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Subject: Unclassified Codes and Compounded Drug Products

THIS MEDICAL COVERAGE GUIDELINE 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 MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs.

Compounded drugs are not FDA-approved. This means that FDA does not verify the safety, or effectiveness of compounded drugs. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed.

There can be health risks associated with compounded drugs that do not meet federal quality standards. Compounded drugs made using poor quality practices may be sub- or super‑potent, contaminated, or otherwise adulterated. Additional health risks include the possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective.

Drug Compounding Facilities

Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly placement of equipment and materials to be used to compound medications. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding or dispensing of non-sterile drug products. The area(s) used for the compounding of drugs shall be maintained in a good state of repair.

Bulk drugs and other materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-use towels.

The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

POSITION STATEMENT:

All FDA approved drugs billed with an unclassified drug code (see **Billing/Coding Information** below) are considered **medically necessary** when administered in accordance with FDA approved indications with three exceptions:

1. The drug has a separate medical coverage guideline outlining its coverage
2. The coverage is a contract exclusion
3. The drug is covered under the pharmacy benefit and coverage guidelines are applied (e.g., Prime Therapeutics documents)

Compounded prescriptions **meet the definition of medical necessity** when all of the following criteria are met:

1. There is a valid prescription order from a physician
2. Active ingredient(s) is an FDA-approved prescription drug with a valid National Drug Code†
3. There is no commercially available product comparable to the compounded product
    a. Example: There are no commercially available progesterone vaginal suppositories, but there is good evidence in the medical literature to support its use.
4. The safety and efficacy of all active ingredients for the diagnosis are supported by medical literature that meets **EITHER** of the following:
    a. Indication for use of the active ingredient(s) is recognized as “recommended” or “accepted” in a standard reference compendium.
    b. Indication for use of requested product is supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each

    NOTE: Case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support for use.
5. **ALL** active ingredients are prescribed for the diagnosis

6. The intended route of administration for the compounded prescription is supported by medical and scientific evidence
7. 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**.
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**.

Examples of compounded preparations that **do not meet the definition of medical necessity** due to insufficient medical evidence to support effectiveness:

1. Bio-identical hormones
2. Verapamil topical cream
3. Nebulized anti-infectives, nasal administration
4. Ketamine topical gel
5. Naltrexone implant
6. Epoprostenol inhalation/nebulization (Flolan/Veletri)

NOTE: This list is not all-inclusive

DOSAGE/ADMINISTRATION:

Not applicable.

PRECAUTIONS:

In 2002, FDA researchers sampled 29 products from 12 compounding pharmacies that market through the Internet. Nine products lacked potency; one was contaminated; and three others failed an initial test but were not counted as failures because an inadequate amount was left for retesting. By comparison, 1% to 2% of drugs from manufacturers fail to meet standard assays.

In a May 29, 2002, Compliance Policy Guide devoted to human pharmacy compounding, the FDA identified factors that it considers in deciding upon enforcement action. These factors include instances where pharmacists are:

- Compounding drug products that have been pulled from the market because they were found to be unsafe or ineffective.
- Compounding drugs that are essentially copies of a commercially available drug product.
- Compounding drugs in advance of receiving prescriptions, except in very limited quantities relating to the amounts of drugs previously compounded based on valid prescriptions.
- Compounding finished drugs from bulk active ingredients that aren't components of FDA-approved drugs, without an FDA-sanctioned, investigational new-drug application.

- Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
- Failing to conform to applicable state law regulating the practice of pharmacy.

BILLING/CODING INFORMATION:

HCPCS Codes

C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics
J7199	Hemophilia clotting factor, not otherwise classified
J7599	Immunosuppressive drug, not otherwise classified
J7699	NOC drugs, inhalation solution administered through DME
J7799	NOC drugs, other than inhalation drugs, administered through DME
J7999	Compounded drug, not otherwise classified
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	Not otherwise classified, antineoplastic drugs

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.

REIMBURSEMENT INFORMATION:

HOI: Must use network pharmacies for compounded prescriptions.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

Medicare Advantage: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

DEFINITIONS:

National Drug Code (NDC): the FDA assigned drug product listed unique number. This number identifies the labeler, product and trade package size.

Active Ingredient: Pharmaceutical drug or substance that has a therapeutic action.

RELATED GUIDELINES:

Intrathecal Drug Therapy for Long-Term Pain Management 09-J1000-31

Drugs and Biologics without a Medical Coverage Guideline (Orphan Drugs and Off-Label and Labeled Use of FDA Approved Drugs), 09-J0000-68

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 03/11/20.

GUIDELINE UPDATE INFORMATION:

07/15/06	New Medical Coverage Guideline.
07/15/07	Reviewed guideline: Maintain current coverage and limitations. Reformatted guideline, and updated references.
05/15/09	Review and revision; consisting of changing name to include unclassified. HCPCS codes and criteria for coverage as well as updating references.

04/15/10	Review and revision; consisting of adding additional coverage criteria for compounded drugs and updating references.
10/15/10	Revision; consisting of addition of exception criteria to position statement.
03/15/11	Review and revision; consisting of updating references.
05/15/11	Revision to guideline; consisting of adding additional exception to the position statement regarding progesterone products.
03/15/12	Review and revision to guideline; consisting of revision of position statement to require all active ingredients have FDA approval
03/15/13	Review and revision to guideline; consisting of reformatting position statement and revising to include definition of quality clinical evidence that is described in other policies.
03/15/14	Review and revision to guideline; consisting of reformatting position statement and updating program exceptions.
03/15/15	Review and revision to guideline; consisting of revising description, revising and reformatting position statement and precautions.
07/01/15	Revision to guideline; consisting of updating coding.
01/01/16	Annual HCPCS coding update: added code J7999 and deleted code Q9977.
03/15/16	Review and revision; consisting of updating position statement.
03/15/17	Review and revision; updated related guidelines.
04/15/18	Review and revision; consisting of updating position statement.
04/15/19	Review; no changes.
04/15/20	Review, updated position statement.
02/27/21	Revision consisting of updating position statement.