Compounded Drug Products

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Compounded Drug Products policy is to determine coverage when medications subject to compounding cost more than $500 to ensure they are utilized in accordance with FDA-approved indications, supported uses, and routes of administration found in the compendia including American Hospital Formulary Service Drug Information (AHFS), Micromedex, or other current accepted practice guidelines.

POLICY

Compounded drug products utilizing excluded ingredients whose total prescription ingredient cost is $500 or more may be considered **medical necessary** when the following criteria are met:

- The request is for any of the following: intravenous (IV) injection or infusion, anti-infective for injectable use (e.g., antibacterials, antivirals, antifungals), total parenteral nutrition (TPN), leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1 mg per 0.2 mL kit), pyrimethamine, sirolimus for tuberous sclerosis where other dermatological treatments (e.g., laser therapy, surgery, dermabrasion) are inappropriate

OR

- The request is for tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant

OR

- Each of the active ingredients in the compound are FDA-approved drugs [NOTE: Examples of products that typically do not get FDA-approval include bulk ingredients, dietary supplements, vitamin and mineral products, botanical or herbal products, amino acid products, enzyme supplements.]
  AND

- Each of the active ingredients in the compound are FDA-approved for the indication for which the compound is being prescribed
  AND

- The compound route of administration (ROA) is the same as the FDA-approved route of administration for each active ingredient [NOTE: Examples of ROAs include mucosal, oral, parenteral (by injection), inhalation, topical/dermal.]
  AND

- The dosage or concentration of each active ingredient in the compound is equal to or below the FDA-approved dosage or concentration
  AND

- The request is not for a topical compound or a topical compound kit for use on skin (e.g., cream, gel, lotion, ointment)
  AND

- The compound is not intended for anti-aging or cosmetic use, or is not a compound kit, or does not contain a bulk powder or dietary supplement
  AND

- The request is not for a hormone therapy compound for menopause or for androgen decline due to aging, (e.g., testosterone, estrogen, progestin, bioidentical hormone)
  AND

- Coverage is provided for additional fills of the compounded drug if the patient needs more than 1 fill per month (necessity may include continuation of antibiotic therapy, stability is less than a month, dose adjustment)

AND

- There is a current supply shortage of the commercially manufactured product
  OR

- The patient has a medical need for a dosage form or dosage strength that is not available commercially or manufactured
  OR

- The patient had an intolerance or contraindication to the commercially manufactured product (e.g., allergen or adverse effects due to inactive ingredients)
  OR

- The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness

Duration of Approval (DOA):

- Tacrolimus (Prograf) and everolimus (Zortress) for a patient receiving a transplant:
  - 12 years of age and older DOA: 36 months
  - Less than 12 years of age DOA: up to 12 years of age
- Other drugs and indications DOA: 6 months

Compounded products are considered **not medically necessary** for patients who do not meet the criteria set forth above.

CLINICAL RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines.

Products for intravenous (IV) injection or infusion, anti-infectives for injectable use (e.g., antibacterials, antivirals, antifungals), total parenteral nutrition (TPN), leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1 mg per 0.2 mL kit), pyrimethamine, or sirolimus for tuberous sclerosis where other dermatological treatments (e.g., laser therapy, surgery, dermabrasion) are inappropriate, or tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant are covered.

Topical compounds and topical compound kits for use on skin (e.g. cream, gel, lotion, ointment) are not covered (except sirolimus for tuberous sclerosis).

Compounds for anti-aging or cosmetic use, or compound kits, or compounds that contain a bulk powder or dietary supplement are not covered.

Hormone therapy compounds (e.g. testosterones, estrogens, progestins, bioidentical hormones) for menopause or for androgen decline due to aging are not covered. The FDA is not aware of any credible scientific evidence to support claims made regarding the safety and effectiveness of compounded bio-identical hormone replacement therapy drugs. In addition, the FDA has not approved any drug containing the hormone estriol. There are FDA-approved brand-name and generic manufactured menopausal hormone therapy and hormone replacement therapy products that are available in a variety of strengths and dosage forms (e.g., tablet, patch, gel, injectable, vaginal cream).

Compounding does not include mixing or reconstituting commercial products in accordance with the manufacturer's instructions or the product's approved labeling. Bulk ingredients are not FDA-approved products. Compounded drugs are not FDA-approved. The safety or effectiveness of compounded drugs are not verified by the FDA. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed. The FDA does not allow the marketing of compounding drugs that were withdrawn or removed from the market due to lack of safety or effectiveness; or compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products.

Pharmaceutical compounding is the combining, mixing, or altering of ingredients to create a customized medication that is not otherwise commercially available and is medically necessary for an individual patient in response to a licensed practitioner's prescription. There may be situations where a compound prescription is necessary due to special patient needs for customized therapies. Health needs that commercially available prescription medicines cannot meet may include:

- drug shortages, the need to access drugs or dosage forms withdrawn from the market, or medication is discontinued by or generally unavailable from pharmaceutical companies
- patient is allergic to certain preservatives, dyes or binders in commercially available medications (e.g., allergen-free medications)
- treatment requires tailored dosage strengths for patients with unique needs (e.g., an infant, non-standard doses, and parenteral nutrition)

- patient cannot ingest the medication in its commercially available form and the medication can be prepared in another form that the patient can ingest.

There may be a need to fill the compound prescription more than once per month (necessity may include continuation of antibiotic therapy, stability of water-containing formulation is less than a month, dose adjustment).

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD Diagnostic Codes.

- No applicable codes

REFERENCES

- 21 USC 353a: Pharmacy compounding From Title 21-FOOD AND DRUGS CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT SUBCHAPTER V-DRUGS AND DEVICES Part A-Drugs and Devices. Available at: https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section353a&num=0&saved=%7CKGNvbXBvdW5kIGRydWdzKQ%3D%3D%7CdHJlZXNvcnQ%3D%7CdHJ1ZQ%3D%3D%7C15%7Ctrue%7Cprelim. Accessed February 2024.
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POLICY HISTORY

Policy #: 05.01.88
Policy Creation: November 2015
Reviewed: October 2025
Revised: December 2023
Current Effective Date: February 22, 2024