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| JOHNS HOPKINS HEALTH PLANS | Johns Hopkins Health Plans<br>**Provider Relations and Network Innovation Reimbursement Policy** | *Policy Number* | RPC.011 |
| | | *Effective Date* | 07/05/2024 |
| | | *Approval Date* | 04/23/2024 |
| | *Subject*<br>**National Drug Code Reporting Guidelines** | *Supersedes Date* | N/A |
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This document applies to the following Participating Organizations:

EHP | Johns Hopkins Advantage MD | Priority Partners | US Family Health Plan

**Keywords**: 340B, Drug, NDC, Rx, Vaccine, VFC

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## I. ABOUT OUR REIMBURSEMENT POLICIES

The most current version of the reimbursement policies can be found on www.hopkinsmedicine.org.

Johns Hopkins Health Plan LLC (JHHP) reimbursement policies serve as a guide to assist in accurate claim submissions and outline the basis for reimbursement of services covered by a member's JHHP benefit plan. The determination that a service, procedure, item, etc. is covered under a member's benefit plan is not a guarantee that you will be reimbursed. Services must meet prior authorization and medical necessity guidelines appropriate to the procedure and diagnosis, as well as to the member's state of residence. Providers are expected to and must follow proper billing and submission guidelines. Providers are required to use industry standard, compliant codes on all claim submissions. Services must be billed with valid ICD-10 diagnosis codes, Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, place of service (POS) codes, and/or revenue codes as defined by the Centers for Medicare & Medicaid Services (CMS) and in the American Medical Association's (AMA's) "CPT Manual".

The codes billed should denote the services and/or procedures performed. The billed code(s) are required to be fully supported in the patient's medical record and/or office notes and JHHP reserves the right to request the records. If a corrected claim is filed, it must comply with timely filing to be reprocessed through the claims system. Corrected claims are for administrative errors on the claim (i.e., misspelled name, CPT/HCPCS code transposed, wrong DOB, missing modifier, etc.). Intentionally changing the CPT/HCPCS or diagnosis code in order to get the claim paid, after the billed service was denied, is not a correction. The medical records must match the services billed. Unless otherwise noted within the policy, our policies apply to both participating and nonparticipating providers and facilities.

JHHP policies apply to all providers (e.g., practitioners, hospitals, suppliers, non-physician providers, etc.) eligible to bill the relevant HCPCS/CPT codes pursuant to applicable portions of the Social Security Act (SSA) of 1965, the Code of Federal Regulations (CFR), and Medicare rules. JHHP reimbursement policies are developed based on nationally accepted industry standards, coding principles, and follows the CMS guidelines, and the CMS developed National Correct Coding Initiative (NCCI) program to prevent inappropriate payment of services that should not be reported together. These policies may be superseded by regulatory mandates in provider or state contracts, or state, federal or CMS contracts and/or requirements. If appropriate, when coding/billing guidelines or current reimbursement policies are not followed, JHHP may:

- Reject or deny the claim
- Recover and/or recoup claim payment

JHHP reserves the right to modify policies at any time and publish new versions when necessary. System logic or setup may prevent the loading of policies into the claims platforms in the same manner as described; however, JHHP strives to minimize these modifications. When there is an update, policies will be published on our website.

## II. PURPOSE

To provide basic billing and reimbursement guidance for reporting National Drug Code (NDC) information that is required on professional drug claims and outpatient facility claims that are reported for reimbursement, when rendered by a person who is legally authorized to perform such services in accordance with state and federal laws. Each line of business possesses its own unique contract and guidelines for benefit and payment purposes. As such, there could be various factors that may impact reimbursement, including but not limited to legislative mandates, provider contracts, and/or the member's benefit coverage, including provisions addressing services rendered by non-participating providers, which may supplement, modify, or supersede this policy.

## III. POLICY STATEMENT

This reimbursement policy requires providers to report a valid NDC number, NDC unit of measure and NDC units dispensed for the drug administered. Providers are responsible to verify and confirm with their software vendor, billing service and/or clearinghouse that their billing system can accept and transmit the required NDC data fields, appropriately. In addition to these requirements, JHHP requires providers to append the appropriate modifier and the appropriate diagnosis to the corresponding claim line or the claim may be pended for review or denied. This policy is applicable to both par and non-par providers who submit drug claims on a CMS-1500, CMS-1450, or their electronic equivalents.

*Providers are responsible to review the **"EXCEPTIONS & EXCLUSIONS" Sections** below for specific plan guidance, as some guidelines in this policy may not be applicable to all health plans/products.*

## IV. GENERAL BILLING GUIDELINES and PAYMENT METHODOLOGY

1. A. JHHP aligns with CMS, AMA CPT, and NCCI guidance for the appropriate reporting and reimbursement of NDC claims and their associated services.
   B. The NDC is found on the drug container (vial, bottle or tube). The NDC submitted to JHHP must be the actual NDC number on the actual container from which the medication was administered, or the claim may be denied.
   C. A corresponding diagnosis and appropriate procedure code must accompany an NDC number in order to process the claim.
   D. When an NDC claim is submitted without the appropriate or required diagnosis, CPT code or modifier, the claim will be denied.
   E. The appropriate diagnosis code must be reported when billing for oral, anti-cancer drugs. If the appropriate diagnosis is not reported, will be pended for review or denied.

F. Identification of the drug enables JHHP to pay for the services. When applicable, all required information must be included on claim in order to be reimbursed. This includes (but is not limited to): NDC number, diagnosis, HCPCS/ CPT code, units for both the HCPCS code, modifier, name of drug, dosage, and qualifier.

G. Where the sole purpose of an office visit was for the patient to receive an injection, payment may be made only for the injection service (if it is covered).
   1. Injection services (CPT codes 90782, 90783, 90784, 90788, and 90799) are included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time.
   2. If a patient brings a prescribed medication from a different JHHP physician or a JHHP contracted specialty pharmacy, the provider may only report for the administration of the drug.

H. When the NDC number does not have a specific HCPCS or CPT code assigned to it, providers are to use the appropriate miscellaneous code.

I. To report two (2) NDC numbers for one drug, the additional NDC should be reported in item 19 of the CMS-1500 claim form or the electronic equivalent. Do not report multiple lines of the same drug, or it may result in a denial.

J. Reimbursement for discarded drugs applies only to single-use vials.

K. When the member's plan benefits requires precertification/prior authorization for a certain drug, and an NDC is listed as part of the authorization, the NDC must match the authorized drug that was approved at the time of the member's precertification/authorization was issued. If the NDC number does not match the preapproved drug, the claim may be denied.
   1. Refer to the JHHP Unlisted Codes policy for additional guidance.
   2. Prior authorization is not a guarantee of payment.

L. Report NDC numbers without skipping spaces and without hyphens.

M. When billing a facility claim, providers are to include the applicable Revenue code, NDC number, NDC unit of measure, and NDC units administered, as well as the HCPCS equivalent code when appropriate.
   1. Please refer to the National Uniform Billing Committee (NUBC) Official UB-04 Data Specifications Manual for further guidance.

## V. NDC FORMAT and UNITS of MEASURE (UOM)

Provider reimbursement is based on the HCPCS description and units of service. The NDC number identifies the manufacturer, drug name, dosage, strength, package size and quantity, and is a unique numeric identifier assigned to medications listed under Section 510 of the United States Federal Food, Drug and Cosmetic Act.

1. Consistent with guidance found in 21 CFR 207.33, the NDC must consist of 10 or 11 digits, divided into three segments, in a "5-4-2" format.
2. If the NDC on the label does not contain 11 digits, it will be necessary for the provider to add a leading zero to the appropriate section to create a **5-4-2** configuration (see examples below).
   - *XXXX-XXXX-XX* = ***0****XXXX-XXXX-XX*
   - *XXXXX-XXX-XX* = *XXXXX-****0****XXX-XX*
   - *XXXXX-XXXX-X* = *XXXXX-XXXX-****0****X*
3. NDC units are based upon the numeric quantity administered to the patient and the Unit of Measure (UOM). The actual metric decimal quantity administered and the UOM are required for billing.
   - Use a decimal point if reporting a fraction.
   - For example, if three 0.5-ml vials are dispensed, the correct quantity to bill is 1.5 ML.
4. Any NDC submitted to JHHP for reimbursement must be active or valid for the date of service.

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## VI. GUIDANCE FOR REPORTING THE JW and JZ MODIFIERS

A. The JW and JZ modifiers are mostly reported on claims from the physician's office and hospital outpatient settings for JHHP members who receive drugs incident to physicians' services. The JW and JZ modifier requirements also apply to Critical Access Hospitals (CAHs).

B. JHHP requires the use of the "JW" modifier to identify unused and discarded amounts of drugs or biologicals from single-dose containers or single-use packages.

- The JW modifier must be billed on a separate line for the amount of discarded drug or biological. For the administered amount, one claim line shall include the billing and payment code (such as a HCPCS code) describing the given drug, no modifier, and the number of units administered in the unit field.
- For the discarded amount, a second claim line shall include the same billing and payment code as used for the administered amount, the JW modifier, and the number of units discarded in the unit's field.
- Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.

**JW Billing Example**:

1. *A provider or supplier uses a single-dose container that is labeled to contain 100 mg of a drug to administer 95 mg to the patient and 5 mg are discarded. The drug dose description is 1 mg per unit. The 95 mg dose is billed on one line, with the calculated submitted price for only the amount of the drug given, while the discarded 5 mg must be billed on another line with the JW modifier with the calculated submitted price for only the amount of the drug wasted. Both line items would be processed for payment.*
   - *Drug code – JXXXX*
   - *Single-dose container - 1 mg = 1 unit*
   - *Labeled - 100 mg*
   - *95 mg administered; 5 mg discarded*

C. JHHP requires the use of the modifier JZ to attest that there are no amounts of drugs or biologicals from single-dose containers or single-use packages were unused and discarded.

- For the administered amount, the claim line should include the billing and payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the unit's field.

D. The JW and JZ modifier requirement does not apply for drugs that are:

- Not separately payable (i.e., packaged outpatient prospective payment system (OPPS) or ambulatory surgical center (ASC) drugs.
- Administered in the FQHC or RHC setting.
- Overfilled amounts (any amount of drug greater than the amount identified on the package or label).
- Hospital inpatient admissions that are billed under the IPPS.
- Influenza, pneumococcal, and COVID–19 vaccines or for vaccines described under section 1861(s)(10) of the Act that are furnished from single-dose container.
- Drugs from multiple dose containers.

E. Wound care or cellular and/or tissue-based products for skin wounds that meet the definition of a single-dose drug or biological are subject to billing using the JW and JZ modifier, as appropriate.

## VII. APPROPRIATE USE OF J–CODES

A. Providers must provide the appropriate diagnosis and/or modifier when billing a “J”-code drug, or the claim may be denied.

B. Report unit(s) in multiples based on HCPCS code descriptor.

C. If the units listed in the ”J”-code descriptor can be multiplied to reflect administered dosage:

- Bill on one line and use “J” code, with the appropriate number of units which reflect dosage given.

D. It is not appropriate to use a "J" code with multiplier in the unit field, when there is another "J" code, which more closely describes amount given.

E. An unlisted J-code drug will be pended for review.

## VIII. INAPPROPRIATE BILLING OF SERVICES

A. Providers who report an inactive, invalid, obsolete or expired NDC will not be reimbursed.
B. Claims submitted to JHHP with missing or incomplete information (e.g., without the appropriate or required: modifier, number of units, NDC, HCPCS, etc.) will cause a delay in processing or for JHHP to deny the claim.
C. Providers shall not bill for one manufacturer’s product and dispense another.
D. Multi-use vials are not subject to payment for discarded amounts of the drug.

## IX. EXCEPTIONS and EXCLUSIONS

1. **PPMCO**: Please consult the authoritative guidance found in the Maryland Medicaid Manuals to obtain specific information on policy, benefits, and coverage, not addressed in this policy as JHHP will process claims and reimburse services in accordance with MDH guidance.
    - Providers who participate in the Vaccines For Children (VFC) program must append SE modifier to the vaccine serum code or the code will be denied.
        - Modifier 26 is no longer used for VFC vaccine administration.
    - In alignment with Maryland state regulations, JHHP does not recognize the vaccine administration codes 90471-90474 and only pays on the serum code rather than the vaccine administration code.
    - In alignment with the Maryland Department of Health (MDH), JHHP requires all providers (i.e., ordering, referring, rendering, servicing, billing) delivering services to Maryland Medicaid members to have an active enrollment status in the electronic Provider Revalidation and Enrollment Portal (ePREP) on the date of service.
    - Claims submitted by individual providers, provider groups and facilities who are inactive or unregistered in ePREP will not be reimbursed.
    - Providers are solely responsible for ensuring their information in the ePREP portal is valid and active.
2. **USFHP**: Please consult the authoritative guidance found in the TRICARE Manuals to obtain specific information on policy, benefits, and coverage not addressed in this policy.
3. **340B Program Covered Entities**: Approved providers who are designated as 340B entities are not required to submit National Drug Codes on outpatient hospital claims.

## X. CODES, TERMS and DEFINITIONS

Definition of Terms

| Term | Definition |
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| 340B Program | The 340B Drug Discount Program is a US federal government program that requires drug manufacturers to provide outpatient drugs to eligible providers at significantly reduced prices. Eligible organizations/ covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to purchase 340B discounted drugs. |
| Discarded Drug Amount | In accordance with the U.S. Food and Drug Administration (FDA) guidance, the discarded drug amount is the amount of drug that was unused from a single-dose container or other single-use package of a drug after administering a dose to a patient. |
| National Drug Code (NDC) | The NDC for a drug is a numeric code. Each finished drug product or unfinished drug subject to the listing requirements of this part must have a unique NDC to identify its labeler, product, and package size and type. |
| Physician or Other Qualified Health Care Professional | A Physician or Other Qualified Health Care Professional is an individual 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 |
| Single Dose Container/Single Use Package; Single-dose Drug or Biological | In accordance with FDA guidance, a single-dose container is designed for use with a single patient as a single injection or infusion. The FDA approved labeling for a drug packaged in a single-dose container typically includes statements instructing users to discard unused portions. When the labeling instructs a provider to discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container or other single-use package of a drug after administering a dose to a patient. |

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| Unit of Measure (UOM)/Quantity | NDC units of measure and their descriptions are listed below. There are multiple characters available for quantity.<br><br>• **F2** (international units)-International units will mainly be used when billing for Factors.<br>• **GR** (gram)-Are usually used when an ointment, cream, inhaler or bulk powder in a jar are dispensed. The UOM will primarily be used in the retail pharmacy setting and not for outpatient-administered drug billing.<br>• **ME** (milligram)-ME is a recognized billing qualifier that may be used to identify milligrams as the NDC unit of measure; however, drug costs are generally created at the UN or ML level. If a drug product is billed using milligrams, it is recommended that the milligrams be billed in an equivalent decimal format of grams (GR).<br>• **ML** (milliliter)-If a drug is supplied in a vial in liquid form, bill in milliliters.<br>• **UN** (unit)-If a drug comes in a vial in powder form and has to be reconstituted before administered, bill each vial (unit/each) used. |
| Vaccines for Children (VFC) | VFC is the federal program that provides specific childhood vaccines to health care providers, at no cost, for administration to participants younger than 19 years old. |

Modifiers

| Modifier | Definition |
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| JW | Discarded drug not administered; Drug amount discarded/ not administered to any patient. The JW modifier is required to be reported on a claim **to report the amount of drug that is discarded** and should only be used for claims that bill single-dose container drugs. |
| JZ | Drug wasted; Zero drug amount discarded/not administered to any patient. The JZ modifier is reported on a claim to attest that **no amount of drug was discarded** and is eligible for payment**.** The modifier should only be used for claims that bill for single-dose container drugs. |

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| SE | The SE modifier's standard definition is "State and/ or federally funded programs/services". The Maryland Medicaid program has written special instructions to use this SE modifier to indicate that the vaccine is state supplied. |

## XI. REFERENCES

This policy has been developed through consideration of the following:

A. Code of Federal Regulations (eCFR):: 21 CFR 207.33- National Drug Code (NDC)
B. CPT Copyright American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association
C. Maryland Department of Health CMS-1500 Billing Instructions
D. Maryland Medicaid Provider Program Resources and Fee Schedules
E. Medicare Claims Processing Manual CH. 17- Drugs and Biologicals
F. Medicare Claims Processing Manual CH. 26- Completing and Processing Form CMS-1500 Data Set
G. National Uniform Billing Committee (NUBC)
H. National Drug Code Directory | FDA
I. TRICARE Reimbursement Manual

## XII. APPROVALS

| Date | Review/Revision | Reason for Modification | Approved By |
|---|---|---|---|
| 4/24/2024 | New Policy | N/A | Reimbursement Authorization and Coding Committee (RAC) |