Pharmacy Medical Necessity Guidelines: Compounded Medications

Effective: November 10, 2020

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:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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 The Food and Drug Administration (FDA) does not allow the marketing of compounded drugs that were withdrawn or removed from the market due to lack of safety or effectiveness; or compounding finished drugs from bulk active ingredients that are not per FDA regulations;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.

COVERAGE GUIDELINES

The plan may authorize coverage of compounded prescription medications with an ingredient cost greater than or equal to $2,500 when **ALL** of the following criteria are met:

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

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

   OR

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

   OR

   c. The Member 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

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

LIMITATIONS

- Coverage is **not** provided for compounds applied topically (e.g. creams, gels, lotions, ointments) that contain any of the following ingredients:
  - Amitriptyline

- Baclofen
- Benzocaine
- Cyclobenzaprine
- Duloxetine
- Flurbiprofen (excluding ophthalmic solution)
- Fluticasone
- Gabapentin
- Ketamine
- Ketoprofen
- Nabumetone
- Memantine
- Oxycodone
- Tramadol

- 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

- Coverage is **not** provided in situations where the compound is being used as hormone therapy for treatment of menopause or for androgen decline in the aging male, (e.g., testosterone, estrogen, progestin, bioidentical hormones)

- Initial coverage duration will be 6 months. Any subsequent approval will require documentation of clinical response and if approved the duration will be 12 months.

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.

APPROVAL HISTORY

November 4, 2014 [Effective 1/1/15]: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 10, 2015: Removed the excluded ingredient list.
2. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
3. October 18, 2016: Administrative update due to consolidation of criteria-fluticasone added to the ingredient list for Limitation #1 because included in Tufts Health Together criteria. Effective October 18, 2016 Medical Necessity Guideline applies to Tufts Health Together.
4. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
5. October 17, 2017: No changes
6. August 7, 2018: Administrative update, clarified that the $300 compounding limit applies to all lines of business.
7. August 13, 2019: Changed the max dollar limit to $2,500 for all lines of business. Administrative update to the template.
8. November 10, 2020: 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.