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AETNA BETTER HEALTH® Coverage Policy/Guideline							
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Name: Compounded D		Products	Page:	1 of 3			
Effective Date: 1/13/2025			Last Review Date:	11/26/2024			
Applies	⊠Illinois	⊠Florida	□Michigan				
Applies to:	⊠New Jersey	\square Maryland	⊠Florida Kids				
	⊠Pennsylvania Kids	□Virginia	⊠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) 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
 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 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)

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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: 36 months for members 12 years of age or older; until age 12 years of age for those under 12 years of age
- 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
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