Pharmacy Medical Necessity Guidelines:
Off-Label Use Policy - Freedom

Effective: September 15, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX MD	Department to Review	RxUM Precert

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
MM: 888.415.9055
PRECERT: 617.972.9409

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

OVERVIEW

New Hampshire managed care law Title XXXVII Insurance Chapter 415 Accident and Health Insurance Section 415:18-j Off-label Prescription Drugs requires that coverage for prescription drugs must not exclude drug coverage for a particular indication on the ground that the drug has not been FDA-approved for that indication, if the drug is recognized for treatment of such indication in one of the standard reference compendia or in the medical literature.

New Hampshire has a mandate regarding the treatment for Lyme Disease; New Hampshire House Bill 1693, requires the coverage of long-term antibiotic therapy for tick-borne illness.

Off-label drug use is the use of a drug approved by the U.S Food and Drug Administration (FDA) for other uses or in treatment regimens or patient populations that are not included in the approved labeling. Many off-label uses are effective and well-documented in the literature, and widely used.

COVERAGE GUIDELINES

A. The plan may authorize coverage of a prescription medication for a non-FDA approved indication when the following criteria are met:

a) The drug is FDA-approved

AND

b) The member has tried and failed established FDA approved and/or clinical guideline recommended therapy unless contraindicated

AND

c) A. The drug is recognized for treatment of the requested indication in one of the standard reference compendia
   - American Hospital Formulary Service – Drug Information (AHFS-DI)
   - Thomson Micromedex DrugDex
   - Clinical Pharmacology (Gold Standard)
   - National Comprehensive Cancer Network (NCCN)
   - Facts & Comparisons

OR

B. In the absence of being listed in above named sources, a minimum of at least two articles from major peer-reviewed journals which supports the proposed use for the specific medical condition as safe and effective.

Note: The Plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended indication.

When the Plan evaluates the evidence in published, peer-reviewed medical literature, consideration will be given to the following:

1. Whether the clinical characteristics of the beneficiary and the indication being requested are adequately represented in the published evidence.
2. Whether the administered regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
4. Whether the study is appropriate to address the clinical question
    a. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.);
    b. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and, that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

LIMITATIONS

- The plan will not cover requests for cosmetic uses.
- If the above criteria are met, initial approval will be for three (3) months. Subsequent approval(s) will require clinical documentation of efficacy by the provider, and may be authorized for up to one (1) year.
- If the drug being requested is subject to a quantity limitation or a specialty designated pharmacy those requirements will still apply.

CODES

None

REFERENCES

1. Accident and Health Insurance Chapter 415 RSA 415:18-j
2. DrugDex® System (database online). Greenwood Village, CO: Thomson Micromedex. Available at: micromedexsolutions.com.
3. Facts and Comparisons® (database online). St. Louis, MO: Wolters Kluwer Health, Inc. Available at: factsandcomparisons.com.
4. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (database online). Available at: nccn.org.
5. U.S. Food and Drug Administration (FDA). Off-label and investigational use of marketed drugs, biologics, and medical devices. Available at: fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.

APPROVAL HISTORY

December 08, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. October 18, 2016: No changes
2. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
3. October 16, 2018: Administrative update to template.
4. December 10, 2019: No changes.
5. September 15, 2020: Updated overview to include requirement to cover long-term antibiotic therapy for tick-borne illness.

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.