A4. Effective January 1, 2017, the modifier must be used in order to obtain payment for a discarded amount of drug in single dose or single use packaging under the Medicare discarded drug policy. The modifier is not required if no discarded drug is being billed to any payer. (Overfill is discussed in question #7.)

Q5. In which settings is the JW modifier required?

A5. This policy applies to providers and suppliers who buy and bill drugs and is intended to track discarded amounts of drugs that occur as a result of the preparation of a drug dose for administration to a beneficiary. We anticipate that the JW modifier will be used mostly in the physician's office and hospital outpatient settings for beneficiaries who receive drugs incident to physicians' services. The JW modifier requirement also applies to Critical Access Hospitals (CAHs) since drugs are separately payable in the CAH setting.

The modifier may also apply to some drugs furnished by suppliers such as pharmacies. However, we believe that those suppliers, particularly those who dispense drugs and do not actually administer the drug, or sell partial vials of sterile products, would not have discarded amounts to report on claims. Similarly, entities such as outsourcing facilities or pharmacies that prepare doses of sterile drugs that are administered and billed by other practitioners would not be subject to the requirements for using the JW modifier or documenting discarded drug quantities for a specific beneficiary because they would not be billing for these drugs. Also, in certain situations where sterile product repackaging or compounding is carried out, for example in a hospital pharmacy, and the drug is separately payable under Part B after administration incident to a physician's services, it may not be possible to quantify discarded quantities of drugs and associate them with a beneficiary, particularly when batch preparation of products is being done.

The JW modifier does not apply to drugs or biologicals administered in a Rural Health Clinic (RHC) or a Federally Qualified Health Center (FQHC). Drugs and biologicals 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. Exceptions are the influenza, pneumococcal, and Hepatitis B vaccines which are paid separately at cost through an RHC's or FQHC's cost report and not via a claim.

Finally, the JW modifier is not intended for use on claims for hospital inpatient admissions that are billed under the Inpatient Prospective Payment System. (See question #21 for additional information).

Q6. To which drugs does the policy apply? How can a provider or supplier identify a drug that must be billed using the JW modifier?

A6. In general, the modifier policy applies to all separately payable Part B drugs that are designated as single-use or single dose on the FDA-approved label or package insert. Accordingly, use of the modifier is not appropriate for drugs that are from multiple dose vials or packages. Package inserts are available on the FDA website at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.

However, the JW modifier is not required for:

- Drugs that are not separately payable, such as packaged OPPS drugs or drugs administered in the FQHC or RHC setting.
- Drugs paid under the Part B drug Competitive Acquisition Program (CAP). The CAP remains on hold and there is no current list of CAP medications.

Q7. Does the JW modifier apply to drug overfill?

A7. The JW modifier must not be used to report overfill wastage. Beginning January 1, 2011, Medicare issued regulations 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) available at https://www.federalregister.gov/articles/2010/11/29/2010-27969/medicare-program-payment-policies-under-the-physician-fee-schedule-and-other-revisions-to-part-b-for.

Q8. Is the JW modifier applicable when the dose administered is less than the HCPCS billing unit?
A8. CMS does not use fractional billing units to pay for Part B drugs. Therefore, the JW modifier should not be used when the actual dose of the drug administered is less than the HCPCS billing unit.

Q9. Does a provider or supplier have the option to bill using the JW modifier now or should they wait until January 1, 2017?
A9. Providers and suppliers may report the JW modifier prior to January 1, 2017.

Q10. What happens if a provider or supplier does not use the JW modifier on claims that include discarded drugs?
A10. Claims for drugs furnished on or after January 1, 2017 containing billing for discarded drugs that do not use the JW modifier correctly may be subject to review.

Billing, Claims, and Documentation

Q11. How are providers and suppliers to bill using the JW modifier on claims?
A11. The drug discarded should be billed on a separate line with the JW modifier. The unit field should reflect the amount of drug discarded. Please refer to the example in the Medicare Claims Processing Manual Chapter 17, section 40 located at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.

Q12. Instead of reporting a second line with the discarded amount and price, may a provider/supplier report one line with the amount used and the adjusted price?
A12. No. To identify and monitor billing and payment for discarded drugs under Medicare Part B, CMS requires the use of the JW modifier on a separate claim line.

Q13. When using the JW modifier, should the dollar amount be included on the wastage line or should the line reflect units only?
A13. General billing rules may require a charge be included on each line on the claim. Also, each MAC that processes claims may have specific billing policies or guidance for certain items or services where there is not national billing guidance from CMS. Please contact your local MAC for further billing information.

Q14. Does CMS have specific requirements regarding documentation for discarded 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 kept? Is there a specific area in the medical record where the administered/discarded amount should be documented?
A14. CMS expects 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 Medicare. General guidance on documentation is available in MLN Matters SE 1316 (http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1316.pdf). 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.

Q15. Will CMS accept an "automatic" calculation of waste, for example a calculation done by software, as documentation of waste within the medical record?
A15. As long as the amount of wastage is accurately documented, the CMS does not dictate how it is calculated.

Hospital Outpatient Prospective Payment System (OPPS)

Q16. When billing for services furnished in the hospital outpatient setting, does the JW modifier apply to all Part B claims including Part B inpatient (Type of Bill 12X)? Are eligible and participating 340B providers exempt from the JW modifier reporting?
A16. The JW modifier requirement applies to all separately payable drugs 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 an unused or discarded amount. Eligible and participating 340B providers are not exempt from reporting the JW modifier.

Q17. Are hospitals required to report the JW modifier only when the applicable drug is billed with revenue code 636?
A17. The requirements for using the JW modifier are independent of revenue codes reporting. Providers should always use the most appropriate revenue code that applies to the service they are reporting.

Q18. Does the JW modifier apply to drugs (as well as skin substitutes and implantable biologicals) administered in the operating room to hospital outpatients?
A18. The JW modifier requirement applies to all separately payable drugs 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 an unused or discarded amount.

Q19. Will the JW modifier be required on hospital outpatient claims for single-dose drugs and biologicals?
A19. The JW modifier is intended to quantify the amount of drug from a single-use or single-dose package that is discarded by the provider, and the modifier must be used in order to obtain

payment for a discarded amount of drug. In many cases, drugs are administered almost immediately after a single-use or single-dose package is opened by the provider. However, we recognize that in certain situations, for example when a hospital pharmacy's sterile preparation area prepares multiple doses of a drug in advance of when they are needed, discarded amounts of drug may not be possible to quantify. In such situations, where the quantity of discarded drug cannot be quantified, the JW modifier is not required. The JW modifier is also not required if the amount of drug that is discarded is less that the amount described by one HCPCS billing unit. See question #4 for additional information.

Q20. Does the JW modifier apply to OPPS drugs with status indicator N?
A20. No. The JW modifier does not apply to drugs assigned status indicator N (Items and Services Packaged into APC Rates) under the OPPS.

Q21. Are hospitals required to transfer the charges related to waste 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?
A21. In circumstances where the 3-day/1-day payment window applies, all hospital outpatient services (and associated charges), including drugs and biologicals, furnished to a beneficiary during the 3 days/1day 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 and biologicals are not separately payable under the inpatient prospective payment system (IPPS) the JW modifier will not be required in this situation.