AETNA BETTER HEALTH®
Coverage Policy/Guideline

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| Name: | Compounded Drug Products | Page: | 1 of 3 |
| Effective Date: | 6/14/2024 | Last Review Date: | 5/2024 |
| Applies to: | ☐Illinois<br>☐New Jersey<br>☐Pennsylvania Kids | ☐Florida<br>☐Maryland<br>☒Virginia | ☐Florida Kids<br>☐Michigan<br>☐Kentucky PRMD |

## Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for compounded drug products under the patient's prescription drug benefit.

## Description:

N/A

## Applicable Drug List:

N/A

## Policy/Guideline:

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

- The request is for any of the following: A) intravenous (IV) injection or infusion, B) anti-infective for injectable use (e.g., antibacterials, antivirals, antifungals), C) total parenteral nutrition (TPN), D) leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1mg per 0.2mL kit), E) pyrimethamine, F) 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

  **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

  **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

### Approval Duration and Quantity Restrictions:

**Approval:**

- Tacrolimus or everolimus for transplant: 12 months
- 6 months for all other approvals

**Quantity Level Limit:** Reference Formulary for drug specific quantity level limits

### References:

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