

Policies Repository



Policy Title Ciclesonide (Alvesco™) Metered Dose Inhaler

Policy Number FS.CLIN.57

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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 **Ciclesonide (Alvesco™)** metered dose inhaler (MDI) is indicated for the treatment of asthma in patients 12 years of age and older.

The use of ciclesonide (Alvesco™) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Ciclesonide (Alvesco™) is a prodrug that is enzymatically hydrolyzed to a pharmacologically active metabolite, C21-desisobutryl-ciclesonide (des-ciclesonide or RM1) following oral inhalation. Des-ciclesonide has anti-inflammatory activity with affinity for glucocorticoid receptors that is 120 times greater than the parent compound and 12 times greater than dexamethasone. The clinical significance of these findings is unknown. Corticosteroids have been shown to have a wide range of inhibitory activities against multiple cell types (e.g., mast cells, eosinophils, basophils, lymphocytes, macrophages, and neutrophils) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in the asthmatic response. Though effective for the treatment of asthma, corticosteroids do not affect asthma symptoms immediately.

Policy Guideline Inclusion

Ciclesonide (Alvesco™) is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of asthma in patients 12 years of age and older
- Documentation of trial and failure of or contraindication/intolerance/allergy to **two** of following:
 - Fluticasone-containing inhalation product
 - Budesonide-containing inhalation product
 - Triamcinolone acetonide (Azmacort) MDI

Policy Guideline Exclusion

Ciclesonide (Alvesco™) is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of asthma in patients 12 years of age and older
- No documentation of a trial and failure of or contraindication/intolerance/allergy to **two** of following:
 - Fluticasone-containing inhalation product
 - Budesonide-containing inhalation product
 - Triamcinolone acetonide (Azmacort) MDI

Policy List of Applicable Drugs

Brand Name	Generic Name
Alvesco	ciclesonide

Dosing and Administration

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

Policy References

Alvesco™. [Micromedex web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed October 6, 2009.

Alvesco® [package insert]. Marlborough, MA: Sepracor Inc.; 2008. Available at: <http://www.alvesco.us/AlvescoPI.pdf>. Accessed October 6, 2009.

Bateman ED, Linnhof AE, Homik L, et al. Comparison of twice daily inhaled ciclesonide and fluticasone propionate in patients with moderate to severe persistent asthma. *Pulmonary Pharmacology and Therapeutics*. 2008;264-275.

Buhl R, Vinkler I, Magyar P, et al. Comparable efficacy of ciclesonide once daily versus fluticasone propionate twice daily in asthma. *Pulm Pharmacol Ther*. 2006; 404-12.

Facts and Comparisons Website [Alvesco]. Available at www.factsandcomparisons.com. Accessed October 6, 2009.

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Guidelines for the diagnosis and management of asthma. National Institutes of Health. National Heart Lung and Blood Institute. Summary Report 2007.

Niphadkar P, Jagannath K, Joshi JM, et al. Comparison of the efficacy of ciclesonide 160mcg qd and budesonide 200mcg bid in adults with persistent asthma: a phase III, randomized, double dummy, open label study. 2005; *Clin Ther*. 1752-63.

Policy Link to Related Policies

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