Harvard Pilgrim Health Care | TUFTS Health Plan

# Pharmacy Medical Necessity Guidelines: **Compound Medications**

*Effective: November 4, 2025*

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| **Guideline Type** | ☐ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☒ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration – Approved Indications**

Pharmaceutical compounding is the combining, mixing, or altering of ingredients to create a customized medication that is not otherwise commercially available. The Food and Drug Administration (FDA) does not allow the marketing of compounded drugs that were withdrawn or removed from the market due to lack of safety or effectiveness; or compounding finished drugs from bulk active ingredients that are not per FDA regulations; or compounding drug products that are commercially available or that are essentially copies of commercially available FDA-approved drug products.

Please note, compounded prescription claims may process for patients under the age of 18 for those compounds with active ingredients on formulary.

## Clinical Guideline Coverage Criteria

For those compounds prescribed for members 18 years of age or older, or exceed $500 per claim, the plan may authorize coverage when **ALL** of the following criteria are met:

**Initial Therapy:**

**Request is for one of the following:**

1. Magic mouth wash
2. All-purpose nipple ointment (APNO) consisting of betamethasone, clotrimazole, and mupirocin
3. Medication indicated for fertility or maintenance of pregnancy

**OR**

**Other compound medication requests**

1. **ALL** of the following:
   a. Each of the active ingredients in the compound are FDA-approved or supported by a nationally recognized compendium for the condition being treated

   **AND**

   b. The therapeutic amounts are FDA-approved or supported by a nationally recognized compendium for the condition being treated in the requested route of delivery

   **AND**

   c. The route of administration for the compound is FDA approved or supported by a nationally recognized compendium for the condition being treated

   **AND**

2. All of the active ingredients included in the compound are FDA-approved

   **AND**

3. If there are existing clinical coverage criteria for any of the active ingredients, those criteria will also need to be met for

these ingredients

**AND**

4. The requested compound is NOT for a cosmetic use

**AND**

5. The patient has had a treatment failure of, or is unable to tolerate, two (2) or more formulary alternative medications within the same therapeutic class and same route of administration (where coverage is listed on the formulary as applicable), and if no alternatives within the same therapeutic class and same route of administration are listed on the formulary, then two or more formulary alternative medications with same FDA-approved indication (where coverage is listed on the formulary as applicable)

**AND**

6. One of the following:
    a. There is a current supply shortage of the commercial product

    **OR**

    i. The patient has a medical need for a dosage form or dosage strength that is not commercially available

    **OR**

    ii. The patient had a trial and intolerance to or contraindication to the commercially available product (e.g. allergen/preservative/dye-free, palatability for pediatrics, adverse effects to binders/fillers/other inactive ingredients)

    **OR**

    iii. The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness

**Reauthorization:**

1. Requested medication is a renewal

**AND**

2. The patient has experienced improvement while on therapy

**Note**: All of the active ingredients included in the compound need to be included on the request for authorization.

## Limitations

- Approval for compound medications will be authorized for 12 months except for the following:
    - Compound medication due to supply shortages will be authorized for three (3) months
- For reauthorization requests, the plan requires evidence of utilization within the past 365 days per patient's claim profile otherwise initial criteria will be applied.
- Coverage is not provided in situations where the compound is intended for cosmetic use (e.g. anti-aging, anti-wrinkle, hair growth/removal, scar diminishing, skin lightening/tanning) OR performance enhancement. Examples include but are not limited to:
    - Arginine used for exercise performance
    - Chorionic gonadotropin (HCG) used for performance enhancement or anti-aging
    - Clomiphene used for performance enhancement or anti-aging
    - Coenzyme Q10 (ubiquinol / ubidecarenone) used for performance enhancement
    - Testosterone used for performance enhancement
- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

## Codes

None

## References


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2. Application of Federal Law to Practice of Pharmacy Compounding from Food and Drug Administration Modernization Act of 1997. fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155666.htm. Accessed June, 2014.
3. International Academy of Compounding Pharmacists. iacprx.org/displaycommon.cfm?an=1&subarticlenbr=1. Accessed February, 2014.

4. USP Compounding Standards & Resources. usp.org/usp-healthcare-professionals/compounding. Accessed July, 2014.
5. Compounding Quality Act. U.S. Food and Drug Administration. Pharmacy Compounding. Available at: gpo.gov/fdsys/pkg/BILLS-113hr3204enr/pdf/BILLS-113hr3204enr.pdf. Accessed July, 2014.
6. Drug Nomenclature Monographs. Route of Administration. Available at: fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManual monographs/ucm071650.htm. Accessed February, 2014.
7. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed June, 2014.
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9. Newman, Jack. "All-Purpose Nipple Ointment (APNO)" International Breastfeeding Centre, Updated September 2021, Available at: https://ibconline.ca/information-sheets/all-purpose-nipple-ointment-apno/. Accessed Aug 2022.
10. National Institutes of Health (2020). Dietary Supplements for Primary Mitochondrial Disorders Available at: https://ods.od.nih.gov/factsheets/PrimaryMitochondrialDisorders-HealthProfessional/. Accessed Aug 2022.

## Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 2022 e-vote: Updated criteria to include magic mouthwash, APNO, and medications indicated for fertility or maintenance of pregnancy. Clarified cosmetic uses and reauthorization criteria. Updated guideline type to administrative.
- September 12, 2023: No changes.
- November 12, 2024: Effective January 1, 2025, criteria for compound containing melatonin or nutritional supplements used for a mitochondrial disorder or mitochondrial cocktail was removed due to lack of clinical evidence. Updated criteria for other compounds medications to add prerequisite trial of two formulary alternatives. Minor administrative updates to verbiage.
- November 4, 2025: No changes.

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.