NDC

Purpose

This policy is intended to ensure correct provider reimbursement and serves only as a general resource regarding Molina Healthcare's reimbursement policy for the services described in this policy. It is not intended to address every aspect of a reimbursement situation, nor is it intended to impact care decisions. This policy was developed using nationally accepted industry standards and coding principles. In a conflict, federal and state guidelines, as applicable, and the member's benefit plans supersede the information in this policy. Also, to the extent of conflicts between this policy and the provider contract language, the Provider contract language will prevail. Coverage may be mandated by applicable legal requirements of a State, the Federal government or the Centers for Medicare and Medicaid Services (CMS). References included were accurate at the time of policy approval. If there is a state exception, please refer to the state exception table listed below.

Policy Overview

This policy outlines the mandatory National Drug Code (NDC) information requirements for professional and outpatient facility drug claims submitted for reimbursement. NDC numbers serve as the standardized identifiers for medications, ensuring transparency in medication administration. The NDC number encompasses essential details, including the manufacturer, drug name, dosage, strength, package size, and quantity. To qualify for reimbursement on forms such as the 1500 Health Insurance Claim Form (CMS-1500), 837-professional transaction, UB-04 Claim Form, or 837i facility transaction, the following NDC details must be provided: a valid NDC number, NDC unit of measure, and NDC units dispensed for the administered drug.

The NDC is a unique 11-digit numeric identifier assigned to medications under Section 510 of the United States Federal Food, Drug, and Cosmetic Act. This 11-digit NDC is structured as 5-4-2 segments:

- The first five digits represent the drug manufacturer and are assigned by the Food and Drug Administration (FDA).
- The remaining six digits, assigned by the manufacturer, specify the product and package size.

In cases where the NDC on the label lacks 11 digits, you should add a leading zero to create the 5-4-2 configuration (e.g., 66733-0948-23 becomes 066733-0948-23). Ensure that the NDC submitted on the medical claim does not contain spaces or hyphens. Additionally, please note that the NDC on the medication container might differ from that on the external package. When submitting a claim, use the valid NDC number from the container used for medication administration. For instance, if a medication has both interior and exterior packaging with NDCs, report the NDC from the interior packaging on the claim.

To summarize, the NDC format is as follows:

XXXX-XXXX-XX should be formatted as **0**XXXX-XXXX-XX.
XXXXX-XXX-XX should be formatted as XXXXX-**0**XXX-XX.
XXXXX-XXXX-X should be formatted as XXXXX-XXXX-**0**X.

NDC Unit of Measure (UOM)

UOM	Description	General Guidelines
F2	International unit	International units will 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 is 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 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: While 'ME' is a valid unit of measure, we recommend using the appropriate 'UN' (unit) or 'ML' (milliliter) indicator, as this aligns with the standard pricing conventions for drugs.

NDC Units Dispensed:

The actual quantity administered, including decimal values, along with the appropriate units of measurement must be included in the claim. If reporting a partial unit, use a decimal point (e.g., if dispensing three 0.5 ml vials, report as ML 1.5).

Accepted unit indicators include:

- GR 0.045
- ML 1.5
- UN 2.0

The quantity field allows for a maximum of eight digits before the decimal point and three digits after the decimal point. When entering whole numbers, omit the decimal point. Avoid using commas and do not zero-fill; leave any unused positions blank. Refer to the following examples for clarification:

- 1234.56
- 2
- 12345678.123

Requiring NDC information distinguishes drugs with the same HCPCS (Healthcare Common Procedure Coding System), CPT (Current Procedural Terminology), or Revenue codes, enhancing the reimbursement process and drug preference differentiation.

Reimbursement Guidelines

In instances where the National Drug Code (NDC) information is absent, incorrect, incomplete, or incompatible with the Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology (CPT) codes submitted, it could lead to the denial of the claim. Should a claim be denied for these reasons, it can be resubmitted with the accurate NDC information for reconsideration of reimbursement.

Please be aware that the quantity of units specified for a medication should not surpass the maximum units indicated by the NDC number or the increments specified by the drug's packaging. Maximum units per package apply to specific drugs where a predefined number of units must align with the NDC of the package. Claims that exceed the maximum allowable units per package or do not align with the package increments will be declined.

It's important to note that the NDC requirement does not pertain to child and adult immunization drug codes. However, NDC codes are mandatory for Radiopharmaceutical drugs. Molina Healthcare maintains consistent NDC standards for both Participating (Par) and Non-Participating (Non-Par) providers, irrespective of their

provider type. Additionally, providers must adhere to any state-specific requirements associated with the Centers for Medicare & Medicaid Services (CMS) rebate Labeler program.

Lastly, it's crucial to underscore that Molina Healthcare will not provide reimbursement for drugs listed on the National Drug Data Exchange (NSDE) if their marketing date has not been approved by the Food and Drug Administration (FDA) when billed. Failure to adhere to the NDC guidelines may lead to a delay and/or denial of payment, and it could also result in the recovery of previously paid claims.

Claim Submission Requirements

Bill using UB-04 and CMS-1500 paper claim forms:

Form type	Form locator	Format
UB-04	FL43	N4 + NDC + UOM + quantity Example: N4555103026710ML5.5 You must use the decimal point if reporting a fraction of a unit.
CMS-1500	FL24 (*Shaded line*)	N4 + NDC + *3 spaces* + UOM + quantity Example: N4555103026710 ML5. You must use the decimal point if reporting a fraction of a unit.

Bill using 837I and 837P EDI (Electronic Data Interchange) transactions:

Data element	Loop	Segment/element	Information
Product or Service ID Qualifier	2410	LIN02	If billing for an NDC, enter “N4”
NDC		LIN03	If billing for drugs, include the 11-Digit NDC
UOM (Unit of measurement)		CTP05-01	
Unit price		CTP03	

Quantity		CTP04	If an NDC was submitted in LIN03, include the administered NDC quantity.
Note: The NDC unit price in CTP03 is required to complete the 837 requirements for Loop 2410.			

Revenue Codes that Require NDC Codes:

- **0250**
- **0251**
- **0252**
- **0253**
- **0254**
- **0255**
- **0256**
- **0257**
- **0258**
- **0259**
- **0634**
- **0635**
- **0636**

Supplemental Information

Definitions

Term	Definition
CMS	Center for Medicare and Medicaid
NDC	National Drug Code-Pharmacies use the NDC to ensure that they dispense the correct medication to patients, while healthcare providers and insurance companies use it for billing, reimbursement, and record-keeping purposes. It's an essential component of drug information and tracking within the healthcare system
CMS-1500	The CMS-1500 form, also known as the HCFA-1500 form, is a standard paper claim form used in the United States for healthcare professionals and suppliers to bill Medicare and Medicaid and other government and private health insurance plans. CMS stands for the Centers for Medicare & Medicaid Services, a federal agency that administers these government healthcare programs
837 Professional Transaction	The 837 Professional Transaction, often referred to simply as an "837P," is a standard electronic data interchange (EDI) transaction format used in the United States healthcare industry. It is part of the HIPAA (Health Insurance Portability and Accountability Act) transaction set and is used for the electronic submission of healthcare claims by healthcare providers, such as physicians, hospitals, and clinics, to insurance payers or clearinghouses
UB-04 Claim Form	The UB-04 Claim Form, also known as the CMS-1450 form, is a standard claim form used for submitting healthcare claims for reimbursement for services provided in a hospital or other inpatient and institutional healthcare settings. The UB-04 form is named after the National Uniform Billing Committee (NUBC), which developed and maintains the form.
837i facility transaction	The 837I, often referred to as the "Institutional" or "Facility" transaction, is a standard electronic data interchange (EDI) format used in the United States

	healthcare industry for the electronic submission of healthcare claims by institutional providers. Institutional providers typically include hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and other healthcare institutions.
The Food and Drug Administration (FDA)	The Food and Drug Administration (FDA) is a federal agency of the United States Department of Health and Human Services (HHS) responsible for protecting and promoting public health by regulating and supervising various products, including food, drugs, medical devices, vaccines, biopharmaceuticals, blood transfusions, radiation-emitting devices, veterinary products, and cosmetics. The FDA's mission is to ensure the safety and efficacy of these products to benefit the health and well-being of the American public

State Exceptions

State	Exception
TX	Revenue codes are not used for NDC requirements, instead HCPCS/CPT is.
FL	Medicaid regulations require that all pharmaceutical claims for injectable medications must include National Drug Codes (NDC) to permit the invoicing for federal or state supplemental rebates from manufacturers. Claims for drug products with missing, invalid, or incomplete NDC information will be denied unless the drug product is exempt from federal rebate requirements 1. All Dialysis claims require NDCs on J codes and specific Q codes when billed by a free-standing dialysis center. 2. All Outpatient Hospital claims require NDCs for services under rev codes 258, 631, 632, 633, 634, 635, 636 and 637. 3. All Professional Claims (CMS-1500) require NDC on all J codes and certain A, C, S and Q codes.

Documentation History

Type	Date	Action
Published	11/03/2022	New Policy
Revised Date	09/01/2023	Updated
Revised Date	12/12/2024	Updated the Template
Revised	02/25/2025	Added FL state exceptions

References

This policy was developed using.

- CMS
- State Medicaid Regulatory Guidance
- State Contracts

Agency	Document Name	Reference Link
CMS-ASP	On a quarterly basis CMS publishes HCPCS /NDC Xwalk Document that payors can follow to gather appropriate NDC information from providers. CMS guidance requires physicians and other providers to bill using the appropriate HCPCS or CPT code and to accurately report the units of service.	2022 ASP (Average Sales Price) Drug Pricing Files | CMS

FDA	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.	National Drug Code Directory | FDA
NUCC	1500 Claim form Billing Rules that are published by NUCC (National Uniform Committee)-version 9.0 (**Page 45 onwards**)	National Uniform Claim Committee - 1500 Instructions (nucc.org)
CMS IOM	1500 Claim UB (Uniform Billing) Claim	CMS Manual System CMS Manual System
CMS-Lesser of NDC Pricing		https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf
340B drug discount rules and regulations		340B Drug Pricing Program | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)
NADAC (National Average Drug Acquisition Cost) pricing files		National Average Drug Acquisition Cost (medicaid.gov)
FUL (Federal Upper Limit)		ACA Federal Upper Limits (medicaid.gov)
Palmetto GBA	NDC and HCPCS Crosswalk	PDAC - NDC/HCPCS Crosswalk (palmettogba.com)
Noridian		Drugs, Biologicals and Injections - JE Part B - Noridian (noridianmedicare.com)
Medicaid Labeler code list		Drug Manufacturer Contacts (medicaid.gov) New/Reinstated & Terminated Labeler Information | Medicaid
CA		Medi-Cal: National Drug Code: FAQs (Frequently Asked Questions) Physician-Administered Drugs – NDC (physician ndc) (ca.gov)

		Medi-Cal Rx | Homepage
FL	Summary of Drug limitations Florida Medicaid Preferred Drug program NDC Carve outs	Florida Medicaid Preferred Drug List (PDL) (myflorida.com) Florida Medicaid Preferred Drug Program (myflorida.com) https://ahca.myflorida.com/medicaid/Policy_and_Quality/Quality/fee-for-service/hemophilia.shtml
OH		Hospital Billing Guidelines (ohio.gov)
MI		Managed_Care_Common_Formulary_Listing.pdf (michigan.gov) MEDICAID POLICY BULLETIN (michigan.gov) MEDICAID POLICY BULLETIN (michigan.gov)
IL	UD modifier for 340B 634 and 635 revenue code also require an NDC	Provider Notice Issued 04/15/2021 | HFS (illinois.gov) DEFINITIONS (illinois.gov) h200.pdf (illinois.gov)
WA	340B pricing Drugs administered to managed care clients but reimbursed through fee-for-service Professional administered drugs	340B Drug Pricing Program | Washington State Health Care Authority MCO-admin-drugs-reimbursed-FFS.xlsx (live.com) Provider billing guides and fee schedules | Washington State Health Care Authority
TX		Vendor Drug Program | TMHP 2_Outpatient_Drug.fm (tmhp.com)
WI	NDC search tool Provider administered drugs	Print (wi.gov) Print (wi.gov) ForwardHealth Provider Type: 31 Physicians (wi.gov) ForwardHealth Provider Type: 24, Pharmacy (wi.gov) Medicaid Drug Rebate Program (MDRP) | Medicaid
MS		Pharmacy | Mississippi Division of Medicaid (ms.gov)
AZ	NDC Billing requirements Additional NDC billing requirements 340B Rule	Pharmacy Updates and Information (azahcccs.gov) NDCBillingRequirementsFAQs_Additional.pdf (azahcccs.gov) Pharmacy Updates and Information (azahcccs.gov)
NY	Reimbursable drugs Physician procedure codes: Medicine and drugs Fee schedules: Drugs If a code has an BR- then evaluate the drug cost through invoice validation	eMedNY : Information : Formulary File eMedNY : Provider Manuals : Physician
MA	MassHealth Acute Hospital Carve-Out Drugs List	MassHealth Drug List - Health and Human Services (conduent.com)

	MassHealth Pharmacy Covered Professional Services List	
VA	340B drug program Hospital manual chapter IV	VAMPS_FAQ_340B.pdf (virginiamedicaidpharmacyservices.com)