National Drug Codes (NDC)

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Disclaimer

Highmark Wholecare medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

This policy provides information regarding the coverage of, as determined by applicable federal and/or state legislation.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Pennsylvania Department of Health (DHS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Wholecare – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Wholecare members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Wholecare currently services Pennsylvania Medicaid: PA HealthChoices.

National Drug Code (NDC)-Drugs are identified and reported using a unique, three-segment number called the National Drug Code (NDC), which serves as the FDA's identifier for drugs. The three segments:

- **Labeler Code:** Identifies the manufacturer, repackager, or distributor. This is assigned by the FDA.
- **Product Code:** Identifies a specific drug formulation, strength, and dosage form. The labeler assigns this code.
- **Package Code:** Identifies package size and type. The labeler assigns this code.

PROCEDURES

Prior Authorization may be required. Please validate codes on the Prior Authorization Lookup Tool
https://providers.highmark.com/wholecare/provider-resources/prior-authorization-code-lookup

The Affordable Care Act (ACA) includes language to extend the Medicaid National Drug Rebate Agreement (NDRA), which is a federal rebate to drugs covered by the Medicaid Managed Care Organizations (MCOs). The language requires the State to collect the NDC and NDC units for all outpatient drug claims, regardless if payment is made based on HCPCS code, in order to invoice the manufacturers for the federal rebates.

Consequently, Highmark Wholecare requires the use of NDCs when billing HCPCS (or "J codes") for drugs. The NDC must correspond to the drug and dosage of the HCPCS billed in order to considered reimbursement.

Conversion of NDCs from 10-digits to 11-digits

It should be noted that many National Drug Code (NDC) are displayed on drug packing in a 10-digit format. Proper billing of a National Drug Code (NDC) requires an 11-digit number in a 5-4-2 format. However, not all drug manufacturers follow the 5-4-2 format Converting National Drug Code (NDC) from a 10-digit to an 11-digit format requires a strategically placed zero, dependent upon the 10-digit format.

The following table shows common 10-digit National Drug Code (NDC) formats indicated on packaging and the associated conversion to an 11-digit format, using the proper placement of a zero. The correctly formatted, additional "0" is in a bold font and underlined in the following example. Note that hyphens indicated below are used solely to illustrate the various formatting examples for the National Drug Code (NDC).

10-digit format on package	10-digit format example	11-digit format on package	11-digit format example
4-4-2	0002-7597-001 Zyprexa 10mg vial	5-4-2	**0**0002-7597-01
5-3-2	50242-040-62 Xolair 150mg vial	5-4-2	50242-**0**040-62
5-4-1	60575-4112-1 Synagis 50mg vial	5-4-2	60575-4112-**0**1

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Wholecare contract.

Reference

United States Food and Drug Administration. (2022). National Drug Code Directory. Retrieved from https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

Centers for Medicaid and Medicare. (2024). Medicare Claims Processing Manual: Chapter 17-Drugs and Biologicals. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf