Clinical Policy: Montelukast Oral Granules (Singulair)

Reference Number: HIM.PA.129
Effective Date: 12.01.17
Last Review Date: 11.22
Line of Business: HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Montelukast (Singulair®) is a leukotriene receptor antagonist. Prior authorization is required for the oral granules.

FDA Approved Indication(s)

Singulair is indicated for the:

- Prophylaxis and chronic treatment of asthma in patients 12 months of age and older
- Acute prevention of exercise-induced bronchoconstriction in patients 6 years of age and older
- Relief of symptoms of allergic rhinitis: seasonal allergic rhinitis in patients 2 years of age and older, and perennial allergic rhinitis in patients 6 months of age and older. Reserve use for patients who have an inadequate response or intolerance to alternative therapies.

Limitation(s) of use: Singulair is not indicated to treat an acute asthma attack.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Singulair oral granules are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Singulair Oral Granules (must meet all)**:**

1. Age ≥ 6 months;
2. Member meets one of the following (a or b):
   a. Age < 6 years;
   b. Documentation supports member's inability to use regular or chewable montelukast tablets;
3. If request is for brand Singulair granules, member must use generic montelukast granules, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 4 mg (1 packet of oral granules) per day.

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable

II. Continued Therapy

A. Request for Singulair Oral Granules (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member meets one of the following (a or b):
   a. Age < 6 years;
   b. Documentation supports member's continued inability to use regular or chewable montelukast tablets;
3. If request is for brand Singulair granules, member must use generic montelukast granules, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed 4 mg (1 packet of oral granules) per day.

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to any component of this product
- Boxed warning(s): serious neuropsychiatric events

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Asthma	PO QD	Dosing based on age: • ≥ 15 years: 10 mg tablet • 6-14 years: 5 mg chewable tablet • 2-5 years: 4 mg chewable tablet or oral granules • 6-23 months: 4 mg oral granules
Acute prevention of exercise-induced bronchoconstriction	PO at least 2 hours before exercise	
Relief of symptoms of allergic rhinitis	PO QD	

VI. Product Availability

- Film-coated tablet: 10 mg
- Chewable tablets: 4 mg, 5 mg
- Oral granules: 4 mg

VII. References

1. Singulair Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; June 2021. Available at: www.singulair.com. Accessed July 21, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018 annual review: no significant changes; corrected upper age restriction from 5 to 6 years per PI; references reviewed and updated.	07.02.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.24.19	11.19
4Q 2020 annual review: no significant changes; updated FDA-approved indication with revised indication for allergic rhinitis to specify that use should be reserved for patients with inadequate response to alternative therapies; updated Appendix C to include new boxed warning for neuropsychiatric events; references reviewed and updated.	07.01.20	11.20
4Q 2021 annual review: no significant changes; added limitation of use per updated prescribing information; references reviewed and updated.	06.28.21	11.21
4Q 2022 annual review: no significant changes; added redirection to generic; references reviewed and updated. Template changes applied to continued therapy section.	07.21.22	11.22

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.