



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE SPECIALTY MEDICATIONS

ORIGINAL EFFECTIVE DATE: 10/26/21
LAST REVIEW DATE: 11/21/24
CURRENT EFFECTIVE DATE: 11/21/24
LAST CRITERIA REVISION DATE: 11/16/23
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025

DRUG, BIOLOGIC, BIOSIMILAR WASTAGE

Non-Discrimination Statement is located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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DRUG, BIOLOGIC, BIOSIMILAR WASTAGE

Description:

Wastage occurs when the entire single-dose vial or single-dose pre-filled package of a drug, biologic, or biosimilar cannot be administered and the unused portion must be discarded. Providers are expected to administer and care for patients in a way where drugs, biologics, or biosimilars are used most efficiently to prevent or minimize wastage. Providers must use the most economical combination of vial or packages sizes to minimize and avoid wastage.

Definitions:

Drug Waste: The partial vial, package, or product of drug or biologic that is discarded and not administered to any member.

Modifier JW:

The modifier reports the amount of drug, biologic, or biosimilar that is discarded-or not administered to any individual.

Modifier JW can be billed on a separate line for the amount of the discarded drug, biologic, or biosimilar when the medication waste is more than the HCPCS billing unit description. For example, a single use vial that is labeled to contain 100 units of a drug has 95 units administered to the individual and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units are billed on another line with modifier JW.

Modifier JW should not be used when the billing unit is equal to or greater than the total dose administered, and the amount discarded. For example, one billing unit for a drug is equal to 10 mg of the drug in a single use vial. A 7 mg dose is administered to an individual and the 3 mg of the drug is discarded. The 7 mg dose is billed using one billing unit that represents 10 mg on a single claim line.

Modifier JZ:

The modifier reports that there is no discarded drug, biologic, or biosimilar.

Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts.

Multi-Dose Vials:

A vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication. Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria.

Single-Dose or Single-Use Vial:

A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for individual use for a single case, procedure or injection. Single-dose



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or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.

Overfill:

Any excess product (overfill) is provided without charge to the provider. Providers may not bill for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider.



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Providers, facilities, and suppliers are encouraged to administer and care for individuals in a way that drugs and biologicals are used most efficiently to prevent waste of the product.

Criteria:

- Drug, biologic, or biosimilar wastage of a single-use vial or single-dose pre-filled package is **eligible for reimbursement** with documentation of **ALL** of the following:
 1. Clear and acceptable documentation in the clinical record of **ALL** the following:
 - Amount of drug, biologic, or biosimilar available in the single-use vial or single-dose pre-filled package
 - Drug, biologic, or biosimilar dose administered
 - Drug, biologic, or biosimilar amount not used **AND** reason for the amount wasted/discarded
 - Drug, biologic, or biosimilar name
 - Route of administration
 - Time and date drug, biologic, or biosimilar was administered
 2. Modifier JW is reported on a separate claim line from the administered dose/units, and the appropriate medication or biologic HCPCS code
 3. The units billed must correspond to the smallest dose (single-vial or single-dose pre-filled package) available from the manufacturer(s) that would provide the appropriate dose for the individual and the unused portion is discarded
 4. The National Drug Codes (NDC) of the drug, biologic, or biosimilar that corresponds to the HCPCS code used, must be included
 5. The discarded drug, biologic, or biosimilar is not administered to the same individual or another individual for any reason
 6. The drug, biologic, or biosimilar is not a self-administered formulation

- Drug, biologic, or biosimilar wastage is **not eligible for separate reimbursement** when:
 - Drug, biologic, or biosimilar wastage is for multi-dose vials.
 - The dose administered is less than the HCPCS billing unit description.
 - For unclassified HCPCS codes, the dose administered is not provided using the most efficient package based on the available manufacturer packaging.
 - Multi-use vials and multi-use packages will not be reimbursed for discarded amounts of drugs or biologicals when billing includes pricing per HCPCS code or NCD units.
 - Single-use vials which have been reimbursed for wasted/discarded drugs, using the JW modifier for one member, may not be billed for use on other members or patients.



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- A provider will not be reimbursed for purchase of larger packaging of drugs or biologicals when more appropriate packaging can be purchased.
 - Reimbursement will not be given to a provider or hospital due to a member missing an appointment or the member changes their mind after the drug is prepared.
 - The JW modifier is used on claims for hospital inpatient admissions.
 - Volumes of quantities of the drug or biological billed over the manufacturer’s labeled package volume or mass (“overfill”) will not be reimbursed and must not be billed for use on members.
 - A drug device misfires or does not administer the drug correctly [note: advise member to contact the manufacturer for replacement]
 - The member mishandles or damages the drug, requiring a replacement dose. [note: advise member to contact the manufacturer for replacement]
 - Drug is stored outside the storage requirements described within the product(s) prescribing information.
 - The shipping company damages the drug when in route to the member.
 - The provider mishandles, damages, or does not appropriately reconstitute the drug.
 - Theft from provider or shipping company.
- Whole Vial or Package Waste:
- Whole vials or packages billed as waste will not be reimbursed in most circumstances. Whole vial, package, or product waste due to manufacturer defect, shipping damage, improper storage, or provider administration error may not be reimbursed. In some limited circumstances, whole vials or packages billed as waste may be reimbursed. Scenarios of reimbursable whole vial or package waste include, but are not limited to:
 - Intrauterine Device (IUD) insertion billed on same date of service.
 - Member death, hospitalization, or incapacitation after drug has been shipped (for home delivery providers only).
 - Replacement drug after dispensing due to disasters such as flooding, fires, etc.
 - Theft from member.

<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Pharmacy and Therapeutics Committee	11/21/24	Review without revisions
Pharmacy and Therapeutics Committee	11/16/23	Review with revisions
Pharmacy and Therapeutics Committee	12/01/22	Review with no changes
Medical Policy Panel	10/26/21	Approved guideline
Legal Division	10/06/21	Review with no changes
Clinical Pharmacist	08/26/21	Development



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Coding:

HCPCS: Various
MODIFIER: JW, JZ



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Resources:

Literature reviewed 11/21/24. We do not include marketing materials, poster boards and non-published literature in our review.

1. Blue Cross Blue Shield of Arizona. 2024 Provider Operating Guide. Accessed August 28, 2024.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: JW Modifier Billing Guidelines (A55932). Revised 03/21/2024. Accessed September 4, 2024. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55932>.
3. Center for Medicare & Medicaid Services. Medicare Claims Processing Manual Chapter 17 Drugs and Biologicals. Revised 02/15/2024. Accessed September 4, 2024. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf>.
4. Center for Medicare & Medicaid Services. Medicare Program, Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Accessed 08/29/2023. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>



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Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>