moda HEALTH	Reimbursement Policy Manual	Policy #:	RPM015
Policy Title:	**Modifiers JW & JZ – Drugs and Biologicals, Wastage and/or Discarded Amounts**		
Section:	Modifiers	Subsection:	None

Scope: This policy applies to the following Medical (including Pharmacy/Vision) plans:

Companies:	☒ All Companies: Moda Partners, Inc. and its subsidiaries & affiliates ☐ Moda Health Plan ☐ Moda Assurance Company ☐ Summit Health Plan ☐ Eastern Oregon Coordinated Care Organization (EOCCO) ☐ OHSU Health IDS
Types of Business:	☒ All Types ☐ Commercial Group ☐ Commercial Individual ☐ Commercial Marketplace/Exchange ☐ Commercial Self-funded ☐ Medicaid ☐ Medicare Advantage ☐ Short Term ☐ Other: _____
States:	☒ All States ☐ Alaska ☐ Idaho ☐ Oregon ☐ Texas ☐ Washington
Claim forms:	☒ CMS1500 ☒ CMS1450/UB (or the electronic equivalent or successor forms)
Date:	☒ All dates ☐ Specific date(s): _____ ☐ Date of Service; For Facilities: ☐ n/a ☐ Facility admission ☐ Facility discharge ☐ Date of processing
Provider Contract Status:	☒ Contracted directly, any/all networks ☒ Contracted with a secondary network ☒ Out of Network

Originally Effective:	12/1/2006	Initially Published:	7/6/2011
Last Updated:	9/19/2023	Last Reviewed:	9/20/2023
Last update includes payment policy changes, subject to 28 TAC §3.3703(a)(20)(D)? Yes			
Last Update Effective Date for Texas:		9/20/2023	

Reimbursement Guidelines

A. General Policy Statement

We follow CMS requirements for all claims and all lines of business.

1. Providers and suppliers are required to report the JW modifier on all professional and outpatient facility claims for separately reimbursable drugs and biologicals (hereafter, drugs) with unused, wasted, and/or discarded amounts (hereafter, discarded amounts or wastage) from single-dose vials, single-dose containers or single- use packages (hereafter, single-dose containers).

2. Also, the amount of discarded drug(s) must be clearly documented in the medical record.

3. Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all professional and outpatient facility claims for separately reimbursable drugs from single-dose containers when there are no discarded amounts.

4. Practitioners and facilities are expected to care for and administer drugs and biologicals to patients in such a way as to use the drugs in the most efficient manner, minimize waste, and in a clinically appropriate manner. (CMS[1, 5, 6])

B. NDC Numbers

Please include NDC numbers in addition to the HCPCS code when billing for drugs, to facilitate accurate pricing of the drug supply.

C. Correct Reporting of Units

Units of service must be reported correctly.

Each HCPCS/CPT code has a defined unit of service for reporting purposes. A physician or facility should not report units of service for a HCPCS/CPT code using a criterion that differs from the code's defined unit of service. (CMS[3])

D. Discarded or Wasted Amounts

1. Discarded or wasted amounts of drug from multi-dose vials are not eligible for reimbursement.

2. Discarded or wasted amounts of drug will be reimbursed **only** when all of the following requirements are met:

    a. The drug is only supplied in single-dose containers.

    The determination of a single-dose or single-use vial is based on FDA-approved labeling. (CMS[4])

    b. The drug must be considered eligible for wastage reimbursement under CMS guidelines, which includes the definition of a "refundable single-dose container or single-use package drug." (CMS[8])

    c. The physician's orders for the drug must be clearly and completely documented in the medical record. When the physician order for the drug is written in terms of patient specific factors (weight, body surface area, etc.), records documenting current measurements of those specific factors must also be included with the records provided for review.

    d. The amount of drug administered, and the amount discarded must be clearly and completely documented in the medical record.

        i. If the drug is wasted in the Pharmacy area at the time the infusion is mixed and prepared, the Pharmacy Dispense documentation must reflect the amount of drug prepared for administration and the amount of drug wasted. An example of acceptable documentation is:

Ipilimumab
GIVEN: 276 mg
Pharmacy dispense: NDC: 00003232711 Dispensed/Waste: 76mg/24mg
Pharmacy dispense: NDC: 00003232822 Dispensed/Waste: 200mg/0mg
Pharmacy plan: Dispense/Waste: 276/0mg
Given Dose/Discard: 276/0mg
Given Date: 4/16/2019
Given Time: 10:06 am
Given By: Jane Doe, RN

ii. If during administration the drug is discontinued before completion for any reason, and the medication administration record (MAR) must include:

1) The reason for discontinuation.

2) The date and time the additional drug was discarded,

3) The amount discarded (an estimate of the amount or cc's remaining is acceptable),

4) The name, licensure, and signature of the person who administered the drug.

5) If a separate person performed the discontinuation and wastage, the name, licensure and signature of that person is also needed.

iii. A charge capture report is not considered part of the medical record and is not acceptable documentation to support drug wastage charges.

See Example of a Charge Capture Report in the Appendix.

e. The amount of drug that is actually administered to the member is billed on one line on the claim.

f. The amount of drug that was wasted or discarded is billed separately on a second line item, with modifier JW attached. (CMS[1])

g. Reimbursement will be allowed for only the minimum amount of drug above what was ordered to arrive at the nearest whole vial using the vial size and dose that result in the smallest possible discarded amount.

i. For example:

1) If the physician orders for the patient to receive 180 mg of the drug in question, and the drug is manufactured in both a 100 mg single-use vial and a 150 mg single-use vial, then we will only reimburse for 20 mg of wastage (the result of using two 100 mg vials).

2) If the provider only has 150 mg single-dose containers on hand on the date of service in question and two 150 mg vials are used for the 180 mg dose, 120 mg will be wasted. In this instance, we will still only reimburse for 20 mg of wastage. The remaining 100 mg of wasted drug is excess wastage that is not eligible for reimbursement and becomes a business expense or loss incurred by the billing provider due to not having the 100 mg vials available when needed.

ii. Any excess wastage amount (billed with modifier JW but greater than the minimum wastage amount possible as described above) will be denied to provider write off as bundled or included in the reimbursement for the drug administered.

Should extenuating circumstances not allow for vial optimization and minimizing wastage, a written appeal with an explanation may be submitted for review by Pharmacy Services for a possible rare exception to allow the full amount of wastage.

3. Any excess drug billed without modifier JW which is above what is ordered or administered and documented will be denied to provider write off as not documented or supported in the medical record.

4. Claim reviews and audits for this and other concerns will be conducted by our staff and/or our business associates (contracted claim review vendors). When records are received in response to the records request, the items received are deemed to be the total documentation needed to

support the services billed; any items later received are deemed not to have existed at the time the claim was submitted.

a. Amended records will not be accepted once the audit review is complete. Missing documentation not included in the initial records submitted will be accepted for reconsideration
b. Therefore, it is the responsibility of the billing provider to ensure that their responses to records requests are both prompt and complete.
c. If the physician's order, drug administered, and amount wasted or discarded are not clearly, completely, and properly documented in the medical records supplied for review, any excess billed amounts will be denied to provider write-off due to the insufficient documentation.

5. Denials of drug amounts following a claim review/audit may be disputed by submitting a written appeal.

   a. The documentation submitted for appeal consideration should include a written explanation of how the records provided for the original review support the items and quantities billed, and how the number of billed units was calculated from those physician's orders and records.

   b. Additional records not submitted for the original review cannot be considered in the appeal process.

E. When No Drug is Wasted

Effective July 1, 2023, modifier JZ must be reported on all claim line items for drugs eligible for separate reimbursement when there is no discarded amount from single-dose containers. (CMS[4, 5, 6])

F. Wastage Status Must Be Declared with Modifier JW or JZ

1. CMS requirements for drug wastage are followed for all types of plans.

2. Effective for dates of service beginning July 1, 2023, all claims for separately reimbursable drugs from single-dose containers must be billed with either modifier JW to declare the amount of wastage or modifier JZ to declare the full amount was given and there was no wastage.

3. Effective for dates of service beginning October 2, 2023, procedure codes of separately reimbursable drugs with single-dose containers billed without either modifier JW or JZ will be denied for missing a required modifier.

4. Claims for procedure codes of separately reimbursable drugs with single-dose containers billed without either modifier JW or JZ for dates of service July 1, 2023 through October 1, 2023 may be subject to audits and denials for missing a required modifier.

G. For Further Questions

For further questions about the use of modifiers JW and JZ, please see:

- "Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions." (CMS[6])

- "CY2023 Part B Final Rule, Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts - Refundable Single-Dose Container or Single-Use Package Drug." (CMS[8])

Codes, Terms, and Definitions

Acronyms & Abbreviations Defined

Acronym or Abbreviation		Definition
AMA	=	American Medical Association
CCI	=	Correct Coding Initiative (see "NCCI")
CMS	=	Centers for Medicare and Medicaid Services
CPT	=	Current Procedural Terminology
DRG	=	Diagnosis Related Group (also known as/see also MS DRG)
eMAR	=	Medication Administration Record, electronic version
HCPCS	=	Healthcare Common Procedure Coding System (acronym often pronounced as "hick picks")
HIPAA	=	Health Insurance Portability and Accountability Act
MAR	=	Medication Administration Record
MS DRG	=	Medicare Severity Diagnosis Related Group (also known as/see also DRG)
NCCI	=	National Correct Coding Initiative (aka "CCI")
NCD	=	National Drug Code
RPM	=	Reimbursement Policy Manual (e.g., in context of "RPM052" policy number, etc.)
UB	=	Uniform Bill

Definition of Terms

Term	Definition
Medication Administration Record (MAR or eMAR)	The report or document that serves as a record of the drugs administered to a patient at a facility by a health care professional. This document must contain the following minimum information: Patient first & last name, name of drug, dose of drug, route of administration, date of administration, time of administration, signature (name) and title of person administering. For single-dose containers, if any drug wastage, note the amount wasted.
Multi-use Multi-dose	FDA-approved labeling for the drug indicates the product is safe to use for dispensing multiple doses within a specified period of time from when the seal is initially broken/opened.

Term	Definition
Single-use Single-dose	FDA-approved labeling for the drug indicates the product is not safe to use for dispensing multiple doses and must be discarded after the first dose is dispensed.

Modifier Definitions:

Modifier	Modifier Description & Definition
Modifier JW	Drug amount discarded/not administered to any patient
Modifier JZ	Zero drug amount discarded/not administered to any patient

Coding Guidelines & Sources - (Key quotes, not all-inclusive)

Modifier JW is a HCPCS Level II modifier similar to modifiers AS, LT, RT, finger modifiers F1-FA, toe modifiers T1-TA, etc. While modifier JW was created by CMS, and CMS contractors may or may not require its use, the use of modifier JW is not limited exclusively to CMS members or plans.

"When processing claims for drugs and biologicals (except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP)), local contractors may require the use of the modifier JW to identify unused drug or biologicals from single use vials or single use packages that are appropriately discarded. This modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. For example, a single use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units may be billed on another line by using the JW modifier. Both line items would be processed for payment.

The JW modifier is only applied to the amount of drug or biological that is discarded. A situation in which the JW modifier is not permitted is when the actual dose of the drug or biological administered is less than the billing unit." (CMS[1] pre-6/19/2016 version)

"Effective January 1, 2017 when processing claims for drugs and biologicals (except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP)), local contractors shall require the use of the modifier JW to identify unused drugs or biologicals from single use vials or single use packages that are appropriately discarded. This modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. For example, a single use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95 unit dose is billed on one line, while the discarded 5 units shall be billed on another line by using the JW modifier. Both line items would be processed for payment. Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.

The JW modifier is only applied to the amount of drug or biological that is discarded. A situation in which the JW modifier is not permitted is when the actual dose of the drug or biological administered is less than the billing unit." (CMS[1] 6/19/2016 update effective for DOS 1/1/2017 & following. "May require" is now changed to "shall require.")

"Physicians must report units of service correctly. Each HCPCS/CPT code has a defined unit of service for reporting purposes. A physician should not report units of service for a HCPCS/CPT code using a criterion that differs from the code's defined unit of service." (CMS[3])

"With regard to the exclusion of radiopharmaceuticals and imaging agents, we recognize contrast agents as a category of imaging agents as described in FDA's Guidance for Industry referenced in the proposed rule. Therefore, we clarify that contrast agents are excluded from the definition of refundable single-dose container or single-use package drug." (CMS[8])

Cross References

None.

References & Resources

1. CMS. *Medicare Claims Processing Manual* (Pub. 100-4). Chapter 17 – Drugs and Biologicals, § 40.

2. Verhovshek, G. John, MA, CPC. "Drug Waste = Money." AAPC. August 20, 2010. April 7, 2011 < http://news.aapc.com/index.php/2010/08/drug-waste-money/>.

3. CMS. *National Correct Coding Initiative Policy Manual*. Chapter 1 General Correct Coding Policies, § A.

4. CMS. "New JZ Claims Modifier for Certain Medicare Part B Drugs." *MLN Matters,* MM13056, June 2, 2023. https://www.cms.gov/files/document/mm13056-new-jz-claims-modifier-certain-medicare-part-b-drugs.pdf .

5. CMS. "Discarded Drugs and Biologicals: Updated FAQs on JW & JZ Modifiers." MLN Connects Newsletter, Friday, July 27, 2023. 2023-07-27-MLNC. https://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/provider-partnership-email-archive/1368246344/2023-07-27-mlnc .

6. CMS. "Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions." Last updated: July 27, 2023; last accessed July 27, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf .

7. CMS. "New JZ Claims Modifier for Certain Medicare Part B Drugs." MLN Connects Newsletter, June 15, 2023, 2023-06-15-MLNC. https://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/provider-partnership-email-archive/2023-06-15-mlnc .

8. CMS. "CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts - Refundable Single-Dose Container or Single-Use Package Drug." See sections III.A.3.a-c, pages 69719 - 69724. Published November 18, 2022; Effective January 1, 2023; Last accessed September 19, 2023. https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other .

Background Information

A large majority of drugs and biologicals are issued in multi-dose vials. However, some drugs and biologicals do not have the stability needed for multi-dose vials and are packaged in single-dose containers. The package insert for each individual drug or biological will specify the dosing and administration instructions, stability of the product, and time frames when the substance may be safely administered and after which it must be discarded.

CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. For instance, some chemotherapy drugs are both highly effective and highly expensive. Oncology and chemotherapy clinics commonly schedule multiple patients to receive treatments of the same drug concurrently. However, there may be occasions when the remainder of a single dose vial or single use package must be discarded after administering a dose/quantity of the drug or biological to a member.

In this policy, both drugs and biologicals are collectively referred to with the generic terms "drug" or "drugs."

Modifier JW was created effective 1/1/2003. Effective 1/1/2017 CMS began to require the use of modifier JW to report the drug wastage for single use vials. (CMS[1]) Prior to 1/1/2017 the use of modifier JW was encouraged but not required.

Modifier JZ was created effective 1/1/2023. Effective 7/1/2023 CMS began to require that all claims for separately payable drugs under Part B from single-dose vials must be reported with either modifier JW or modifier JZ. Effective 10/2/2023 CMS will deny line items for these drugs if not submitted with either modifier JW or modifier JZ.

IMPORTANT STATEMENT

The purpose of this Reimbursement Policy is to document our payment guidelines for those services covered by a member's medical benefit plan. Healthcare providers (facilities, physicians, and other professionals) are expected to exercise independent medical judgment in providing care to members. Our Reimbursement Policy is not intended to impact care decisions or medical practice.

Providers are responsible for submission of accurate claims using valid codes from HIPAA-approved code sets and for accurately, completely, and legibly documenting the services performed. Billed codes shall be fully supported in the medical record and/or office notes. Claims are to be coded appropriately according to industry standard coding guidelines (including but not limited to UB Editor, AMA, CPT, CPT Assistant, HCPCS, DRG guidelines, CMS' National Correct Coding Initiative [CCI] Policy Manual, CCI table edits and other CMS guidelines).

Benefit determinations will be based on the member's medical benefit plan. Should there be any conflicts between our Reimbursement Policy and the member's medical benefit plan, the member's medical benefit plan will prevail. Fee determinations will be based on the applicable provider fee schedule, whether out of network or participating provider's agreement, and our Reimbursement Policy.

Policies may not be implemented identically on every claim due to variations in routing requirements, dates of processing, or other constraints; we strive to minimize these variations.

***** The most current version of our reimbursement policies can be found on our provider website. If you are using a printed or saved electronic version of this policy, please verify the information by going to https://www.modahealth.com/medical/policies_reimburse.shtml *****

Policy History

Date	Summary of Update
9/20/2023	Clarification/Update: Section D.2.b: Added for clarification in response to provider inquiry/appeal. Section G: Second reference added. Coding Guidelines: One quote added. References & Resources: Added 1 entry.
8/9/2023	CMS/Update: Moved to Modifiers section. Section A: General Policy Statement added. Updates to include new information related to modifier JZ: Policy Name change, Sections E & F, 1 entry added to References & Resources, Background Information. Section D.2.f.ii: Clarification added re: extenuating circumstances. Section C added & minor rephrasing/simplification throughout. Section G added. Acronym Table: 2 entries added. Definition of Terms Table added. References & Resources: 3 entries added.
12/14/2022	Policy Change/Update: Change to new header; includes Idaho. Section C.2.c: Wastage documentation requirements revised to better address Pharmacy wastage at time of infusion preparation versus discontinuation of infusion at time of administration. (This change is subject to 28 TAC.) Acronym table: 1 entry added. Coding Guidelines: Added updated version of quote from (CMS[1]) with explanation of change. Background Information: Added paragraph # 4 history of modifier JW. Policy History section: Added. Entries prior to 2022 omitted (in archive storage).
7/6/2011	Policy initially approved by the Reimbursement Administrative Policy Review Committee & initial publication.
12/1/2006	Original Effective Date (with or without formal documentation). Policy based on Claims Management administrative decision based on CMS optional instructions to local Medicare Administrative Contractors (CMS[1] pre-6/19/2016 version)

Appendix

IKnowMed Generation2 Charge Capture Report
3/29/2020

Patient Name:	Primary Ins:	Attending Physician:
DOB:	Secondary Ins:	Billing Provider:
MRN:	Practice:	Seen by:
Appointment:		Location:

Captured Charges

Code	Count	Description	ICD	NCD	Comments
96361	1	Hydration – Additional	C43.61, Z51.11		
96413	1	Chemo Infusion – Initial			
96415	1	Chemo Infusion – Additional			
96417	1	Chemo Infusion – Sequential			
J7040	1	Sodium Chloride IV 0.9%, 500 mL			D/W: 500/0 mL
J9228	300	Ipilimumab IV, 1 mg		00003232711, 00003232822	D/W: 276/24 mg
J9299	100	Nivolumab IV, 1 mg		00003377412	D/W: 92/8 mg

D/W = Dispensed/Wasted

Medication Administration Detail

Start	Stop	Min*	Drug	Waste	Route	Admin Code	Description
10:03 AM	10:33 AM	30	Nivolumab IV 92 mg	8 mg	Piggyback	96417*1	Chemo Infusion- Sequential
10:36 AM	12:09 PM	93	Ipilimumab IV 276 mg	24 mg	Intravenously	96413*1	Chemo Infusion – Initial Chemo Infusion – Additional
12:10 PM	12:41 PM	31	Sodium Chloride IV 0.9%, 500 mL	0 mL	Intravenously	96361*1	Hydration - Additional

** The number of elapsed minutes between start and stop time minus any minutes when there was simultaneous administration with higher RVU's*

Problem List