

# PRIOR AUTHORIZATION CRITERIA

## DRUG CLASS

## COMPOUNDED DRUG PRODUCTS

**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 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 (1mg per 0.2mL kit), pyrimethamine, hydroxyprogesterone, sirolimus for tuberous sclerosis where other dermatological treatments (e.g., laser therapy, surgery, dermabrasion) are inappropriate

#### **OR**

- Each of the active ingredients in the compound are FDA-approved drugs
- Each of the active ingredients in the compound are FDA-approved for the 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 for use on skin (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 a bulk powder or dietary supplement
- 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 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

#### REFERENCES

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