MEDICAL COVERAGE POLICY	
SERVICE:	**Drugs & Biologicals Wastage**
Policy Number:	**318**
Effective Date:	**07/01/2025**
Last Review:	**05/12/2025**
Next Review:	**05/12/2026**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

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PRIOR AUTHORIZATION: not applicable

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to Medicare LCA (Local Coverage Article) A53049 Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents

For Medicaid plans, please refer to Section 7.1 JW Modifier Claims Filing Instructions in the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM).

Baylor Scott & White Health Plan (BSWHP) follows the Centers for Medicare & Medicaid Services (CMS) policy for drug wastage modifiers (JW and JZ). The CMS encourages physicians, hospitals and other providers and suppliers to care for and administer drugs and biologicals to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. According to the Social Security Act (SSA) Section 1861(v)(1)(A), the reasonable cost of any service is the cost actually incurred, excluding any part of an incurred cost found to be unnecessary in the efficient delivery of needed health services. On this basis, the definition of a reasonable cost for a drug or biological is met when the beneficiary is administered the required dose of the drug or biological in an efficient manner.

JW Modifier Requirement

The JW modifier is used to identify unused drugs or biologicals from single use vials or single use packages that are appropriately discarded. The discarded amount shall be billed on a separate claim line using the JW modifier. Providers are required to document the discarded amounts of drugs or biologicals in the patient's medical record.

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

1. The vial/package must be a single-use vial/package.
2. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer/supplier that could provide the appropriate dose for the patient.

a. For example, if a 5 milligram (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 1 milliliter (mL) vial, 5 mg per 1 mL vial, and 10 mg per 1 mL vial, the correct single dose vial to use would be the 5 mg/1 mL vial as this involves the use of only one vial and there would not be any drug wastage.
b. If a larger dose is used when a smaller one suffices, reimbursement would only be for the smallest dose available that could provide the appropriate dose. If only larger doses are available, providers may request coverage through the appeals process. As part of the appeal documentation, an explanation will be required as to why the higher dose vials were utilized. In addition to the explanation, a corrected claim may be required with the appeal showing a breakout of charges for the allowed waste for the smaller dosing, billed amount and NDC and another line showing the excessive waste, billed amount and NDC. Payment is limited to the dosing for the smaller vials and any associated waste with that dosing if applicable.

3. The left-over amount must actually be discarded and may not be used for another patient.

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 mg of a drug is administered, it is appropriate to bill for 3 units if the HCPCS defines the unit for this drug as 1 mg.

The JW modifier is not permitted when the actual dose of the drug or biological administered is less than the billing unit. 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 a patient while 3 mg of the remaining drug is discarded. The 7 mg dose is billed using one billing unit that represents 10 mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10 mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3 mg of drug is not permitted because it would result in overpayment. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted.

CMS guidelines state to report the drug amount administered on one line, and on a separate line report the amount of drug not administered (discarded) with modifier JW appended to the associated CPT/HCPCS code. When more than one vial is administered with different National Drug Codes (NDCs), each NDC used should be reported on a separate claim line along with the appropriate units given from each vial. An additional line is then added indicating the discarded units with modifier JW. The JW modifier is only applicable to the amount of the drug discarded and not the amount administered.

<u>Billing Examples:</u>

Example #1: If 750 mg of rituximab is administered, it is proper to bill for 75 units J9312 since the CPT/ HCPCS code J9312 defines the unit for rituximab as 10mg. If 800mg total are used, but only 750 mg are administered, then 50 mg are wasted and documented in the medical record. Since the

administered amount requires billing 75 units of J9312, 50 mg of wastage is billed on a separate service line as 5 units of J9312 (along with the JW modifier) that is not used.

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

Example #3: Rituximab is available in single-use vials of 100 mg/10 mL and 500 mg/50 mL. The CPT/HCPCS code and description for rituximab is J9312, rituximab 10 mg. If 750 mg are administered to the member, the most proper combination of Rituxan vials to minimize wastage for a 750 mg dose is one 500 mg/50 mL 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 reimbursement review as this combination does not meet the requirement to use the most appropriate packaging that can be purchased to make the member's administered dose and minimize waste.

JZ Modifier Requirement

Providers must report the JZ modifier (Zero drug amount discarded/not administered to any patient) when there is no wastage to report. This must be reported on all claims that bill for drugs when there is no discarded amount from single-dose containers or single-use packages. For the amount administered, the claim line must include the billing and payment code, the JZ modifier showing no discarded amounts, and the number of units administered in the units' field.

The JW and JZ modifier policy does not apply for drugs that are not separately payable, such as packaged OPPS or ASC drugs, or drugs administered in the FQHC or RHC setting or to drugs assigned status indicator N (Items and Services Packaged into APC Rates) under the OPPS. Similarly, the JW and JZ modifiers do not apply to drugs assigned payment indicator "N1" (ASC).

POLICY HISTORY:

Status	Date	Action
New		New policy

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can

be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services.
2. Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
3. Centers for Medicare and Medicaid Services, CMS Manual System or other CMS publications and services

***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.