| Reference number(s) |
| --- |
| 1114-A |

# Initial Prior Authorization Compounded Drug Products

## Coverage Criteria

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

- The request is for ANY of the following: Intravenous (IV) injections or infusion; Anti-infective for injectable use [NOTE: 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)
    - 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)

- 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)

- 1114-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 6 months

# References

1. 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.
2. Compounding Quality Act. U.S. Food and Drug Administration. Pharmacy Compounding. Available at: https://www.govinfo.gov/app/details/BILLS-113hr3204enr. Accessed July 2024.
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.
4. Human Drug Compounding. Available at: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding. Accessed July 2024.
5. Compounding and the FDA: Questions and Answers. Available at: https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers. Accessed July 2024.
6. USP Compounding Standards. Available at: https://www.usp.org/compounding. Accessed July 2024.
7. USP Compounding Standards and Beyond-Use Dates (BUDs). Available at: https://www.mbp.ms.gov/sites/default/files/2023-03/USP_Compounding_BUD_Fact_Sheet.pdf. Accessed July 2024.

8. USP-NF Chapters on Pharmacy Compounding, 795. https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc795.pdf. Accessed July 2024.
9. Is it Really FDA Approved? Available at: https://www.fda.gov/forconsumers/consumerupdates/ucm047470.htm. Accessed July 2024.
10. FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-cautions-about-using-testosterone-products-low-testosterone-due. Accessed July 2024.
11. Menopause. Available at: https://www.fda.gov/consumers/womens-health-topics/menopause. Accessed July 2024.
12. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on the Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy, Jackson L.M., Parker R.M., & Mattison D.R. (Eds.). (2020) *The clinical utility of compounded bioidentical hormone therapy: A review of safety, effectiveness, and use*. National Academies Press (US).
13. Drug Information (Drugs@FDA). Available at: http://www.fda.gov/Drugs/default.htm. Accessed July 2024.
14. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com Accessed July 2024.
15. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (*cited: 07/2024*).
16. Tuberous Sclerosis. Available at: https://rarediseases.info.nih.gov/diseases/7830/tuberous-sclerosis. Accessed July 2024.
17. Drug Nomenclature Monographs. Route of Administration. Available at: https://www.fda.gov/drugs/data-standards-manual-monographs/route-administration. Accessed July 2024.