

## 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) antiinfective for injectable use (e.g., antibacterials, antivirals, antifungals), C) total parenteral nutrition (TPN), D) pyrimethamine, E) 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
- 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**

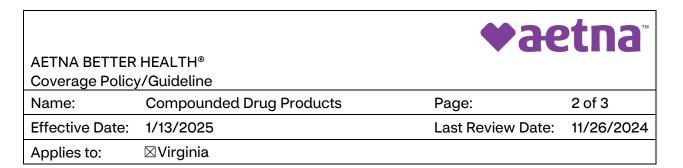
 The dosage or concentration of each active ingredient in the compound is equal to or below the FDA-approved dosage or concentration

## AND

• The 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:**

- 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 July 2024.
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- 3. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pharmacy-compounding-human-drug-products-under-section-503a-federal-food-drug-and-cosmetic-act. Accessed July 2024.
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# **AETNA BETTER HEALTH®**

Coverage Policy/Guideline

Name: Compounded Drug Products Page: 3 of 3

Effective Date: 1/13/2025 Last Review Date: 11/26/2024

Applies to: ⊠Virginia

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