

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	COMPOUNDED DRUG PRODUCTS
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Status: *CVS Caremark Criteria*
Type: *Initial Prior Authorization*

POLICY

COVERAGE CRITERIA

Compounded drug products will be covered with prior authorization when the following criteria are met:

- The request is for injectable or intravenous use [e.g., anti-infective/antibiotic, heparin, total parenteral nutrition (TPN), hydroxyprogesterone, leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1mg per 0.2mL kit)], or pyrimethamine

OR

- Each of the active ingredients in the compound are FDA-approved drugs
- Each of the active ingredients in the compound are used for an FDA-approved indication for which the compound is being prescribed
- The compound route of administration (ROA) is the same as the FDA-approved route of administration for each active ingredient
- The dosage or concentration of each active ingredient in the compound is equal to or below the FDA-approved dosage or concentration
- The request is not for a topical compound or a topical compound kit (e.g., cream, gel, lotion, ointment)
- The compound is not intended for anti-aging or cosmetic use, or is not a compound kit, or does not contain any of the following ingredients: bulk powder (e.g., cidofovir, estriol, fentanyl, fluticasone, heparin, hydromorphone, ketamine, mometasone, morphine, oxycodone), or dietary supplements (e.g., hydroxocobalamin, lipoic acid, resveratrol, tetrahydrobiopterin)
- 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)
- Coverage is provided for additional fills of the compounded drug if 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, adverse effects to inactive ingredients)
OR
- The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness

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