**Pharmacy Medical Necessity Guidelines: Montelukast (Singulair) Granules**

*Effective: July 11, 2017*

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<th>Prior Authorization Required</th>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

**Fax Numbers:**
- RXUM: 617.673.0988

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**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Montelukast granules are indicated for:
- Acute prevention of exercise-induced bronchoconstriction in patients 6 years of age and older.
- Prophylaxis and chronic treatment of asthma in patients 12 months of age and older.
- Relief of symptoms of seasonal allergic rhinitis in patients 2 years and older and perennial allergic rhinitis in patients 6 months and older.

**COVERAGE GUIDELINES**

The plan may authorize coverage of montelukast granules for Members when all of the following criteria are met:

**Asthma**
1. The Member tried and failed therapy with montelukast chewable tablets, or the provider indicates clinical inappropriateness of therapy with montelukast chewable tablets

**Allergic rhinitis**
1. The Member tried and failed concurrent therapy with a non-sedating antihistamine and a nasal corticosteroid, or the provider indicates clinical inappropriateness of therapy with a non-sedating antihistamine and a nasal corticosteroid

**Exercise-induced bronchoconstriction or bronchospasm**
1. The Member tried and failed therapy with an inhaled beta-agonist agent, or the provider indicates clinical inappropriateness of therapy an inhaled beta-agonist agent

**LIMITATIONS**
1. The quantity is limited to one packet per day.
2. Requests for brand-name products, which have AB-rated generics, will also require approval of Brand Name criteria.

**CODES**
None
REFERENCES

APPROVAL HISTORY
February 10, 2015: Reviewed by Pharmacy & Therapeutics Committee; approval duration is limited to one year; chewable tablets preferred prior to use of the granules.

Subsequent endorsement date(s) and changes made:
- January 1, 2016: Administrative change to rebranded template.
- April 12, 2016: Removed Limitation #2 “Requests for quantities that exceed the quantity limit will also be reviewed according to the Drugs with Quantity Limitation criteria.”
- April 11, 2017: Administrative update, adding Tufts Health RTTogether to the template.
- July 11, 2017: 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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.