Discarded Drugs and Biologicals Waste

Purpose

This policy is intended to ensure correct provider reimbursement and serves only as a general resource about Molina Healthcare's reimbursement policy for the services described in this policy. It is not intended to address every aspect of a reimbursement situation, nor is it intended to change care decisions. This policy was developed using nationally accepted industry standards and coding principles. In a conflict, federal and state guidelines, as applicable, and the member's benefit plan document supersede the information in this policy. Also, to the extent of conflicts between this policy and the provider contract language, the Provider contract language will prevail. Coverage may be mandated by applicable legal requirements of a State, the Federal government or the Centers for Medicare and Medicaid Services (CMS). References included were correct at the time of policy approval. If there is a state exception, please refer to the state exception table listed below.

Policy Overview

This policy delineates the reimbursement guidelines concerning Discarded Drugs and Biologicals, named by modifier JW, administered from single-use vials, single-use packages, and multi-use vials. Providers may receive reimbursement for Discarded Drugs and Biologicals when compliant with the policy's reimbursement guidelines. All services covered by this policy may also be subject to more reimbursement policies from Molina Healthcare Inc, including the NCCI Editing Policy and Maximum Frequency per Day, among others. The primary aim of the Wasted/Discarded Drugs and Biologicals Clinical Payment and Coding Policy is to mitigate potential waste and/or abuse by offering guidance on proper billing and reporting practices for discarded drugs and biologicals. It is important to note that this policy is not intended to influence care decisions or medical practice.

Reimbursement Guidelines

When a physician, hospital, or other provider or supplier must dispose of the remaining contents of a single-use/dose vial (SDV) or other single-use/dose package after administering a drug or biological, reimbursement may be provided for both the administered dose and the amount discarded, up to the quantity indicated on the vial or package label.

When billing for drugs, units of service should be invoiced in multiples of the dosage specified in the complete CPT/HCPCS descriptor. This descriptor may not always align with the actual dose administered. Ideally, the units billed should correspond with the smallest available dose (vial) from the manufacturer(s) that can deliver the proper dose for the patient, while minimizing wastage.

Molina Healthcare will not reimburse for wastage where the drug is not separately payable.

Molina Healthcare will conduct a thorough evaluation of any drugs and biologicals billed to ensure they align with the smallest available dose (vial) from the manufacturer that can effectively deliver the prescribed dosage to the patient. Charges that exceed the billing procedure based on the smallest dose (vial) will not be included in the final claim payment calculation.

For instance, if the CPT/HCPCS code for Drug A specifies 1 unit as 30 mg, and Drug A is available in vials of 60 mg and 90 mg, with a prescribed dosage of 48 mg, if the provider uses a 90 mg vial, they may only submit 2 units (rather than 3 units), as the doses available from the manufacturer permit the prescribed amount to be administered with a 60 mg vial.

The JW modifier is exclusively allowed to show discarded amounts from a single vial or package of drug or biological. It is inappropriate to append the JW modifier to a multi-dose vial (MDV).

It's important to note that Molina Healthcare does not reimburse for the wastage of drugs from multi-dose vials or packages. Any charges associated with waste from multi-dose vials or packages, as substantiated by the medical record and itemized bill, will be excluded from the final claim payment calculation.

CMS guidelines dictate reporting the administered drug amount on one line and the discarded amount (with modifier JW) on a separate line alongside the associated CPT/HCPCS code. If multiple vials with different National Drug Codes (NDCs) are administered, each NDC should be reported on a separate claim line along with the proper units dispensed from each vial. An added line should then show the discarded units with modifier JW, applicable only to the discarded amount, not the administered amount.

The JW modifier is not permissible when the actual dose administered is less than the billing unit. To prevent overpayment, providers and facilities must always round the administered amount up to the next billing unit and round down when reporting the discarded amount.

For instance, if a CPT/HCPCS code is billable in 10 mg increments and 77 mg is administered from a 100 mg SDV, eight units may be reported as administered on one line, with 2 units reported on a separate line with modifier JW to indicate the discarded amount.

Both the administered and discarded amounts of the drug or biological must be documented in the patient's medical record. 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 decided 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.

JW Modifier Usage

The JW modifier is a CPT/HCPCS Level II modifier 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 must 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 must 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 supply 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 are clearly 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 part is discarded.
- The units billed correspond with the smallest dose or vial available for purchase from the manufacturer(s) that supplies the proper dosage for the member.
- National Drug Codes (NDC) show 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.

- The JW modifier will not be reimbursed when billed and another claim line for the administered drug is not billed for the same drug and date of service. Claims for whole vial or packages submitted with the JW modifier will not be reimbursed.
- The JW modifier will be reimbursed for wastage for oral products, bulk powders, or self-administered formulations.

Billing Examples:

- Example #1: If 750 milligrams (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 750mg are administered, then 50mg are wasted and documented in the medical record. Since the administered amount requires billing seventy-five units of J9312, 50mg of wastage is billed on a separate service line as five units of J9312 (along with the JW modifier) that is not used.

- Example #2: Trastuzumab is available in 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 used. When 600mg are used but only 575mg are administered, then 25mg are wasted and documented in the medical record. The correct billing is fifty-eight 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 proper 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 proper packaging can be bought.

- Reimbursement will not be given to a provider or hospital due to a member missing an appointment or the member declining administration 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 members.

- On-body injector system that has been applied, but the drug does not deliver. Examples include, but are not limited to, Neulasta OnPro® (J2506- Injection, pegfilgrastim, excludes biosimilar, 0.5 mg eff 1/1/2022, J2505- Injection, pegfilgrastim, 6 mg pre 1/1/2022) or UDENYCA (pegfilgrastim-cbqv) co-packaged with on-body injector (Q5111- Injection, pegfilgrastim-cbqv (udenyca), biosimilar, 0.5 mg eff 1/1/2019).

- 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 in route to the member or provider.

- The provider mishandles, damages, or does not appropriately reconstitute the drug.

- Theft from provider or shipping company.

- Drug or biologicals for members enrolled in a program which requires drug manufacturers to enter into a National Drug Rebate Agreement (NDRA) and the NDC is not eligible for rebate on the date of service.

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 the same date of service.
- Member 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 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.

Audit and Recovery Process:

- **Review:** Claims will be meticulously examined against Molina Healthcare's standards.
- **Discrepancy Identification:** Any inconsistencies or errors found will be documented.

- **Recovery:** Overpayments due to inaccuracies will be recovered either by offsetting from future payments or through direct refund requests.
- **Appeals:** Providers reserve the right to contest any claim adjustments or denials. Details of the appeal process will go with the notification.

Policy Monitoring, Review, and Updates:

- The policy will undergo annual reviews or as needed, ensuring its alignment with industry best practices, regulatory mandates, and Molina Healthcare's operational necessities. Any updates will be promptly communicated to providers.

Supplemental Information

Definitions

Term	Definition
CMS	the Centers for Medicare & Medicaid Services. It is a federal agency within the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Health Insurance Program (CHIP), and health insurance portability standards.
Discarded Drug or Biological	The amount of a single use/dose vial or other single use/dose package that remains after administering a dose/quantity of a Drug or Biological.
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 two be withdrawn for administration by injection or infusion. (Note, use of modifier JW is not proper for drugs that are from multiple dose vials or packages.)
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.

Documentation History

Type	Date	Action
Published		
Revised Date		

References

- CPT® (Current Procedural Terminology) | AMA (ama-assn.org)
- HCPCS - General Information | CMS
- Medicare Claims Processing Manual (cms.gov)
- Drugs and biologicals Part B – Using the JW and JZ modifiers (novitas-solutions.com)

- Article - Billing and Coding: Erythropoiesis Stimulating Agents (A58982) (cms.gov)
- FDA Drug Shortages
- Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions (cms.gov)
- Federal Register, Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Accessed June 4, 2020: Federal Register :: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011
- National Council for Prescription Drug Programs (NCPDP) Standards: Standards - Access to Standards (ncpdp.org)
- National Uniform Claim Committee (NUCC) 1500 Health Insurance Claim Form, Reference Instruction Manual: National Uniform Claim Committee - Search (nucc.org)
- High-Dollar-Pharmacy.pdf (molinahealthcare.com)
- MI 3 day_iDay Rule (molinahealthcare.com)
- NDC.pdf (molinahealthcare.com)

This policy is designed to supply guidance and is not a guarantee of payment. Healthcare providers should make medical necessity determinations based on the individual clinical circumstances of each patient.