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Origination: Converted Medical Policy
Last Review: New Policy
Next Review: July 31, 2026
Effective Date: November 1, 2025

Description

This policy describes how we will consider benefits for the appropriately discarded amount of a single-use drug/biological product after administering what is reasonable and necessary for the patient's condition.

Policy & Guidelines

Blue Cross and Blue Shield of Vermont (Blue Cross VT) will provide benefits for the appropriately discarded amount of a single-use drug/biological product after administering what is reasonable and necessary for the patient's condition only when conditions are met.

When billing drugs, units of service must be billed in multiples of the dosage specified in the full HCPCS descriptor.

If the dosage given is not a multiple of the HCPCS code, the provider rounds to the next higher unit in the HCPCS description for that code.

> **For example:** if 2.5 milligrams of Zoledronic Acid is administered, it is appropriate to bill for 3 units, as the HCPCS J3487 defines the unit for Zoledronic Acid as 1 milligram.

Additionally, if after administering the prescribed dosage of any given drug, the provider must discard the remainder of a single-use vial or other package, Blue Cross VT may cover the amount of the drug discarded along with the amount administered according to the criteria described below.

Eligible

The following elements must be followed in order for the discarded amount to be eligible for benefits:

1. The vial must be a single use vial. Multi-use vials are not subject to payment for any discarded amounts of the drug.

2. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose forthe patient.

For example: If a 5 mg dose of a drug needs to be given and the doses available from the manufacturer in single-dose glass vials include 1 mg per 1cc vial, 5 mg per 1cc vial, and 10mg per 1 cc vial, the correct single dose vial to use would be the 5mg/1cc vial as this involves the use of only one vial and there would not be any drug wastage.

When both elements above are present; **AND**

1. Drug wastage is documented in the patient's medical record with date, time, amount administered, 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; and

2. All doses are drawn by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique and

3. All doses from a given vial are drawn and administered within the time period specified on the package insert; and

4. Only one vial of a given concentration of the medication is 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; and

5. 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; and

6. 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.

Blue Cross VT follows the guidelines issued by the Centers for Disease Control and Prevention (CDC) with respect to the use of single-dose/single-use vials. See CDC Guidelines on infection safety and the use of single dose vials.
https://www.cdc.gov/injection-safety/hcp/clinical-safety/?CDC_AAref_Val=https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html

The Centers for Disease Control and Prevention's guidelines call for medications labeled as "single-dose" or "single-use" to be used for only one patient. This practice protects patients from life-threatening infections that occur when medications get contaminated from unsafe use. Concerns have been raised about whether these guidelines and related policies contribute to drug shortages and increased medical costs to healthcare providers. CDC recognizes the problem of drug shortages; however, such shortages are a result of manufacturing, shipping, and other issues unrelated to the above guidelines (https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages). CDC's priority is protecting patients from harm. CDC routinely investigates and is apprised of infectious

disease outbreaks involving single- dose/single-use vials being used for multiple patients. These outbreaks cause extensive harm to patients, and they are associated with significant healthcare and legal expenses. Therefore, CDC continues to strongly support its current policies regarding single-dose/single- use vials. It is imperative that drug shortages and drug waste concerns are dealt with appropriately and do not lead to unsafe medical practices that impose increased disease risk on patients. Shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards to subdivide contents of single - dose/single-use vials, as stated in United States Pharmacopeia General Chapter ‹797› Pharmaceutical Compounding – Sterile Preparations.

Not Eligible

- If any of the described criteria under “Eligible” are not met.
- The administered plus wasted drug cannot exceed the labeled quantity on the vial.
- Waste cannot be billed for a no-show.
- The billing of drug waste for a multi vial use package.
- Any waste reimbursed by Blue Cross VT must not be billed for use on any other patient.

Coverage does not apply if the provider chooses to purchase larger packages (for a lower per unit cost) when smaller, more appropriate packaging is available.

Additional Considerations

Each facility will 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.

Provider Billing Guidelines and Documentation

Append HCPCS Level II modifier -**JW** [drug amount discarded/not administered to any patient] to identify unused drugs or biologicals from single use vial/package. Bill on separate line for payment of discarded drug/biological.

Benefit Determination Guidance

Payment for services is determined by the member's benefits. It is important to verify the member's benefits **prior** to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Eligible services are subject to applicable member cost sharing such as co-payments, co- insurance, and deductible.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information, please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits **prior** to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Inter Plan Programs (IPP): In accordance with the Blue Cross and Blue Shield Association's Inter-Plan Programs Policies and Provisions, this payment policy governs billing procedures for goods or services rendered by a Vermont-based provider (Blue Cross VT is the local Plan), including services rendered to out-of-state Blue members. Provider billing practices, payment policy and pricing are a local Plan responsibility that a member's Blue Plan must honor. A member's Blue Plan cannot dictate the type of claim form upon which services must be billed, codes and/or modifiers, place of service or provider type, unless it has its own direct contract with the provider (permitted only in limited situations). A member's Blue Plan cannot apply its local billing practices on claims rendered in another Plan's service area. A member's Blue Plan can only determine whether services rendered to their members are eligible for benefits. To understand if a service is eligible for payment, it is important to verify the member's benefits **prior** to providing services. In certain circumstances, the member may be financially responsible for services beyond the benefit provided for eligible services.

Claims are subject to payment edits that are updated at regular intervals and generally based on Current Procedural Terminology (CPT®), Health Care Procedural Coding System (HCPCS), Internal Classification of Diseases, CMS National Correct Coding Initiative Edits, Specialty Society guidelines, etc.

Eligible Providers

This policy applies to all providers/facilities contracted with the Plan's Network (participating/in-network) and any non-participating/out-of-network providers/facilities.

Audit Information

Blue Cross VT reserves the right to conduct audits on any provider and/or facility to ensure adherence with the guidelines stated in the payment policy. If an audit identifies instances of non-adherence with this payment policy, Blue Cross VT reserves the right to recover all non-adherence payments.

Legislative and Regulatory Guidelines (not applicable)

Related Policies (not applicable)

Document Precedence

The Blue Cross VT Payment Policy Manual was developed to provide guidance for providers regarding Blue Cross VT payment practices and facilitates the systematic application of Blue Cross VT member contracts and employer benefit documents, provider contracts, Blue Cross VT corporate medical policies, and Plan's claim editing logic. Document precedence is as follows:

1) To the extent that there may be any conflict between the Blue Cross VT Payment Policy Manual and the member contracts or employer benefit documents, the member contract or employer benefit document language takes precedence.
2) To the extent that there may be any conflict between the Blue Cross VT Payment Policy Manual and provider contract language, the provider contract language takes precedence.
3) To the extent that there may be any conflict between the Blue Cross VT Payment Policy Manual and corporate medical policy, the corporate medical policy takes precedence.
4) To the extent that there may be any conflict between the Blue Cross VT Payment Policy Manual and the Plan's claim editing solutions, the Plan's claim editing solution takes precedence.

Policy Implementation/Update Information

This policy was originally implemented in November 2010

Date of Change	Effective Date	Overview of Change
07/31/2025	11/01/2025	This policy is moving from a Medical Policy to a Payment Policy. Formatting changed and moved to new template.

Approved by **Update Approved: 07/31/2025**

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