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Reimbursement Policy:

National Drug Code (NDC) Submissions

Commercial, Medicare and Medicaid

POLICY NUMBER	EFFECTIVE DATE:	APPROVED BY
RPC20210017	10/01/2021 Medicaid	**RPC (Reimbursement Policy Committee)**
	5/01/2022 Commercial and Medicare	

Reimbursement Guideline Disclaimer: We have policies in place that reflect billing or claims payment processes unique to our health plans. Current billing and claims payment policies apply to all our products, unless otherwise noted. We will inform you of new policies or changes in policies through postings to the applicable Reimbursement Policies webpages on emblemhealth.com and connecticare.com. Further, we may announce additions and changes in our provider manual and/or provider newsletters which are available online and emailed to those with a current and accurate email address on file. The information presented in this policy is accurate and current as of the date of this publication.

The information provided in our policies is intended to serve only as a general reference resource for services described and is not intended to address every aspect of a reimbursement situation. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to, legislative mandates, physician or other provider contracts, the member's benefit coverage documents and/or other reimbursement, and medical or drug policies. Finally, this policy may not be implemented the same way on the different electronic claims processing systems in use due to programming or other constraints; however, we strive to minimize these variations.

We follow coding edits that are based on industry sources, including, but not limited to, CPT® guidelines from the American Medical Association, specialty organizations, and CMS including NCCI and MUE. In coding scenarios where there appears to be conflicts between sources, we will apply the edits we determine are appropriate. We use industry-standard claims editing software products when making decisions about appropriate claim editing practices. Upon request, we will provide an explanation of how we handle specific coding issues. If appropriate coding/billing guidelines or current reimbursement policies are not followed, we may deny the claim and/or recoup claim payment.

Overview:

This policy describes the National Drug Code information that is required on professional and outpatient facility drug claims that are reported for reimbursement.

National Drug Code (NDC) numbers are the industry standard identifier for drugs and provide full transparency to the medication administered. The NDC number identifies the manufacturer, drug name, dosage, strength, package size and quantity.

For purposes of this policy, a valid NDC number, NDC unit of measure and NDC units dispensed for the drug administered will be required for reimbursement of professional drug claims on a 1500 Health Insurance Claim Form (CMS-1500), the 837-professional transaction, a UB-04 Claim Form or the 837i facility transaction.

Guidelines:

The NDC is a unique numeric identifier assigned to medications listed under Section 510 of the United States Federal Food, Drug and Cosmetic Act. The 11-digit NDC is separated into three segments in a 5-4-2 format. They are as follows:

- The first five digits identify the manufacturer of the drug and are assigned by the Food and Drug Administration (FDA).
- The remaining 6 digits are assigned by the manufacturer and identify the specific product and package size

Reimbursement Policy:

National Drug Code (NDC) Submissions

Commercial, Medicare and Medicaid

Sometimes the NDC on the label does not include the 11 digits. If this occurs, it will be necessary to add a leading zero to the appropriate section to create a 5-4-2 configuration (i.e. 66733-**0**948-23 in the following sample). A valid NDC without spaces or hyphens should be placed on the medical claim. The NDC number on the container may be different than the NDC number on the external package; therefore, the NDC submitted must be the actual valid NDC number on the container from which the medication was administered.

XXXX-XXXX-XX = **0**XXXX-XXXX-XX
XXXXX-XXX-XX = XXXXX-**0**XXX-XX
XXXXX-XXXX-X = XXXXX-XXXX-**0**X

New York State Medicaid Guidelines (EmblemHealth Medicaid Plans):

As per New York Health Department, National Drug Code (NDC) numbers are required for Medicaid, HARP, and Child Health Plus State-Sponsored programs claims as of 10/01/2021.

- 298 Professional encounters that include a procedure code from the NY State Department of Health Procedure Code Inclusion List must be submitted with a corresponding NDC or they will be denied

- 299 Institutional encounters that include a procedure code on the Department's Procedure Code Inclusion List **and** contain one of the designated Bill Type Codes below must be submitted with a corresponding NDC or they will be denied

- **Claims appended with modifier 'UD', denoting 340B price, are *not* exempt from this requirement and will deny if submitted without corresponding NDC**

Facility/Institutional Type of Bill Code List:

Type of Bill Code	Description
12	Hospital Inpatient (Medicare Part B Only)
13	Hospital Outpatient
14	Hospital—Lab Services Provided to Nonpatients
23	Skill Nursing—Outpatient
32	Home Health—Inpatient (Plan of Treatment Part B Only)
33	Home Health—Outpatient (Plan of Treatment Part A, including DME)
34	Home Health—Other (For Medical/Surgical Service, No Plan)
43	Religious Nonmedical Health Care Institutional—Outpatient
71	Clinic—Rural Health
72	Clinic—Hospital-based or Independent Renal Dialysis Center

Reimbursement Policy:

National Drug Code (NDC) Submissions

Commercial, Medicare and Medicaid

Type of Bill Code	Description
73	Clinic—Freestanding
74	Clinic—Outpatient Rehabilitation Facility (ORF)
75	Clinic—Comprehensive Outpatient Rehabilitation Facility (CORF)
76	Clinic—Community Mental Health Center
77	Clinic—Federally-qualified Health Center (FQHC 04/01/10)
78	Licensed Freestanding Emergency Medical Facility (7/1/12)
79	Clinic—Other
81	Hospice (Nonhospital based, Institutional)
82	Hospice (Hospital based, Institutional)
83	Ambulatory Surgery Center (Institutional)
84	Freestanding Birthing Center (Institutional)
87	Freestanding Non-Residential Opioid Treatment Program
89	Special Facility - Other

Billing Requirements – Commercial, Medicare and Medicaid:

Note: The NDC requirement will not apply to child and adult immunization drug codes.

NDC Unit of Measure (UOM):

UOM:	Description:	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	Millimeter	If a drug is supplied in a vial in liquid form, bill in millimeters.
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.

Note: ME is also a valid unit of measure, but we recommend using the appropriate UN or ML indictor as this is generally how drugs are priced.

Reimbursement Policy:

National Drug Code (NDC) Submissions

Commercial, Medicare and Medicaid

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 ML1.5).

• GR0.045
• ML1.5
• UN2.0

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. Do not zero fill, leave remaining positions blank.

Please refer to the following examples:

• 1234.56
• 2
• 12345678.123

Requiring the NDC information will differentiate drugs that share the same HCPCS, CPT, or Revenue codes for drug preferences and enhance reimbursement processes.

If the NDC information is missing, invalid, incomplete, or does not match the HCPCS or CPT submitted, the claim may be denied. If the claim is denied, it can be resubmitted with the appropriate NDC information for reconsideration of reimbursement.

Maximum Units per Package:

Units submitted for a drug should not exceed the package maximum units available based on the NDC number or in increments associated with the drug package. Maximum units will be applied for specific drugs where a specific and standard number of units should be submitted per the NDC of the package.

When units submitted exceed the maximum units allowed per package or when units submitted are not in increments of the package, the units over the maximum unit will be denied.

Claim Form Instructions:

Paper Claims:

Using the CMS 1500 form, enter the NDC information in field 24. There are six service lines in field 24 with shaded areas.

Place the NDC information in the line's top shaded part.

When you're entering the supplemental NDC information for the NDC, add it in the following order:

Reimbursement Policy:

National Drug Code (NDC) Submissions

Commercial, Medicare and Medicaid

- "N4" qualifier
- 11-digit NDC code
- Add one space
- Two-character unit of measure and the quantity; see Q5 and Q6 for more information

Using the UB 04 form, fill out the following fields:

- Field 42: Include the appropriate revenue code
- Field 43: Include the 11-digit NDC code, unit of measurement and quantity
- Field 44: Include the HCPCS code if required

Electronic Claims:

EDI Requirements for Professional (837p) and Institutional (837i) Claims

Loop	Segment	Element Name	Instructions	Additional Information
2410	LIN	02	Product or Service ID Qualifier	If billing for an NDC, enter "N4".
2410	LIN	03	Product or Service ID	If billing for drugs, include the 11-digit NDC. Sample: LIN**N4*12345678901
2410	CTP	04	Quantity	If an NDC was submitted in LIN03, include the administered NDC quantity. See Q5 for unit information.
2410	CTP	05-1	Unit or Basis for Measurement Code	If an NDC was submitted in LIN03, include the unit or basis for measurement code for the NDC billed. See Q6 for unit information. Sample: CTP****3*UN
2410	REF	01	VY: Link Sequence Number XZ: Prescription Number	The Link Sequence Number is used to report components for compound drug.
2410	REF	02	Link Sequence Number or Prescription	Sample: REF01*VY*123456

FAQ's

If the medication comes in a box with multiple vials, should I use the NDC number on the box or the NDC number on the individual vial?

You'll use the NDC information from the vial that was administered to the member. This includes the NDC number and the quantity administered with the unit of measurement. There are exceptions when drug manufacturers don't provide pricing at the individual vial level. Generally, only NDC

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Reimbursement Policy:

National Drug Code (NDC) Submissions

Commercial, Medicare and Medicaid

numbers with available pricing are considered valid. In these instances, you should bill using the NDC information from the outside packaging and include the correct units administered. When missing vial level NDC's are identified we add these exceptions to our validation tables so your claims will process accurately.

If the medication comes in a box with two different drugs that are mixed, should I use the NDC number on the box?

Yes. The NDC number from the outer box is required when different drugs from the package are mixed.

Do I have to bill with all of the NDC information in addition to revenue, HCPCS or CPT codes?

Yes. Complete NDC information must be submitted on the claim in addition to the applicable revenue, HCPCS or CPT codes and the number of Revenue, HCPCS or CPT units. You'll continue to need the valid revenue, HCPCS or CPT code with units of service on the claim because claims are priced based on revenue, HCPCS or CPT codes and the units of service. If the NDC number on the claim doesn't have a specific revenue, HCPCS or CPT code assigned to it, please assign the appropriate miscellaneous code.

What if there are multiple NDCs administered for the same revenue or HCPCS code?

You may have multiple NDCs when you administer multiple drug strengths to a patient or when a drug is comprised of more than one ingredient. Submit each NDC number as a separate claim line with the appropriate revenue, HCPCS or CPT drug code.

Standard revenue, HCPCS or CPT code billing accepts the use of the following modifiers to determine when more than one NDC is billed for a service code.

Paper Claim
KP: First drug of a multiple drug unit dose formulation
KQ: Second or subsequent drug of a multiple drug unit dose formulation

Electronic Claim
The compound drug should be reported by repeating the LIN and the CPT segments in the 2410 identification loop.

Will claims with NDC information be subject to any clinical edits?

Yes. Examples of claims editing that may apply are:
- NDC and HCPCS verification edits identify potentially incorrect billing when the NDC number and HCPCS codes don't match.
- NDC max unit edits target drugs that have specific strengths where the claim exceeds the expected number of units.
- Inactive NDC number edits look for inactive or obsolete drugs.

Do I have to bill with all of the NDC information if submitting a claim for a drug with 340B pricing and modifier UD appended?

Yes. As per New State Department of Health, claims appended with modifier 'UD', denoting 340B pricing, are not exempt from this requirement and will deny if submitted without corresponding NDC.

Reimbursement Policy:

National Drug Code (NDC) Submissions

Commercial, Medicare and Medicaid

References:

You can find more information about NDC online:

- The U.S. Food and Drug Administration (FDA) package insert includes the NDC information. Online, the FDA publishes an online searchable National Drug Code Directory and has other public resources.

- The Centers for Medicare & Medicaid Services (CMS) publishes a CMS HCPCS/NDC Crosswalk

- The National Uniform Claim Committee includes NDC billing instructions with their 1500 Claim Form Reference Instruction Manual

- Medicaid Update Article, June 2007: National Drug Code Required on Medicaid Claims

- Medicaid Update Article, September 2012: Reporting of the National Drug Code (NDC) is now required for all Physician Administered Drugs for Medicaid Managed Care and Family Health Plus (FHPlus) Plans

- Medicaid Update Article, February 2019: Reporting of the National Drug Code is Required for all Fee-for-Service Physician-Administered Drugs

- Medicaid Update Article, March 2019: Reminder: Reporting of the National Drug Code is Required for all Fee-for-Service Physician-Administered Drugs

- Medicaid Update Article, April 2019: Reporting of the National Drug Code is Required for all Fee-for-Service Physician Administered Drugs

- Medicaid Update Article, August 2021: Clarification on Previous Guidance: National Drug Code Usage for Physician Administered Drugs with Ambulatory Patient Groups

Revision History

Company(ies)	DATE	REVISION
EmblemHealth ConnectiCare	12/01/2021	- Updated to include NY State Medicaid Guidelines - Reformatted and reorganized policy, transferred content to new template with new Reimbursement Policy Number