

# Coding Systems

Understanding NDC and HCPCS

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## National Drug Code

The National Drug Code (NDC) serves as a universal product identifier for prescription medications for human consumption. According to the U.S. Food and Drug Administration (FDA), the Drug Listing Act of 1972 requires registered drug establishments to provide the FDA with a current list of “all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution.”<sup>1</sup> An NDC number serves as a universal product identifier for over-the-counter and prescription medication packages and inserts in the US. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.

The FDA's mission is to ensure the safety, efficacy, and security of human medication products. A comprehensive list of medications allows the FDA and other Federal agencies to quickly identify a drug product, especially in the case of a recall. NDC numbers were originally developed for outpatient drug reimbursement under Medicare, and have since evolved. The FDA maintains a publicly accessible database of drug manufacturers and drug products, called the National Drug Code Directory. Serving as an inventory of drug facilities and commercially marketed medication products, the NDC Directory is an important part of protecting the public's health.

## Why are NDC numbers important?

NDC numbers help ensure that patients receive the correct strength, dosage form, and type of drug. An NDC uniquely identifies each drug product. It helps pharmacists recognize the difference between products that may look or sound alike. Also, should an issue arise, it can help identify the product in question.

## What does an NDC number mean?

It identifies the specific labeler, product, and trade package size of a medication.

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### What does an NDC number look like?

It is a unique 10-digit number that is displayed in three segments. The length of the segments can be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.

#### Examples:

XXXX - XXXX - XX

XXXXX - XXX - XX

XXXXX - XXXX - X

### What makes up an NDC number?

Each drug product's NDC consists of a:

- ▶ **Labeler Code:** This is assigned by the FDA and identifies the labeler or **WHO** manufactures or distributes the product (i.e., Pfizer, Mylan, Watson, Teva, etc.). The labeler code is four or five numbers. The labeler code is unique to each drug firm and is assigned at the time of registration.
- ▶ **Product Code:** Identifies a specific strength, dosage form, and formulation for a particular manufacturer. It represents **WHAT** the product is (i.e., lisinopril hydrochloride 20mg tablet). The product code is three or four numbers.
- ▶ **Package Code:** Identifies the size or type of **PACKAGE**. These numbers vary by manufacturer and are not standardized. (i.e., "90" may mean there are 90 tablets in a bottle, or "02" might represent a patch rather than a pill or liquid). The package code is one or two numbers.

#### Example

12345 - 6789 - 0

Labeler Code	Product Code	Package Size/Type

### Why do the configurations differ?

NDC numbers can vary depending on when the code was assigned by the FDA. While many Labeler Codes consist of five digits, some may only be four digits. To maintain the common configurations of the NDC, a manufacturer with a five-digit Labeler Code must choose between a three-digit Product Code with a two-digit Package Code or a four-digit Product Code with a one-digit Package Code. This lack of standardization can lead to confusion, especially between organizations.

### Why are there sometimes 11 digits?

In order to standardize and allow better synchronization across computer systems between various organizations, such as with pharmacies and the Centers for Medicare and Medicaid Services (CMS), many manufacturers now add an eleventh number to the NDC. This is typically a leading zero, which is inserted into the labeler, product, or package-size section of the NDC to accommodate for variation between sections. This eleventh number simply acts as a place holder to help a manufacturer maintain consistency.

#### Example 1:

12345-0678-09 (11 digits) could be

12345-678-09 or 12345-0678-9

#### Example 2:

01234-5678-90 (11 digits) is actually

1234-5678-90

### Why do certain products have more than one NDC number?

Each product will have a different NDC number depending on who manufactures or distributes it, and what size or type of packaging it comes in. The following are some examples of when the same drug may have more than one different NDC number:

- ▶ If a drug is manufactured by different companies.
  - **Example:** The same drug manufactured by Pfizer and Teva will have entirely different NDC numbers because the Labeler Code (the number that identifies the manufacturer) will be different.
- ▶ If a drug comes in different package sizes.
  - **Example:** A package of 30 tablets will have a different NDC number than a package of 100 tablets of the exact same drug and manufacturer.
- ▶ If the same drug with the same manufacturer changes the appearance of the product.
  - **Example:** If a tablet is made with a white color and it also comes in pink, each pill will have a different NDC number.

- ▶ If the exact drug and manufacturer comes in different dosage forms.
  - **Example:** *A drug that comes in a pill that is also available as a liquid by the same manufacturer will have different NDC numbers.*
- ▶ If a drug comes in immediate-release and extended-release formulations that are made by the same manufacturer.
  - **Example:** *Metoprolol succinate is a sustained-release formulation and metoprolol tartrate is an immediate-release formulation; they have different NDC numbers.*

### Why do prices vary among different NDC numbers for the same medications?

As mentioned earlier, an NDC number is specific to a particular manufacturer, drug product, strength, and dosage form. Since a similar product may be manufactured by several different drug companies, it is possible that multiple products that contain the same active ingredient will have a different NDC number. According to the FDA, a manufacturer can be defined as a drug's initial manufacturer; however, repackagers and relabelers can be categorized as "manufacturers" as well. A repackager or relabeler is typically defined as a company or entity that takes existing drug products (i.e., medications that already have an NDC assigned) and repackages and/or relabels them into unit-dose packages or proprietary packaging.

The FDA mandates that these companies must also generate an NDC number for newly repackaged or relabeled items. Since this NDC will likely vary significantly from the medication's original NDC, it is possible that variations may exist between the same drug products "manufactured" by different companies. Since pricing is determined by the "manufacturer," it is also possible that pricing will differ between these products.

### How is price established for an NDC by the manufacturer and/or repackager?

Average Wholesale Price (AWP) is reported by the manufacturer or AWP is calculated based on a markup specified by the manufacturer. This markup is typically based on the Wholesale Acquisition Cost (WAC). The AWP is linked to the medication's NDC and is reported to the industry AWP databases (e.g., First DataBank,

Medi-Span®, Red Book) for publication. If an AWP is not provided, then the database source may calculate the AWP based on the WAC provided and a multiplier of no more than 1.2.

When a medication is repackaged and/or relabeled from the original manufacturer's package, a unique NDC must be generated and submitted for approval. The companies that repackage the medication are responsible for assigning the AWP for the new NDC and reporting this information to the industry AWP databases.

There are no regulations or laws on how the manufacturer or repackager assigns the AWP or on how high the AWP can be. When a medication is repackaged, this typically results in the AWP for the new NDC to be much higher than the AWP of the original NDC.

### Does an NDC number mean it is FDA-approved?

Assignment of an NDC number does not in any way denote FDA approval of the product. Any representation that creates an impression of official approval because of possession of an NDC number is misleading and constitutes misbranding. (21 CFR 207.39) Additionally, an NDC number does not determine that the product is a medication as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), nor does it denote that a product is covered or eligible for reimbursement by Medicare, Medicaid or other payers. Non-drug products are not permitted to be assigned an NDC number.

## Healthcare Common Procedure Coding System

Healthcare Common Procedure Coding System (HCPCS) code set created by CMS to simplify medical billing and ensure that Medicare and other health insurance programs process claims in an orderly and consistent manner. Initially, use of the codes was voluntary, but with the implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) use of the HCPCS for transactions involving health care information became mandatory.

### How are HCPCS used?

The HCPCS codes are used by both public and private health plans. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. Level

It contains Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association (AMA) to identify medical services and procedures provided by physicians and other health care professionals. Level II of the HCPCS is a standardized coding system used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. HCPCS coding is intended to be used to identify DMEPOS in a consistent fashion for billing purposes. However, health plans such as Medicare and Medicaid often use HCPCS codes as a method for formulating fee schedules for durable medical equipment.

### Why are HCPCS codes important?

How a product is coded can determine whether the item is considered medically necessary and therefore, available to the injured persons. Codes can also effect the reimbursement amount. If a coding mistake is made, the vendor could stop supplying the item based on insufficient reimbursement, or the payer could deny the product or service completely.

### What does a HCPCS/CPT Code look like?

A HCPCS code is a unique, 5-digit alpha numeric number; the first letter of a HCPCS code identifies which category the item or service falls into. For example 'A-codes' are typically categorized as disposable supply items, while 'E-codes' are reserved for more traditional durable medical equipment or "bent metal" items. CPT codes are also unique, 5-digit codes.

### HCPCS Example:

- E0100 is defined as Cane; all materials, adjustable or fixed, with tip
- A4927 is defined as Gloves, nonsterile, per 100

### CPT Example:

- 97001 is Physical Therapy Evaluation

### Does every piece of equipment have a different HCPCS code?

No, unlike an NDC, HCPCS codes are more generic. Like pharmaceuticals, there are many different

providers and manufacturers of similar DME items. However, HCPCS are not specific to brand and usually hundreds of different products can fall under the same HCPCS. In addition, some HCPCS codes are meant to include certain services such as evaluations and fitting fees. Likewise, codes for home health services often include supplies for the service.

### How do units of measure influence the coding?

Some supply codes have very specific units of measure which can result in HCPCS quantities that are not whole numbers and can result in mathematical errors or rounding.

### Example:

- HCPCS code A4450 has a unit of measure of 'per 18 square inches.' This HCPCS is assigned to a roll of tape that is 2 inches by 5.4 yards, equalling 388.8 square inches. The quantity for this HCPCS code would therefore be 21.6.

Additionally, some HCPCS codes specify 'per pair' or 'each,' so understanding the actual supply is important to determine the appropriate quantity.

### What if an item doesn't have a specific code?

CMS has created a number of miscellaneous codes that have generic definitions and can be used when no other CPT or HCPCS code matches the description of the product or service provided. These codes are not to be used when there is a more appropriate code. For example, K0108 is defined as 'wheelchair component or accessory, not otherwise specified;' most wheelchair parts have an actual code outside of this one and could be more appropriate while also carrying a lower allowable amount.

Miscellaneous codes can be easily abused either unintentionally due to lack of knowledge, or intentionally because these codes typically do not carry a fee schedule and therefore can be reimbursed at higher amounts than a non-miscellaneous code.

### What is a supplemental modifier or identifier?

HCPCS and CPT codes are often billed with a supplemental modifier or identifier, which is a billing value that further clarifies the HCPCS/CPT code that is billed. It is often most appropriate to include a

modifier because it will tell the payer more about the service/product being billed. Modifiers influence the reimbursement because many fee schedules differ depending on which modifier is reported. Common modifiers include: purchase (NU), rental (RR), or in maintenance mode (MS). A rental for example, does not warrant the same reimbursement as a purchase. Your place of service modifier also can influence your rate. Some state fee schedules also assign alternate allowable amounts based on lesser known modifiers.

### Example:

- K0001 = 'STANDARD WHEELCHAIR'
- K0001 RR = 'STANDARD WHEELCHAIR' that has been rented. Fee schedule may be \$45.
- K0001 NU = 'STANDARD WHEELCHAIR' that has been purchased. Fee schedule may be \$500.

### How do you know if the rental is daily or monthly?

By default, a HCPCS with a modifier of 'RR' is a rental per month. However, in some cases a provider may bill for a device daily and therefore interpret the fee schedule as daily rather than monthly. In this scenario, the provider may bill with a daily unit of measure, billing a quantity of 30 instead of the allowable amount of one. For devices that are rented daily, such as a negative pressure wound therapy device or continuous passive motion device, it is important to understand the unit of measure being used (monthly or daily) and be mindful that the daily billing exceeds the monthly allowable.

### How does diagnosis influence HCPCS allowable amounts?

Fee schedules are assigned at the HCPCS level. Some HCPCS change based on the diagnosis of the injured person and therefore, the allowable amount could fluctuate. For example, depth-inlay shoes are coded as an Orthotic (L - code) if the patient does not have a diabetic diagnosis and is using the shoes for orthopedic reasons. The same depth-inlay shoe may be used for a diabetic patient but it would warrant an A-code, which can have a higher reimbursement level.

### How are HCPCS codes maintained?

CPT codes are republished and updated annually by the AMA; CMS maintains and distributes HCPCS Level II Codes.

### Where can I find HCPCS Codes?

CMS provides a list that contains the Level II alphanumeric HCPCS procedure and modifier codes, their long and short descriptions, and applicable Medicare administrative, coverage and pricing data on their website at <http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>

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#### About Helios:

Helios, the new name for Progressive Medical and PMSI, is bringing the focus of workers' compensation and auto no-fault pharmacy benefit management, ancillary services, and Settlement Solutions back to where it belongs – the injured party. Along with this new name comes a passion and intensity on delivering value beyond just the transactional savings for which we excel. To learn how our creative and innovative tools, expertise, and industry leadership can help your business shine, visit [www.HeliosComp.com](http://www.HeliosComp.com). © 2014 Helios™ All Rights Reserved.

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