Pharmacy Medical Necessity Guidelines: Montelukast (Singulair) Granules

Effective: October 13, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Montelukast is 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.

Montelukast is not indicated for the treatment of acute asthma attack.

COVERAGE GUIDELINES

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

1. The Member tried and failed 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. Requests for brand-name products, which have AB-rated generics, will be 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 2023. Available at: https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf. Accessed 31 July 2023. http://www.nhlbi.nih.gov/health/prof/lung/asthma/astpreg/astpreg_full.pdf.
3. Singulair (montelukast) [package insert]. Jersey City, NJ: Organon LLC; November 2023.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: No changes.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. October 13, 2026: 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.

Provider Services