

In the event of a conflict between a Clinical Payment and Coding Policy and any plan document under which a member is entitled to Covered Services, the plan document will govern. Plan documents include but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions and other coverage documents.

In the event of a conflict between a Clinical Payment and Coding Policy and any provider contract pursuant to which a provider participates in and/or provides Covered Services to the eligible member(s) and/or plans, the provider contract will govern.

Providers are responsible for accurately, completely, and legibly documenting the services performed including any preoperative workup. The billing office is expected to submit claims for services rendered using valid codes from the Health Insurance Portability and Accountability Act (HIPAA) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (UB) Editor, American Medical Association (AMA), Current Procedural Terminology (CPT®), CPT® Assistant, Healthcare Common Procedure Coding System (HCPCS), National Drug Codes (NDC), Diagnosis Related Group (DRG) guidelines, Centers for Medicare and Medicaid Services (CMS) National Correct Coding Initiative (CCI) Policy Manual, CCI table edits, National Council for Prescription Drug Program (NCPDP) and other CMS guidelines. Claims are subject to the code auditing protocols for services/procedures billed.

Wasted/Discarded Drugs and Biologicals Guideline

Policy Number: CPCP017

Version 5.0

Clinical Payment and Coding Policy Committee Approval Date: 06/26/2019

Plan Effective Date: October 25, 2019 (Blue Cross and Blue Shield of Texas Only)

Description

The intent of the Wasted/Discarded Drugs and Biologicals Clinical Payment and Coding Policy is to prevent waste and abuse when the dose or combination of appropriate dosage for drugs has not been administered to a patient and therefore may result in incorrect billing practices. **This policy is not intended to impact care decisions or medical practice.**

Definitions/Acronyms:

Multi-use vials/packages: A drug or biologic package that allows more than one (1) dose to be withdrawn for administration by injection or infusion.

Single-use vials/packages: A drug or biologic package that allows only one (1) dose to be withdrawn for administration by injection or infusion.

Drug Waste: The amount of drug or biologic that is discarded and not administered to any patient.

Reimbursement Information:

Reimbursement information provided in this policy for wasted and/or discarded drugs and biologicals may not cover every reimbursement type situation for a patient. Reimbursement and payment are determined by the Plan Documents under which the member is entitled to Covered Services. Providers and facilities are urged to administer drugs and biologicals in an efficient manner to prevent waste of the product.

When billing drugs, units of service must be billed in multiples of the dosage specified in the full CPT/HCPCS description. If the amount administered is not a multiple of the CPT/HCPCS code, round to the next highest unit in the CPT®/HCPCS description for that code. Total dose, administered and wasted, must not exceed the vial amount.

Example #1: If 750 milligrams (mg) of rituximab is administered, it is appropriate to bill for 75 units J9312, since the CPT/ HCPCS code J9312 defines the unit for rituximab as 10mg. If 800mg total are utilized, but only 750mg are administered, then 50mgs are wasted and documented in the medical record. Since the administered amount requires billing 75 units of J9312, 50mg of wastage is billed on a separate service line as 5 units of J9312 (along with the JW modifier) that is not utilized.

JW Modifier Usage

The actual dosage of drugs or biologicals must be reported with the correct CPT/HCPCS and correct units of service. The amount discarded must also be billed on a separate line with the JW modifier for all non-inpatient places of service. The JW modifier is a CPT/HCPCS Level II modifier that is used to report the amount of a drug or biological that is discarded. Hospitals, suppliers and providers are encouraged to administer and care for patients in a way that drugs and biologicals are used most efficiently to prevent or minimize drug wastage.

JW Modifier Usage (cont.)

Suppliers and providers are required to utilize the JW modifier on claims for discarded drugs and biologicals from single use vials and or single use packages when discarded. In addition, suppliers and providers are required to document the amount of discarded drugs or biologicals in the patient's medical records. The JW modifier will only be applied to the amount of the drug or biological that is discarded. The JW modifier should be billed on a separate line than what was administered to the patient. The plan will provide reimbursement for the discarded amount of a single use dosage drug or biological product that is discarded and administered to the patient up to the amount indicated on the vial or package label that is necessary for the patient's condition.

The plan will provide reimbursement for drugs and biologicals reported with the JW modifier provided the criteria below are met:

- The dose administered, discarded amount, exact date and time of administration and reason for wastage are clearly and acceptably documented in the medical record.
- The discarded amount is billed on a separate line than the administered amount with the correct CPT/HCPCS code, units, and JW modifier for all non-inpatient places of service.
- The discarded drugs or biologicals are not administered to another patient.
- The drug or biological administered is only available in a single use vial or single use package.
- The drug or biological is administered to the patient appropriately for the patients' medical condition and the unused portion is discarded
- The units billed correspond with the smallest dose or vial available for purchase from the manufacturer(s) that provides the appropriate dosage for the patient.
- National Drug Codes (NDC) identify drugs using a unique three segment product identifier number. These codes must be included with the CPT/HCPCS code when billing for drugs to receive NDC-based reimbursement. When billing drugs, CPT/HCPCS units of service must be billed in multiples of the dosage specified in the full CPT/HCPCS description. If the amount administered is not a multiple of the CPT/HCPCS code, round to the next highest unit in the CPT/HCPCS description for that code. The NDC units billed should correspond to the CPT/HCPCS units billed.

Example #2: Trastuzumab is available in a single use, 150mg vial. The CPT/ HCPCS code and description for trastuzumab is J9355, trastuzumab 10mg. If 575mg are administered to the patient, then four 150mg vials (total 600mg) should be utilized. When 600mg are utilized but only 575mg are administered, then 25msg are wasted and documented in the medical record. The correct billing is 58 units J9355 on one line of the claim, and 2 units J9355JW on another line.

Example #3: Rituximab is available in single use vials of 100mg/10mL and 500mg/50mL. The CPT/HCPCS code and description for rituximab is J9312, rituximab 10mg. If 750mg are administered to the patient, the most appropriate combination of Rituxan vials to minimize wastage for a 750mg dose is one 500mg/50ML single use vial and three 100mg/10ML single use vials. Billing Rituxan 750mg dose using two 500mg/50ML vials as 75 units J9312 to reflect amount administered and 25 units J9312 to reflect wastage may be subject for review as this combination does not minimize wastage.

When Drugs and Biologicals are not Eligible for Reimbursement

- ✓ Multi-use vials and multi-use packages will not be reimbursed for discarded amounts of drugs or biologicals.
- ✓ Discarded/wasted drugs that have been reimbursed for one patient may not be billed for use on other patients.
- ✓ A provider will not be reimbursed for purchases 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 patient missing an appointment or the patient changes their mind after the drug is prepared.
- ✓ The JW modifier is used on claims for hospital inpatient admissions.
- ✓ Volumes or 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 patients.
- ✓ The drug or biological is discontinued by the manufacturer with prior notice, but the patient is not transitioned to a market-available alternative.

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 a manufacturer defect, shipping damage, improper storage, or provider administration error may not be reimbursed. Some scenarios of the non-reimbursable whole vial or package waste include, but are not limited to:

- ✓ A Neulasta® OnPro® (J2505) that is administered but fails to deliver the drug.
- ✓ The drug or biological is discontinued by the manufacturer with prior notice, but the patient is not transitioned to a market-available alternative
- ✓ The patient mishandles or damages the drug, requiring a replacement dose.
- ✓ A drug stored outside the storage requirements described within the product(s) prescribing information.
- ✓ The shipping company damages the drug en route to the patient.
- ✓ The provider mishandles, damages, or does not appropriately reconstitute the drug.
- ✓ Theft from provider or shipping company.
- ✓ Reimbursement will not be given to a provider or hospital due to a patient missing an appointment or the patient changes their mind after a drug is prepared.



Whole Vial or Package Waste (cont.)

In some limited circumstances, whole vials or packages billed as waste may be reimbursed. Some scenarios of a reimbursable whole vial or package waste include, but are not limited to:

- ✓ Intrauterine Device (IUD) insertion billed on the same date of service.
- ✓ Patient death, hospitalization, or incapacitation after the drug has been shipped (for home delivery providers only).
- ✓ Replacement drug after dispensing due to disasters such as hurricanes, earthquakes, flooding, fires, etc.
- ✓ Theft from a patient.

Wasted/Discarded Drugs and Biologicals will be evaluated on a case-by-case basis and may include a review of applicable medical documentation including documentation of drug product preparation.

Billing Information

Refer to the Provider section of our website, and the provider contract, for the most up to date billing guidelines.

References:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>

<https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

<https://www.ashp.org/drug-shortages/current-shortages>

Policy Update History:

| Approval Date | Description |
|---------------|---------------|
| 06/29/2018 | New policy |
| 06/26/2019 | Annual Review |

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