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Unclassified Drugs Including Compound Drug Products

THIS PAYMENT POLICY IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS PAYMENT POLICY APPLIES TO ALL LINES OF BUSINESS AND PROVIDER OF SERVICE. IT DOES NOT ADDRESS ALL POTENTIAL ISSUES RELATED TO PAYMENT FOR SERVICES PROVIDED TO FLORIDA BLUE MEMBERS AS LEGISLATIVE MANDATES, PROVIDER CONTRACT DOCUMENTS OR THE MEMBER'S BENEFIT COVERAGE MAY SUPERSEDE THIS POLICY.

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: 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 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- Coding and Filing Claims-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 ASP, reimbursement will be based on 80% of the

Average Wholesale Price (AWP) unit price (AWPU) associated with the corresponding NDC quantity submitted. Florida Blue will update pricing at least two times per calendar year.

Reimbursement Exception:

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

To review the list of approved drugs identified within the Reimbursement Exception Drug List, refer to <http://providermanual.bcbsfl.com/ARS/cr/bg/Pages/Medical%20Pharmacy.aspx>

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 submitted for the dose administered to the member.

Example of information required to accompany an unclassified drug:

HCPCS Code	NDC	NDC Description	NDC Quantity*
J3490	00409156029	Bupivacaine, 0.50% 1ml	10.00
J9999	55566830101	Degarelix 1 UN	1.00
J3490	00409427001	Lidocaine 1ml	6.50

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

F2 = International Unit

GR=Gram

ML = Milliliter

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.
- *EXCEPTION: 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.**

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 a surgically implanted pain med pump (40ml total volume):

HCPCS Code	NDC	Description	NDC Quantity*
J3490	00000000070	Compounding Fee	1
J3490	38779067303	Morphine 50mg/ml	2.00
J3490	38779052403	Bupivacaine 20mg/ml	0.80
J3490	38779056106	Clonidine 1mg/ml	0.04

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

F2 = International Unit

GR=Gram

ML = Milliliter

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:

CPT Coding

62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming
95990	Refilling and maintenance of implantable pump or reservoir for drug delivery spinal (intrathecal, epidural) or brain (intraventricular)
95991	Refilling and maintenance of implantable pump or reservoir for drug delivery spinal (intrathecal, epidural) or brain (intraventricular); administered by physician

HCPCS Coding

J3490	Unclassified drugs
J3590	Unclassified biologic
J7599	Immunosuppressive drug, NOC
J7699	NOC drugs, inhalation solution administered through DME
J7799	NOC drugs, other than inhalation, administered through DME
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

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:

- 1. Unlisted CPT Codes; P0000006
- 2. Unclassified Codes and Compound Drug Products; 09-J0000-58

OTHER:

REFERENCES:

- 1. American Medical Association CPT Coding (current edition)
- 2. Centers for Medicare & Medicaid (CMS). Medicare Benefit Policy manual. Chapter 15, Section 50-Covered Medical and Other Health Services
- 3. HCPCS Level II, Expert (current edition)
- 4. Stedman’s Concise Medical Dictionary for the Health Professional (4th Edition)

COMMITTEE APPROVAL:

This Payment Policy was approved by the Florida Blue Payment Policy Committee on 05/14/10

PAYMENT POLICY UPDATE INFORMATION:

05/20/11	Revised Reimbursement section to include Reimbursement Exception to unclassified drug payment policy.
05/14/10	New payment policy.
08/21/12	Revised – Change name from BCBSF to Florida Blue

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