CLINICAL PAYMENT AND CODING POLICY

If a conflict arises between a Clinical Payment and Coding Policy (CPCP) and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions and other coverage documents. BCBSTX may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSTX has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from 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), ICD-10 CM and PCS, National Drug Codes (NDC), Diagnosis Related Group (DRG) guidelines, Centers for Medicare and Medicaid Services (CMS) National Correct Coding Initiative (NCCI) Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Wasted/Discarded Drugs and Biologicals Guideline

Policy Number: CPCP017

Version 3.0

Clinical Payment and Coding Policy Committee Approval Date: September 11, 2020

Plan Effective Date: January 10, 2021 (Blue Cross and Blue Shield of Texas)

Description

The intent of the Wasted/Discarded Drugs and Biologicals Guidelines Clinical Payment and Coding Policy is to minimize potential waste and/or abuse by providing a guideline for appropriate billing and reporting practices for discarded drugs and biologicals. This policy is not intended to impact care decisions or medical practice.

Definitions:
Drug Waste: The partial vial, package, or product of drug or biologic that is discarded and not administered to any member**.**
JW Modifier: Drug amount discarded/not administered to any member.
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.
Overfill: Any excess product (that is, 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.
Single-use vials/packages: A drug or biologic package that allows only one (1) dose to be withdrawn for administration by injection or infusion.

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 member. Reimbursement and payment are determined by the Plan Documents under which the member is entitled to Covered Services. Providers, facilities and suppliers are encouraged to administer and care for members in a way that drugs and biologicals are used most efficiently 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.

JW Modifier Usage

The JW modifier is a CPT/HCPCS Level II modifier that is used to report the amount of drug or biological that is discarded. The actual dosage of drugs or biologicals must be reported with the correct CPT/HCPCS code and the correct units of service. The discarded amount must be billed on a separate line with the JW modifier for all non-inpatient places of service.

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

Eligible reimbursement for drugs and biologicals when reported with the JW modifier must meet the following criteria:

- The dose administered, discarded amount, exact date and time of administration and reason for wastage is 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 member/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 member appropriately for the members' 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 member.
- 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.

Billing Examples:

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 50mg 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.

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 member, then four 150mg vials (total 600mg) should be utilized. When 600mg are utilized but only 575mg are administered, then 25mg 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 member, 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 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.

When Drugs and Biologicals are not Eligible for Reimbursement

Examples of non-reimbursable drugs and biologicals, including whole vial or package waste, are:

- ✓ 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 NDC units.
- ✓ Single-use vials which have been reimbursed for discarded/wasted drugs, using the JW modifier, for one member may not be billed for use on other members or 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 member missing an appointment or the member changes their mind after 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 members.
- ✓ A Neulasta OnPro® (J2505) that is applied but fails to deliver the drug.
- ✓ The member mishandles or damages the drug, requiring a replacement dose.
- ✓ Drug stored outside the storage requirements described within the product(s) prescribing information.
- ✓ The shipping company damages the drug en 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 hurricanes, earthquakes, flooding, fires, etc.
- ✓ Theft from member.

The Plan reserves the right to request supporting documentation. Claim(s) that do not adhere to coding and billing guidelines may result in a denial or reassigned payment rate.
Wasted/discarded drug and biological claim submissions are evaluated on a case-by-case basis that may include a review of applicable medical documentation including documentation of drug product preparation.

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

References:

CPCP018 Outpatient Facility and Hospital Claims: Revenue Codes Requiring CPT or HCPCS Codes

CMS Medicare Claims Processing Manual, Chapter 17, Drugs and Biologicals
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

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf

Federal Register, Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Accessed June 4, 2020:
https://www.federalregister.gov/documents/2010/11/29/2010-27969/medicare-program-payment-policies-under-the-physician-fee-schedule-and-other-revisions-to-part-b-for

Policy Update History:

Approval Date	Description
06/29/2018	New policy
06/26/2019	Annual Review
09/11/2020	Annual Review, Disclaimer update, Verbiage updates