Pharmacy Medical Necessity Guidelines: Compounded Medications

Effective: September 15, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

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 The Food and Drug Administration (FDA) does not allow the marketing of compounded drugs that were withdrawn or removed from the market due to lack of safety or effectiveness; or compounding finished drugs from bulk active ingredients that are not per FDA regulations;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 under $500 may process for patients under the age of 18 when the active ingredients are on the Preferred Drug List (PDL).

COVERAGE GUIDELINES

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 and limitations do not apply:

Initial Request:

Compound containing Melatonin or Nutritional supplements used for a mitochondrial disorder or for a mitochondrial cocktail

1. The requested compound is for a patient 17 years of age or younger

AND

2. Request is for a compound containing ONE of the following:
    a. Nutritional supplements used for a mitochondrial disorder or for a mitochondrial cocktail
    b. Melatonin

Other compound medication requests

1. The indication, therapeutic amount, and route of administration of each of the active ingredients in the compound are FDA-approved or supported by CMS-recognized compendia

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. And one (1) of the following:
    a. There is a current supply shortage of the commercial product

    OR

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

    OR

    c. 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 active ingredients)

OR

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

OR

e. Request is for one of the following:
    i. Magic mouth wash
    i. All-purpose nipple ointment (APNO) consisting of betamethasone, clotrimazole, and mupirocin

Reauthorization:

1. Requested medication is a renewal as determined by utilization within the past 365 days per member's claim profile

AND

2. The patient has experienced improvement while on therapy

LIMITATIONS

1. Coverage is **not** provided in situations where the compound is intended to be used for an excluded purpose (e.g., cosmetic use, sexual dysfunction, infertility).
2. Approvals for compounds containing melatonin or nutritional supplements used for a mitochondrial disorder or for a mitochondrial cocktail will be approved until the patient reaches their 18th birthday
3. Other compound medication approvals will be limited to 12 months.
4. For a request for a non-covered medication, please refer to the Pharmacy Medical Necessity Guidelines for Pharmacy Products Without Specific Criteria (Tufts Health RITogether).

CODES

None

REFERENCES

1. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Available at: fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf. Accessed July 2014.
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/DataStandardsManualmonographs/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.
8. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. micromedexsolutions.com [available with subscription]. Accessed June, 2014.
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 HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: No changes.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. September 15, 2026: 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.

Provider Services