Policy Information			
Policy Title	Reimbursements for Drugs, Biologics and Other Pharmaceuticals	**Current Version Publish Date**	11/2025
Policy Manual	Reimbursement	**Original Effective Date**	11/2025
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Policy Applicability (LOB)			
☒Medicare Inc	☒Commercial IA	☒Commercial IL	☒Health Choices
☒Medicare WI	☒Commercial WI	☒CPPHP (Kansas)	

Policy Statement and Purpose

This policy addresses the criteria for reimbursement of pharmaceuticals billed to the medical benefit indicated herein. The stipulations are based on CMS coding and payment requirements. Adhering to these guidelines does not imply payment, only eligibility for reimbursement. Actual payment for services will be guided by the administration of pharmaceuticals documented in the medical record, specifically the Medication Administration Record (MAR), as applicable, and the coverage criteria in the patient's contracted medical plan for whom the services are rendered.

This policy is expressly incorporated into and made a part of all reimbursement agreements and will provide context and clarity to the extent there is ambiguity in payment terms and notwithstanding contrary claims with regard to industry standards or practices.

Policy Definitions

CMS: Centers for Medicare and Medicaid Services

CPT: Current Procedural Terminology. A medical code set maintained by the American Medical Association (AMA) that is used to report medical, surgical, and diagnostic procedures and services to entities such as physicians, health insurance companies and accreditation organizations. CPT is included in Level I Healthcare Common Procedure Coding System (HCPCS).

Deprecated NDC: A National Drug Code that is no longer active or in use by the manufacturer, although the code itself remains valid for historical purposes. This status typically indicates that the product associated with the code has been discontinued, reformulated, or otherwise removed from active distribution.

Discarded Drug: The residual amounts of medication or biological product left in syringes or vials after the prescribed dose has been administered. Those portions from single dose vials should be discarded. This discarded portion is also called waste.

Emergency Use Authorization (EUA): As defined by the U.S. Food and Drug Administration (FDA) is a regulatory mechanism that allows the FDA to facilitate the availability and use of medical countermeasures, including vaccines, drugs, diagnostic tests, and medical devices, during public health emergencies.

HCPCS Level II is the national procedure code set for healthcare practitioners, providers, and medical equipment suppliers when filing health plan claims for medical devices, supplies, medications, transportation services, and other items and services.

Indication: A diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given.

Itemized Bill (IB): A statement of all charges billed by a provider for the services rendered for a specific episode of care.

Medication Administration Record (MAR): A comprehensive, organized record of all medications administered to a patient during their stay in a healthcare facility or under a specific care plan. The MAR is considered a legal document as it tracks details of medication administration including medication name, dosage, route of administration, time of administration, and the name and signature of the healthcare professional who administered the dose. The MAR is used in various healthcare settings and are often integrated into electronic health record (EHR).

Modifier JW: A Healthcare Common Procedure Coding System (HCPCS) Level II modifier required to be reported on a claim to report the amount of drug that is discarded and eligible for payment under the discarded drug. The modifier should only be used for claims that bill single-dose container drugs.

Modifier JZ: A Healthcare Common Procedure Coding System (HCPCS) Level II modifier reported on a claim to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for single dose container drugs.

National Drug Code (NDC): A unique 10-digit or 11-digit, 3-segment number, and a universal product identifier for human drugs in the United States. Each medication is assigned a number under Section 510 of the U.S. Federal Food, Drug and Cosmetic Act. It identifies the manufacturer, product and package size.

National Correct Coding Initiative (NCCI): The Centers for Medicare & Medicaid Services (CMS) developed these edits to promote consistent, correct coding and appropriate payment. These coding edits are developed based on the AMA CPT code set and the HCPCS code set, as well as analysis of standard medical and surgical practice and input from various groups, including specialty societies, other national health care organizations, Medicare contractors, providers, and consultants.

Off-label Drug: A non-FDA approved indication that is not listed on the drug's official label/prescribing information. Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication. This includes but is not necessarily limited to, dosage, route of administration, duration, and frequency of administration, and population to whom the drug would be administered.

Qualified Healthcare Practitioner: A physician or other qualified health care professional who is qualified by education, training, licensure/regulation (when applicable) and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service.

Revenue Code: A three or four digit numeric code used to categorize the location or department for a type of service, procedure, or item provided to a patient within a healthcare facility.

Single Dose Vial (SDV): A vial of medication administered via injection or infusion that is meant for use in a single patient for a single injection. Single dose vials lack an antimicrobial preservative making them unsuitable for reuse or storage for future use. Single dose vials are labeled by the manufacturer as "single dose" or "single use" or “preservative free”.

TPN: Total Parenteral Nutrition

Unbundling: Reporting multiple HCPCS/CPT codes when a single code exists for the services performed.

Waste: The discarded portion of a single dose vial or single use drug.

Policy Provisions and Required Procedures

What are the billing requirements to receive payment for administered pharmaceuticals?
Medical Associates Health Plans conforms to CMS coding guidelines. These include the following industry standard codes and code sets: NUBC Revenue Codes, Internal Classification of Disease 10th revision, Clinical Modification (ICD-10-CM) diagnosis code, active Current Procedural Terminology (CPT), Healthcare Common Procedure Coding Systems (HCPCS), and National Drug Codes (NDC). Pharmaceutical charges may be eligible for reimbursement when the reimbursement request is compliant with the coding requirements. Complete and accurate coding is required so that the accuracy of the charge may be determined. Proprietary coding is not acceptable for any charge including those for pharmaceuticals, drugs or biologics. Such charges may result in the denial of the charge.

- **What are the billing requirements for prescription drugs?**
  All prescription drug charges, regardless of setting, must be billed with a valid and active NDC that is approved by FDA and deemed effective for the indication unless FDA has deemed the drug approved for Emergency Use Authorization (EUA). Charges associated with invalid, inactive, or deprecated NDCs for the date of service that the drug was administered will not be reimbursed.

  The HCPCS Level II codes and units administered must also be billed. The billed units must be consistent with the AMA billing units for the drug. The drug or biologic administered must be documented in the medical record as well as the medical necessity of the substance.

  If an itemized bill is requested, it must include for each pharmaceutical charge the Revenue code, the NDC, the HCPCS Level II code and the appropriate billing units for the dose administered.

  Pharmaceutical charges without the requisite coding that is complete, valid and active may result in the denial of the charge.

- **Newer drugs may not have an assigned HCPCS Level II code. How should these drugs be billed?**
  The following unlisted codes should be used for drugs and biologics without assigned HCPCS Level II coding.

  Bill one unit for any of the following unlisted codes. If more than one unit is billed, additional units may be denied as *excessive unit charge*.

  - INPATIENT FACILITIES
    - J3490 Unclassified drugs
    - J3590 Unclassified biologics
    - J9999 Unclassified anti-neoplastic drug

  - OUTPATIENT FACILITIES
    - C9399 Unclassified drugs or biologics

  - OFFICE SETTING
    - J3490 UNCLASSIFIED DRUGS
    - J3590 UNCLASSIFIED BIOLOGICS
    - J9999 UNCLASSIFIED ANTI-NEOPLASTIC DRUG

  Billing an unlisted code for a drug or biologic that has been assigned a HCPCS Level II code will result in an *incorrect coding denial*.

- **What are the documentation requirements for the administration of drugs and biologics in the medical record?**
  The documentation requirements are specific to the setting. They are as follows:

  - FACILITY SETTING (including operative settings and anesthesia administered via conscious sedation)
    All medication administrations must be documented in the Medication Administration Record (MAR). If the medication in a facility setting is not documented in the MAR, even if documented in the progress notes, operative or procedure notes, the drug will not be reimbursed. The MAR contains all the information that determines whether or not the charge is eligible for reimbursement.

    The MAR must contain all of the following information:
    - **Medical order** signed by a Qualified Healthcare Practitioner PRIOR to discharge
    - **NDC** of the pharmaceutical that was administered
    - **Dose** administered
    - **Amount wasted,** if applicable
    - **Date and time** of administration
    - **Route** of administration
    - **Name of the licensed professional** that administered the drug

  - FACILITY SETTING (general anesthesia administered by an anesthesiologist or CRNA)
    Medication administrations provided for the purposes of general anesthesia do not have to be reported in the MAR but must be documented in the anesthesia record.

    The anesthesia record must contain all of the following information:
    - **NDC** of the pharmaceutical that was administered
    - **Total Dose** administered during the anesthesia
    - **Date and time** of administration
    - **Route** of administration
    - **Name of the anesthesiologist or CRNA** that administered the drug

  - OFFICE SETTING
    Medication administrations must be reported in the encounter notes of the Qualified Healthcare Practitioner rendering the service. The record must include all of the following as it pertains to the medication administration:
    - **Medical necessity**
    - **NDC** of the pharmaceutical that was administered
    - **Dose** administered
    - **Date and time** of administration
    - **Route** of administration
    - **Name of the licensed professional** that administered the drug

- **Are drugs administered off-label reimbursable?**
  Off-label use of drugs and biologicals may be reimbursable for anti-cancer chemotherapeutic regimens. Use of such drugs must have pre-authorization prior to administration. Prior authorization requests must include the following information:
  - Name of the drug
  - Dose administered
  - Route of administration
  - NDC
  - CPT/HCPCS
  - Invoice price including all components of a compounded drug

  If a prior authorization is not obtained, we may deny the charge.

- **Are over-the-counter (OTC) drugs reimbursable?**
  OTC drugs are not reimbursable in any setting. These drugs are considered a component of room and board in an institutional setting and a component of evaluation and management in an office setting.

Are there supplies/services related to pharmaceutical administration that are not reimbursable?
The following **supplies** are a component of the drug/biologic administration and not separately reimbursable:

- IV tubing, catheters regardless of the type of intravenous line
- IV insertion supplies/needles or IV insertion kits
- IV bags
- DME related to IV administration including but not limited to poles and pumps
- Diluents of any type even if reconstitution is required to prepare the drug for administration
- Fluids or drugs regardless of type used to maintain the patency of an IV
- TPN administration sets both commercially purchased or facility prepared

The following **services** are a component of the service where the medication was administered and not separately reimbursable:

- IV fluids administered in an Emergency Department (ED)
- Any drug or biologic or pharmaceutical preparation administered during procedure
- Preparation of any type of medication including compound medications and admixtures
- Administration of member's own medications
- Pharmacy consultation, any setting and including diabetes management/insulin administration
- Transfer coordination of medication regimens to a tertiary care facility, LTAC or other inpatient facility

How are compounded medications and admixtures paid?
The component ingredients of compounded medications and admixtures including TPN are not eligible for separate reimbursement. Compounded medications and admixtures may not be unbundled but must be billed with a single code as one billing unit. Billing more than one unit may result in an "excess charge" denial. For both inpatient and outpatient facility billing use J7999 (Compounded drug, not otherwise classified)

Exception: If a physician's order stipulates separate administration of one or more components of a compounded medication or admixture, these component ingredients are eligible for separate reimbursement when appropriately coded with the HCPCS of the component.

How are wasted/discarded medications paid?
The CDC directs that a SINGLE-DOSE VIAL (SDV) is approved for use on a SINGLE patient for a SINGLE procedure or injection. SDVs typically lack an antimicrobial preservative that multi-dose vials have and preservative free medications can grow harmful bacteria that can grow in a short period of time and infect a patient.

Medical Associates conforms to CMS requirements for payments for discarded drugs and biologics. When a drug that is eligible for separate payment is administered from a single-dose container or single-use package to our member, MAHP will pay the provider or facility for both administered and discarded amounts of the drug up to the labeled amount of the product.

- **How are wasted/discarded drugs identified?**
  Providers should report the following modifiers on their claims:
  - **JW modifier:** Use this modifier on claim lines for discarded amounts from single-dose containers or single-use packages along with the charge for the administered amount of the drug on a separate claim line (with no modifier).

If the JW modifier is not appended to the HCPCS code for the drug, the discarded portion will not be paid even if it is reported as discarded in the medical records.

- **JZ modifier**: Use this modifier on all claims that bill for drugs from single-dose containers or single-use packages when there are no discarded amounts. The JZ modifier is reported on a claim line to attest that no amount of drug was discarded and eligible for payment.

Charges for drugs from single-dose containers that do not append the appropriate modifiers may be denied until the charges are submitted correct modifiers. The use of these modifiers is applicable to all healthcare settings where drugs from single dose containers or single-use packages are utilized.

- **What discarded/wasted drugs are not eligible for reimbursement?**
  - Undocumented waste as indicated above
  - Discarded portions of multi-use vials
  - Waste from the use of larger size vials when smaller single dose vials are commercially available.
    - In the event of documented industry shortages due to national and/or civil emergencies at or near the date of administration, waste from larger size vials are eligible for separate reimbursement.
  - Fractional units of waste
  - Waste for drugs that were never administered even if the drug was specifically prepared for the patient and the drug could not be administered, regardless of the reason.

Billing medications and biologics by the box/carton/tray

Billing any drug or biologic by the NDC of the carton/box/tray that individual vials/cartridges/bags were packaged in will not be eligible for reimbursement unless the individual vial/cartridge/bag within the carton does not have a separate NDC for the individual components within the carton/box/tray.

Example:
NDC 0409-1283-31 is a carton of 10 hydromorphone cartridges with each cartridge containing 1mg/ml of the drug. The NDC for one individual cartridge within the carton is 0409-1283-03. If a provider bills a medication with the NDC for the carton of 10 cartridges, such charges are not eligible for reimbursement.

Example:
NDC 62332-409-31 is a bottle of 100 capsules of Clomipramine Hydrochloride. There is no NDC for each individual capsule within the bottle. If a providers bills with the NDC for the bottle, such charges are eligible for reimbursement.

Related Policies	
Related Training/ Job Aids	
NCQA Standard	
References	Off-Label Use of Drugs and Biologicals for Anti-Cancer Chemotherapeutic Regimen Wolters Kluwer Expert Insights AAPC CMS Payment Rules for Discarded Drugs and Biologics Discarded Drugs Modifier Requirements

Exhibits			
Policy Owners / Reviewers			
Department Owner	Lisa Kuhls	**Date Reviewed**	11/6/2025
Department Reviewer	Network Strategy Committee	**Date Reviewed**	12/9/2025
Approving Committee if applicable	☐Compliance ☒UMC ☐QIC ☒Board of Directors ☐Other: _____	**Date Approved**	2/2026 3/2026
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Date of revision	*Summary of changes* Prior Reviews:		