

## Policies Repository



**Policy Title** Montelukast (Singulair®)

**Policy Number** FS.CLIN.47

*Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.*

*This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.*

*Members are advised to use participating pharmacies in order to receive the highest level of benefits.*

**Policy** **Montelukast (Singulair®)** is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric individuals 12 months of age and older. It is also indicated for the symptomatic relief of allergic rhinitis (seasonal allergic rhinitis in adults and children 2 years of age and older and perennial allergic rhinitis in adults and children 6 months of age and older). Montelukast (Singulair®) is indicated for the prevention of exercise-induced bronchoconstriction in patients 15 years of age and older.

The use of montelukast (Singulair®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

**Policy Description**

**Montelukast (Singulair®)** is an oral leukotriene receptor antagonist that is used in the treatment of asthma and allergic rhinitis. Leukotrienes are a group of naturally occurring chemicals in the body that promote inflammation in asthma and allergic rhinitis, as well as in conditions in which inflammation is important (such as allergy). Leukotrienes are formed by cells, then released and bound to other cells. When this binding occurs, the cells are stimulated to promote inflammation. Montelukast (Singulair®) reduces the inflammation by inhibiting the cellular binding of some leukotrienes.

Montelukast (Singulair®) can be used as a first-line agent for treating mild persistent asthma; however, it should not be used as rescue medication to treat acute episodes of asthma or to prevent or treat asthma made worse by exercise. Montelukast (Singulair®) should not be abruptly substituted for an oral or inhaled corticosteroid.

**Policy Guideline Inclusion**

**Montelukast (Singulair®)** is approved when **one** of the following inclusion criteria is met:

- Documentation of a diagnosis of asthma in individuals 12 months of age and older
- Documentation for prevention of exercise-induced bronchoconstriction in individuals 15 years of age and older

- Documentation of a diagnosis of allergic rhinitis in individuals 6 months of age and older with documented failure of **at least one** of the following:
  - Prescription nonsedating antihistamine (eg, fexofenadine [Allegra®], desloratadine [Clarinet®], levocetirizine [Xyzal®])
  - Over-the-counter nonsedating antihistamine (eg, loratadine [Claritin®], Alavert®), cetirizine [Zyrtec®])
  - Intranasal corticosteroid (eg, beclomethasone [Vancenase®], budesonide [Rhinocort®], fluticasone [Flonase®], mometasone [Nasonex®], triamcinolone [Nasacort®])

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### Policy Guideline Exclusion

**Montelukast (Singulair®)** is denied when **all** of the following exclusion criteria are present:

- No documentation of a diagnosis of asthma
- Patient age less than 12 months for treating asthma OR less than 6 months for treating allergic rhinitis
- No documentation for prevention of exercise-induced bronchoconstriction in individuals 15 years of age and older
- No documentation of a diagnosis of seasonal allergic rhinitis with undocumented failure of at least one of the following:
  - Prescription nonsedating antihistamine (eg, fexofenadine [Allegra®], desloratadine [Clarinet®], levocetirizine [Xyzal®])
  - Over-the-counter nonsedating antihistamine (eg, loratadine [Claritin®], Alavert®), cetirizine [Zyrtec®])
  - Intranasal corticosteroid (eg, beclomethasone [Vancenase®], budesonide [Rhinocort®], fluticasone [Flonase®], mometasone [Nasonex®], triamcinolone [Nasacort®])

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### Policy List of Applicable Drugs

Brand Name	Generic Name
Singulair	montelukast

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### Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

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### Policy References

American Hospital Formulary Service (AHFS). Drug Information 2003. Montelukast sodium. [Book on CD-ROM]. Jackson, WY: Teton Data Systems; 2003. Based on American Society of Health-System Pharmacists. Bethesda, MD: AHFS; 2003. STAT!-Ref Medical Reference Library. Accessed November 5, 2007.

Merck & Co, Inc. Montelukast sodium (Singulair®). Prescribing information. [Singulair Web site]. July 2008. Available at: <http://www.singulair.com/singulair/shared/documents/english/oi.pdf>. Accessed August 3, 2009.

Merck & Co, Inc. Newsroom. FDA approves Singulair® for seasonal allergic rhinitis [press release]. [Merck Web site]. 01/02/03. Available at: [http://www.merck.com/newsroom/press\\_releases/010203.htm](http://www.merck.com/newsroom/press_releases/010203.htm). [The link to this reference is no longer active on the Merck web site.]. Accessed August 11, 2008.

Singulair® (Montelukast Sodium). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed August 3, 2009.

Singulair® (Montelukast Sodium). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed August 3, 2009.

United States Pharmacopeia Drug Information (USP DI®) for the Healthcare Professional. 23rd ed. Montelukast sodium. [Online through STAT! Ref]. Greenwood Village, CO: Thompson Micromedex; 2003. Accessed November 5, 2007.

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**Policy Link to Related Policies**

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