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Unclassified Drugs

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DESCRIPTION:

The term unclassified is used to describe a drug that does not have a specific designated code in the Healthcare Common Procedure Coding System (HCPCS) or the Current Procedural Terminology (CPT®) Manual. It is the responsibility of the user of the HCPCS or CPT® coding systems to verify the use of an unclassified drug code, and to verify that a valid listed code for the form of drug administered does not exist. The codes for unclassified drugs should be used as a last resort or when instructions specify their use as claims payment can be delayed.

Compound drug: A pharmacy prepared medication containing one or more active ingredients. Compound drugs require a prescription and are prepared by a pharmacist to customize medications to the individual's specific needs.

Compound drugs may be prepared for oral, implanted, injection, topical (cream or gel), nebulized, or intravenous, or intrathecal pump administration. Compounded drug preparations do not have a National Drug Code (NDC), therefore specific HCPCS codes cannot be used, and these drugs are coded as unclassified.

REIMBURSEMENT INFORMATION:

Unclassified HCPCS codes can only be used when there is not a specific HCPCS code available for the drug NDC being billed. Submitting a claim with an unspecified HCPCS code when there is a specific HCPCS code for that drug will result in a denial of payment.

Each NDC associated with an unclassified drug code should be submitted on a separate claim line following the instructions specified in the Manual for Physicians and Providers- Billing Guidelines-Unclassified Drugs. Claims submitted without the correct information, as outlined in the provider manual and required for

processing will be denied and returned to the provider for correction.

For prescription drugs that do not have an established Average Sales Price (ASP), reimbursement will be based on 80% of the Average Wholesale Price (AWP) unit price (AWPU) associated with the corresponding NDC quantity submitted. Truli for Health will update pricing at least two times per calendar year.

Reimbursement Exception:

As determined by Truli for Health, an exception for special pricing may be applied to the identified drugs as a result of market conditions.

To review the list of approved drugs identified within the Reimbursement Exception Drug List, refer to

[Reimbursement Exception Drug List](#)

Point-of-Use Convenience Kits

Since there is typically no applicable HCPCS or CPT® Code unclassified drug codes may be utilized to submit claims for point-of-use convenience kits that are used in the administration of injectable medicines. These prepackaged kits contain not only the injectable medicine, but also non-drug components including, but not limited to, alcohol prep pads, cotton balls, band aids, disposable sterile medical gloves, povidone-iodine swabs, adhesive bandages and gauze. Typically, the cost of a convenience kit exceeds the cost of its components when purchased individually. Non-drug components included in the kits are already included in the practice expense for the administration of the drug and no additional compensation is payable to the provider. Similarly, if one or more drugs are combined into a kit or package, providers often bill more than the combined cost of each drug if billed separately.

Accordingly, claim lines with NDC codes representing these kits will be denied. Providers are expected to report the appropriate HCPCS code for the medication for reimbursement of the drug(s) contained within the kit.

To review a non-exclusive list of convenience kits that will not be reimbursed, refer to the link below. This list will be updated periodically but is not intended to be a complete list of any such kits. Any kits which meet the above description are not reimbursable even if they are not on this list.

[Convenience Kit Example Listing](#)

All of the following information is required to be submitted for reimbursement of a compound drug or any drug billed with unclassified drug codes:

- Valid NDC for each active ingredient utilizing the 11 digit numeric format
- NDC Description
- NDC quantity using an AWP unit price (AWPU) associated with the NDC Code
- assigned unit of measure for the dose administered to the member.

Example of information required to accompany an unclassified drug:

HCPCS Code	NDC	NDC Description	NDC Quantity*	Unit of Measure – UOM (assigned to NDC)
J3590	25682001312	Strensiq 28 MG/0.7ML SOLN	0.7	ML
J9999	00085131201	Sylatron 600MCG Kit	1	EA (UN**)
J3490	00074105305	Lupaneta Pack 11.25 & 5MG Kit	1	EA (UN)

*Two decimals. NDC quantity is based upon the numeric quantity administered to the patient based upon the unit of measurement. The following units of measurement (UOM) are the ONLY measurement values assigned to the NDC Code per NCPDP (National Council for Prescription Drug Programs):

F2 = International Unit GR=Gram

ML = Milliliter

EA = Each (billable unit of measure is UN = Unit)

Compound drugs considered for reimbursement must meet all the following criteria:

- There must be a valid prescription order from a physician with at least one FDA approved ingredient that has a recognized NDC number; **AND**
 - There is no commercially available product comparable to the compound product; **AND**
 - There is good evidence in the medical literature to support the use of all active ingredients; **AND**
 - ALL active ingredients are prescribed for the specific diagnosis; **AND**
 - The intended route of administration for the compounded prescription is supported by medical and scientific evidence **AND**
 - None of the active ingredients are addressed in another medical coverage guideline with coverage limitations disallowing it to be considered a medical necessity.
- EXCEPTIONS:
 1. Bulk powders that have a valid NDC number that are used in compounding drugs for the treatment of severe spasticity of cerebral or spinal cord origin and severe, chronic, intractable pain for use in infusion pumps **meet the definition of medical necessity based upon the published Medical Coverage Guideline.**
 2. Bulk powders that have a valid NDC number that are used in compounding alpha hydroxyprogesterone caproate injection and progesterone vaginal suppositories **meet the definition of medical necessity based upon the published Medical Coverage Guideline.**

Substances primarily utilized as stabilizing agents, that are **inert** ingredients, or diluents used in the compounded drug, are considered incidental to the preparation of the compound and are **NOT eligible** for reimbursement. Non-prescription preparations are NOT eligible for reimbursement.

Additional reimbursement for specific compounded medications must be accompanied by an entry on the claim in an additional line. Below is an example of the allowed compound fee for a surgically implanted pain medication pump refill. Additional compound fee codes specific to a mixture may be added in the future.

Example of information required to accompany an unclassified drug compound for refill of asurgically implanted pain med pump (40ml total volume):

HCPCS Code	NDC	Description	NDC Quantity*	Unit of Measure – UOM (assigned to NDC)
J3490	00000000070	Compounding Fee	1	UN
J3490	38779073105	Hydromorphone POW HCL	1.2	GR
J3490	38779038804	Baclofen POW	0.01	GR
J3490	38779056106	Clonidine 1mg/ml	0.04	GR

*Two decimals. NDC quantity is based upon the numeric quantity administered to the patient based upon the unit of measurement (AWPU). The following units of measurement (UOM) codes are:

F2 = International Unit GR=Gram

ML = Milliliter

EA = Each (billable unit of measure is UN = Unit)

Note: The HCPCS codes are more generic than NDC numbers as the HCPCS only describe drug and billing units. The NDC number is an 11-digit 3 segment unique identifier that identifies the pharmaceutical vendor, product, and trade package size.

BILLING/CODING INFORMATION:

HCPCS/CPT® Coding

A9699	Radiopharmaceutical, therapeutic, NOC
J1599	Injection, Immune Globulin, Intravenous, nonlyophilized (E.G. Liquid), NOS, 500MG
J3490	Unclassified drugs
J3590	Unclassified biologic
J3591	Unclassified drug or biological used for ESRD on dialysis
J7199	Hemophilia Clotting Factor, NOC
J7599	Immunosuppressive drug, NOC
J7699	NOC drugs, inhalation solution administered through DME
J7799	NOC drugs, other than inhalation, administered through DME
J7999	Compound drug, NOC
J8498	Antiemetic drug, rectal/suppository, not otherwise specified
J8499	Prescription drug, oral, nonchemotherapeutic, NOS
J8597	Antiemetic drug, oral, not otherwise specified
J8999	Prescription drug, oral, chemotherapeutic, NOS
J9999	NOC, antineoplastic drug
Q0181	Unspecified oral dosage form. FDA approved prescription antiemetic, for use as a complete therapeutic sub for IV antiemetic
Q2039	Influenza Virus Vaccine, not otherwise specified
Q4082	Drug or biological, NOC, Part B Drug Competitive Acquisition Program(CAP)
S5000	Prescription drug, Generic
S5001	Prescription drug, Brand Name
90399	Unlisted Immune Globulin
90749	Unlisted Vaccine/Toxoid

Hospitals (acute care, long term acute, and inpatient rehabilitation and ambulatory surgical centers):
All drug codes are included as part of these facility reimbursement policies/programs.

DEFINITIONS:

Inert: denoting a drug with or agent having no pharmacologic or therapeutic action.

National Drug Code (NDC): the FDA assigns each drug product listed a unique number. This number, known as the NDC, identifies the labeler, product, and trade package size.

RELATED MEDICAL COVERAGE GUIDELINES OR PAYMENT POLICIES:

- Unlisted CPT® Codes; Payment Policy 10-013
- Unclassified Codes and Compound Drug Products; Medical Coverage Guidelines 09-J0000-58

REFERENCES:

1. American Medical Association, *Current Procedural Terminology (CPT®), Professional Edition*.
2. Centers for Medicare & Medicaid (CMS). Medicare Benefit Policy Manual. Chapter 15, Section 50-Covered Medical and Other Health Services.
3. Centers for Medicare and Medicaid Services, HCPCS Release and Code Sets, <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>
4. Stedman’s Concise Medical Dictionary for the Health Professional (4th Edition)

GUIDELINE UPDATE INFORMATION

02/12/21	Updated Reimbursement Exception Drug Listing
05/13/21	Annual Review
05/12/22	Annual Review – References updated
05/11/23	Annual Review – Reference reviewed and updated.
05/09/24	Annual Review – Reference reviewed and updated.

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