



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Compounded Drug Products Page: 1 of 3

Effective Date: 8/9/2024 Last Review Date: 7/1/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> 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) 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)



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Compounded Drug Products Page: 2 of 3

Effective Date: 8/9/2024 Last Review Date: 7/1/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

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:

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%3AUASC-prelim-title21-section353a&num=0&saved=%7CKGNvbXBvdW5kIGRydWdzKQ%3D%3D%7CdHJlZXNvcnQ%3D%7CdHJlZQ%3D%3D%7C15%7Ctrue%7Cprelim>. Accessed July 2023.
2. Compounding Quality Act. U.S. Food and Drug Administration. Pharmacy Compounding. Available at: <https://www.govinfo.gov/app/details/BILLS-113hr3204enr>. Accessed July 2023.
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 2023.
4. Human Drug Compounding. Available at: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>. Accessed July 2023.
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 2023.
6. USP Compounding Standards. Available at: <https://www.usp.org/compounding>. Accessed August 2023.
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 2023.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Compounded Drug Products Page: 3 of 3

Effective Date: 8/9/2024 Last Review Date: 7/1/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

8. USP-NF Chapters on Pharmacy Compounding, 795.
https://www.uspnf.com/sites/default/files/uspnf_pdf/EN/USPNF/revisions/gc-795-rb-notice-20200424.pdf. Accessed August 2023.
9. Is it Really FDA Approved? Available at:
<https://www.fda.gov/forconsumers/consumerupdates/ucm047470.htm>. Accessed July 2023.
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 2023.
11. Menopause. Available at: <https://www.fda.gov/consumers/womens-health-topics/menopause>. Accessed July 2023.
12. National Academies of Sciences, Engineering, and Medicine. 2020. The clinical utility of compounded bioidentical hormone therapy: A review of safety, effectiveness, and use. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25791>.
13. Drug Information (Drugs@FDA). Available at: <http://www.fda.gov/Drugs/default.htm>. Accessed August 2023.
14. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. August 2023.
15. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. August 2023.
16. Tuberous Sclerosis. Available at: <https://rarediseases.info.nih.gov/diseases/7830/tuberous-sclerosis>. Accessed August 2023.
17. Drug Nomenclature Monographs. Route of Administration. Available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071650.htm>. Accessed August 2023.