AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Compounded Drug Products	Page:	1 of 3
Effective Date:	2/1/2024	Last Review Date:	12/2023

Applies to:	☒Illinois	☒Florida	☒Florida Kids
	☒New Jersey	☒Maryland	☐Michigan
	☒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) 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: 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:

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