Pharmacy Medical Necessity Guidelines: Montelukast (Singulair) Granules

Effective: March 1, 2021

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

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

AND

2. The Member tried and failed concurrent therapy with montelukast chewable tablets, or the provider indicates clinical inappropriateness of therapy with montelukast chewable tablets

Exercise-induced bronchoconstriction or bronchospasm

1. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with one of the following: an inhaled beta-agonist agent or low-dose inhaled corticosteroid-formoterol

AND

2. The Member tried and failed concurrent therapy with montelukast chewable tablets, or the provider indicates clinical inappropriateness of therapy with montelukast chewable tablets

LIMITATIONS

1. Montelukast granules are available without prior authorization for Members 6 through 23 months of age.
2. The quantity is limited to one packet per day.
3. Requests for brand-name products, which have AB-rated generics, will reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324:2301-2317.
2. Global Initiative for Asthma. Global strategy for asthma management and prevention, updated 2020. ginasthma.org/wp-content/uploads/2020/06/GINA-2020-report_20_06_04-1-wms.pdf. Accessed 22 January 2021.
3. National Asthma Education and Prevention Program. Working Group Report on Managing Asthma During Pregnancy: Recommendations for Pharmacologic Treatment, Update 2004. NIH Publication No. 05-5236. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute; March 2005. nhlbi.nih.gov/health/prof/lung/asthma/astpreg/astpreg_full.pdf.
4. Singulair (montelukast) [package insert]. Whitehouse Station, NJ: Merck and Co; April 2020.

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:

1. January 1, 2016: Administrative change to rebranded template.
2. 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."
3. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
4. June 12, 2018: No changes.
5. February 26, 2019: Effective 5/1/2019, updated MNG to indicate that montelukast granules will be covered for members 6 through 23 months of age. Administrative changes made to template.
6. February 11, 2020: No changes.
7. February 9, 2021: Updated criteria for EIB to include low-dose ICS-formoterol as a trial option.

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.