Pharmacy Medical Necessity Guidelines:
New-to-Market (NTM) Drug Evaluation Process

Effective: July 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx/ MED	Department to Review	RXUM/ PRECERT /MM

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

In order to promote clinically appropriate and cost-effective prescription drug use, Tufts Health Plan has several programs in place, one of which is the New-to-Market (NTM) Drug Evaluation Process described below:

NTM Drug Evaluation Process

Due to the faster Food and Drug Administration (FDA) approval process for new drugs, Tufts Health Plan delays coverage determination of many new drug products until the Pharmacy and Therapeutics (P&T) Committee and physician specialists have reviewed the drug. During the evaluation period, beginning when the drug first becomes available on the market, the P&T Committee reviews any additional information on the safety and effectiveness of these new products.

COVERAGE GUIDELINES

When the following criteria are met, the plan may authorize coverage of prescription medications otherwise not covered due to the NTM Drug Evaluation Process:

1. The request for coverage is for an FDA-approved indication for a use that is covered in the Member's benefit document or for a recognized off-label use of an FDA-approved prescription medication used in the treatment of cancer or HIV/AIDS

AND

2. Coverage is determined based on the NTM drug classification as follows:

   Step 1: Does the plan have existing Clinical Coverage Criteria for previously reviewed prescription medications with an FDA-approved indication that is the same indication as the NTM drug?
   a) If **YES**, then coverage for the NTM drug is determined by using those criteria and by using documentation from the requesting physician showing that the Member has had a treatment failure of, or is unable to tolerate, two (2) or more formulary alternative medications.
   b) If NO Existing Clinical Coverage Criteria, then proceed to step 2.

   Step 2: Does the NTM drug have available formulary alternative medications to treat the same condition?
   c) If **YES**, then coverage for the NTM drug is determined by using documentation from the requesting physician showing that the Member has had a treatment failure of, or is unable to tolerate, two (2) or more formulary alternative medications.
   d) If **NO**, then proceed to step 3.

Step 3: Is the NTM drug a novel agent, defined as a "first of its kind drug" in a new class of drugs?

e) If **YES**, then coverage for the NTM drug is determined by using documentation from the requesting physician showing that all other available lines of treatment that are consistent with generally accepted principles of professional medical practice and/or with guidelines from a nationally recognized entity for the disease for which the Member is being treated, have been exhausted.

f) If **YES**, and coverage is being requested for a new agent indicated for the treatment of Duchene muscular dystrophy, documentation from the requesting physician is required showing the Members is ambulatory at the time of the request.

LIMITATIONS

1. The duration of coverage will be limited to one year, or up to a complete course of therapy if less than one year as noted in the medication's FDA-approved package insert, or as deemed clinically necessary by the plan.
2. For excluded drug classes please refer to the Member Handbook or Evidence of Coverage document.
3. For NH and RI Commercial members requesting use of a medication for off-label use please see the medical necessity guidelines for off-label use.
4. Coverage for any new agent indicated for the treatment of Duchene muscular dystrophy will not be authorized for Members who are not ambulatory at the time of the request.
5. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

None

APPROVAL HISTORY

October 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 9, 2004: No changes
- November 8, 2005: No changes
- September 12, 2006: No changes
- September 11, 2007: No changes
- July 8, 2008: No changes
- July 14, 2009: No changes
- January 1, 2010: Removal of Tufts Health Medicare Preferred language (separate criteria have been created specifically for Tufts Health Medicare Preferred).
- July 13, 2010: No changes
- July 12, 2011: No changes
- April 10, 2012: No changes
- April 9, 2013: No changes
- April 8, 2014: Updated the language in Criteria #2, Step-2 to read "Does the NTM drug have available formulary alternative medications to treat the same condition?"
- October 7, 2014: Clarified the criteria that coverage through Step 1 and Step 2 require documentation from the requesting physician showing that the Member has had a treatment failure of, or is unable to tolerate, two (2) or more formulary alternative medications.
- January 13, 2015: Clarified the length of coverage approval.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct
- January 12, 2016: Effective July 12, 2016 Medical Necessity Guideline applies to Tufts Health Together. Added limitation #3 "For excluded drug classes please refer to the Member Handbook or Evidence of Coverage document."
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- July 11, 2017: Added limitation: For NH and RI members requesting use of a medication for off-label use please see the medical necessity guidelines for off-label use.
- June 12, 2018: Updated the limitations section to clarify that duration of coverage will be limited to one year. Also indicated that off-label use criteria also apply to RI Medicaid members.

- September 18, 2018: Administrative update, removing Rhode Island Together from the Medical Necessity Guideline.
- June 11, 2019: Effective October 1, 2019, added criteria and the limitation for requests for any new agents for the treatment of DMD requiring Members to be ambulatory at the time of the request.
- July 14, 2020: Added the following limitation: Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

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.