Reference number(s)
1181-A

Exception Criteria
Compound Exception (Excluded Drugs)

Coverage Criteria

Authorization may be granted for compounded drug products utilizing excluded ingredients when ONE of the following criteria is met:

- The request is for a proton pump inhibitor (PPI) compound kit for an infant or child with a diagnosis of symptomatic gastroesophageal reflux disease (GERD) AND the following criteria is met:
    - The patient had an intolerance or contraindication to ALL Food and Drug Administration (FDA)-approved PPI medications for the patient's age (examples may include allergen or adverse effects due to inactive ingredients). PPIs may include AcipHex sprinkles, Nexium capsules, Nexium granules, Prevacid capsules, Prevacid ODT, Prilosec capsules, Prilosec granules for oral suspension, Protonix granules for oral suspension.
- The request is for ANY of the following: Intravenous (IV) injections or infusion; Anti-infective for injectable use (Examples of anti-infectives may include antibacterials, antivirals, antifungals.); Total parenteral nutrition (TPN); Leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1 mg per 0.2 mL kit); Pyrimethamine; Sirolimus for tuberous sclerosis, where other dermatological treatments, (e.g., laser therapy, surgery, dermabrasion) are inappropriate.
- The request is for tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant.
- Each of the active ingredients in the compound are FDA-approved drugs and ALL of the following are met: [NOTE: Examples of products that typically do not get FDA-approval include bulk ingredients, dietary supplements, vitamin and mineral products, botanical or herbal products, amino acid products, enzyme supplements.]
    - 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 [NOTE: Examples of ROAs include mucosal, oral, parenteral (by injection), inhalation, topical/dermal.].
    - 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).
- The patient meets ONE of the following:
    - There is a current supply shortage of the commercially manufactured product.
    - The patient has a medical need for a dosage form or dosage strength that is not available commercially or manufactured.
    - The patient had an intolerance or contraindication to the commercially manufactured product (examples may include allergen or adverse effects due to inactive ingredients).
    - The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness.

Duration of Approval (DOA)

- 1181-A:
    - tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant: 12 years of age or older: DOA: 36 months; less than 12 years of age: DOA: up to 12 years of age
    - Other drugs and indications: DOA: 3 months

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14. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com Accessed August 2025.
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