National Drug Code (NDC) Billing Requirements

Reimbursement Policy

Purpose

To provide billing guidelines for appropriate reimbursement of covered drug services.

Policy

Community Health Options ("Health Options") reimburses medical drug claims with appropriate use of National Drug Code (NDC) coding for hospital outpatient and professional claims that are reasonable and necessary for the treatment/diagnosis for which they are administered. Reimbursement is subject to prior authorization requirements, coding/billing guidelines, and member eligibility.

NDC information differentiates medications that share common coding for drugs, detects billing errors, and improves reimbursement processes.

Definitions

National Drug Code (NDC) – Drugs are identified and reported using a unique, three-segment number called the NDC which serves as the FDA's (Food and Drug Administration) identifier for drugs. The NDC number identifies the manufacturer, drug name, dosage, strength, package size and quantity.

Billing Guidelines

Health Options follows the industry standard, in alignment with CMS requirements, to require the following information, in designated claim form fields, for drug-related medical claims:

- Appropriate Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology (CPT®) codes
- Units of HCPCS or CPT codes
- Valid eleven (11) digit NDC, including the N4 qualifier
- NDC unit of measurement (F2, GR, ML, or UN)
- NDC units administered/dispensed (must be greater than 0)

Drug-related medical claims are outpatient services billed under:

- CMS-1450 (UB-04, 837i) for hospitals and facilities
- CMS-1500 (837p) for providers

Modifiers – Multiple NDCs for Single HCPCS

In the case of more than one NDC within the HCPCS code (i.e., multiple drug strengths or compound), submit each applicable NDC as a separate claim line. Each drug code line submitted must have a corresponding NDC, NDC unit, and NDC unit qualifier. HCPCS or CPT

code standard billing guidelines accepts the use of the following modifiers for multiple NDC charges:

- KO: Single Drug Unit Dose Formulation;
- KP: First Drug of a Multiple Drug Unit Dose Formulation;
- KQ: Second or Subsequent Drug of a Multiple Drug Unit Dose Formulation:
- JW: Drug Amount Discarded / not administered to the patient (requires a line of >0 units of the same drug being administered on the same claim/same date of service)

Valid NDC Number

A valid NDC is found on the prescription drug label of the container (e.g., vial, bottle, or tube), which may be different than the NDC on the external label (use the container/interior packaging NDC). The NDC is a universal number that identifies a drug or a related drug item. The NDC number consists of eleven digits with hyphens separating the number into three segments in a 5-4-2 format (e.g., 12345-1234-12).

- The first five digits identify the manufacturer/distributer/*labeler* of the drug and are assigned by the U.S. Food and Drug Administration (FDA).
- The next set of four digits is the *product code* assigned by the manufacturer/labeler that identifies the specific strength, dosage form and formulation of a drug.
- The remaining two digits is the *package code*, assigned by the manufacturer/labeler and identify the specific package size and types.

NDC   12345 – 1234 – 12
         Labeler - Product - Package

If the NDC on the label does not include a full series of 11 digits, add a leading zero to the appropriate section to create a 5-4-2 (maximum characters) configuration for a valid NDC. Do not include spaces or hyphens in the NDC digits on the claim.

XXXX-XXXX-XX = OXXXX-XXXX-XX
XXXXX-XXX-XX = XXXXX-OXXX-XX
XXXXX-XXXX-X = XXXXX-XXXX-OX

NDC Unit of Measure

UOM*	Description	General Guidelines
F2	International unit	International units will mainly be used when billing for Factor VIII-Antihemophilic Factors.
GR	Gram	Grams are usually used when an ointment, cream, inhaler, or bulk powder in a jar are dispensed. This unit of measure will primarily be used in the retail pharmacy setting and not for physician-administered drug billing.
ML	Milliliter	If a drug is supplied in a vial in liquid form, bill in milliliters.
UN	Unit	If a drug is supplied in a vial in powder form, and must be reconstituted before administration, bill each vial (unit/each) used.

*ME is also a valid unit of measure to identify milligrams, but we recommend using the appropriate UN or ML indicator as this is generally how drugs are priced.

NDC Units Dispensed

The actual decimal quantity administered and the units of measurement are required on the claim. If reporting a partial unit, use a decimal point. (i.e., if three 0.5 ml vials are dispensed, report ML 1.5).

- GR 0.045
- ML 1.5
- UN 2

The number of digits for the quantity is limited to eight digits before the decimal and three digits after the decimal. If entering a whole number, do not use a decimal. Do not use commas or fill in zeros for numbers; leave the remaining fields blank. Please refer to the following examples:

- 1234.56
- 2
- 12345678.123

837 Electronic Claim Form Reporting Fields

Loop	Segment	Element name	Information	Sample
2410	LIN02	Product or Service ID Qualifier	Enter Product Qualifier or NDC Qualifier N4	LIN**N4*01234567891~
2410	LIN03	Product or Service ID	Enter the NDC	LIN**N4*01234567891~
2410	CTP04	Quantity	Enter quantity billed	CTP****2*UN~
2410	CTP05-1	Unit of Basis for Measurement Code	Enter the NDC unit of measurement code: F2 – International Unit GR – Gram ML – Milliliter UN – Unit ME - Milligram	CTP****2*UN~
2410	REF01	Reference ID Qualifier (used to report Prescription # or Link Sequence Number when reporting components for a Compound Drug)	VY: Link Sequence Number XZ: Prescription Number	REF01*XZ*123456~
2410	REF02	Reference Identification	Prescription Number or Link Sequence Number	REF01*XZ*123456~

CMS-1500 Claim Form

- Valid HCPCS or CPT code must be entered with each NDC.
  - If NDC does not have specific HCPCS or CPT code assigned, a miscellaneous code should be used per Correct Coding Guidelines.
- Units of service for HCPCS or CPT must be consistent with the HCPCS or CPT description of the code.
- <u>Do not</u> bill more than one NDC per claim line

Box 24A (Shaded Area) – Product ID Qualifier (N4 represents NDC) and 11-digit NDC
When entering supplemental information for NDC, add the following in this order, left justified:
     1.N4 qualifier
     2. 11-digit NDC code
     3. one space
     4. two-character unit/basis of measurement qualifier as applicable (i.e., units 'UN', international units 'F2', gram 'GR' or milliliter 'ML'), and quantity (no hyphens).
Box 24D (White Area) – Enter valid HCPCS or CPT code
Box 24F (White Area) – Billed Charges
Box 24G (White Area) – Units of Service

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N400026064871 Immune Globulin Intravenous UN2							N	1B	12345678901
10 01 05 10 01 05	11		J1563	13	500 00	20	N	NPI	0123456789

*All fields are required

CMS-1450 (UB-04) Claim Form

- Valid HCPCS or CPT code must be entered with each NDC.
  - If NDC does not have specific HCPCS or CPT code assigned, a miscellaneous code should be used per Correct Coding Guidelines.
- Units of service for HCPCS or CPT must be consistent with the HCPCS or CPT description of the code.
- <u>Do not</u> bill more than one NDC per claim line

Field 42: Enter valid revenue code
Field 43: Enter in order, left justified:
1. N4 qualifier in the first two (2) positions
2. 11-digit NDC in the 5-4-2 format (no hyphens)
3. Immediately following the last digit of the NDC (no delimiter) the Unit of Measurement Qualifier (F2, GR, ME, ML, UN)
4. Immediately followed by the Unit quantity with a floating decimal for fractional units limited to 3 digits (to the right of the decimal)
   - Note: any spaces unused for the quantity are left blank.

The Description Field on the UB-04 is 24 characters in length. An example of the methodology is shown below:

N	4	1	2	3	4	5	6	7	8	9	0	1	U	N	1	2	3	4	.	5	6	7	

Field 44: Enter valid HCPCS or CPT code
*All fields are required

Non-Covered Services

- Drug/Biologicals billed without a valid NDC number
- Drug/Biologicals billed with a mismatch NDC to HCPCS or CPT code
- Drugs related to the treatment of non-covered, or lacking evidence-based services
- Experimental/Investigational
- FDA unapproved drugs

References / Resources

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS
    publications and services.

National Uniform Billing Committee

National Uniform Claims Committee

U.S. Food & Drug Administration (FDA) National Drug Code Directory:
    https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm

Related Policies

Adverse Utilization Management Decisions   Paper Claims Submission
Facility Revenue Code Requirements   Payment Integrity Audit
Modifier Reference Guide   Unlisted / Unspecified / Miscellaneous Codes

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6/23/2023   Annual review; added to related policies section
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