

**Clinical Policy: Montelukast Oral Granules (Singulair)**

Reference Number: HIM.PA.129

Effective Date: 12.01.17

Last Review Date: 11.19

Line of Business: HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Montelukast (Singulair<sup>®</sup>) 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

**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<sup>®</sup> 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  $\geq$  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. Dose does not exceed 4 mg per day (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. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 a dose increase, new dose does not exceed 4 mg per day (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): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Asthma	PO QD	Dosing based on age:
Acute prevention of exercise-induced bronchoconstriction	PO at least 2 hours before exercise	<ul style="list-style-type: none"><li>• ≥ 15 years: 10 mg tablet</li><li>• 6-14 years: 5 mg chewable tablet</li><li>• 2-5 years: 4 mg chewable tablet or oral granules</li><li>• 6-23 months: 4 mg oral granules</li></ul>
Relief of symptoms of allergic rhinitis	PO QD	

**VI. Product Availability**

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

**VII. References**

1. Singulair Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; February 2, 2019. Available at: [www.singulair.com](http://www.singulair.com). Accessed August 24, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.23.17	11.17
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.24.19	11.19

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and 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.

**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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