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Drug Wastage Corporate Medical Policy

File Name: Drug Wastage
File Code: 5.01.VT201
Origination: 11/2010
Last Review: 06/2024
Next Review: 06/2025
Effective Date: 07/01/2024

Description/Summary

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

The plan 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, BCBSVT may cover the amount of the drug discarded along with the amount administered according to the criteria described below.

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.

When a service may be considered medically necessary

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

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 for the 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.

BCBSVT 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.

When a service is considered not medically necessary

- Any criteria above 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 BCBSVT 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.

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all noncompliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

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.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits

may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

11/2016	External input received from Equicclaim Emdeon
11/2016	Converted Medical policy to new template format. Added the word “mg” to clinical example. Guidance on -JW modifier added in policy language.
04/2017	New language related to exception for SDV for drugs that currently on the FDA Drug Shortage List
01/2019 02/2019	No change to policy statement. References updated. Added allowance for certain qualified healthcare professionals to be exempted from this policy.
01/2020	No changes to policy statements.
02/2021	No changes to policy statements.
01/2022	No changes to policy statements.
06/2023	Minor grammatical changes. Updated reference. No changes to policy statements.
06/2024	Policy reviewed. No change to policy statement.

Health Care Procedure Coding System (HCPCS) codes related to chemotherapy drugs, drugs administered other than oral method, and enteral/parenteral formulas may be subject to National Drug Code (NDC) processing and pricing. The use of NDC on medical claims helps facilitate more accurate payment and better management of drug costs based on what was dispensed and may be required for payment. For more information on BCBSVT requirements for billing of NDC please refer to the provider handbook located here:
<https://www.bluecrossvt.org/documents/provider-handbook>

Qualified healthcare professionals (QHP) practicing within the scope of their license(s) with the exception of those QHP who have facility standard operating procedures inclusive of the CDC statement intent below and their respective Boards of Pharmacy Rules.

Qualified healthcare personnel may repackage medication from a previously unopened single - dose/single-use vial into multiple single-use vehicles (eg syringes). This should only be performed under iso class 5 conditions in accordance with standards in the United States pharmacopeia general chapter 797, pharmaceutical compounding - sterile preparations, as well as the manufacturer’s recommendations pertaining to safe storage of that medication outside of its original container
https://www.cdc.gov/injection-safety/hcp/clinical-safety/?CDC_AAref_Val=https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html

Approved by BCBSVT Medical Directors

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