

Ciclesonide

Product:

CICLESONIDE (Alvesco®)
100mcg/actuation metered dose inhaler,
200mcg/actuation metered dose inhaler

Class of drugs:

Inhaled corticosteroid

Indication:

Treatment of asthma

Manufacturer:

Nycomed Canada Inc.

CED Recommendation

The CED recommended that ciclesonide (Alvesco) be listed on the Ontario Drug Benefit (ODB) Formulary, on the basis that the drug appears to be similar to other inhaled corticosteroids listed on the Formulary with respect to its clinical efficacy, safety and cost.

Executive Officer Decision

Based on the CED's recommendation and a subsequent listing agreement that addresses pricing and utilization, the Executive Officer decided to list ciclesonide (Alvesco) on the ODB Formulary.

Status

Funding available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Ciclesonide (Alvesco) is a drug delivered by an inhaler and is used to treat bronchial asthma in adults 18 and older.
- ◆ Clinical studies support that ciclesonide (Alvesco) is similar to several other inhaled corticosteroids currently listed on the Formulary with respect to its efficacy and side-effects.
- ◆ In comparison to other inhaled corticosteroids, ciclesonide (Alvesco) may be associated with less oral candidiasis, a fungal infection in the mouth and throat that is common with inhaled corticosteroids.
- ◆ Ciclesonide (Alvesco) appears to be similar in costs to fluticasone, another commonly prescribed inhaled corticosteroid.
- ◆ **Overall, the Committee noted that ciclesonide (Alvesco) appears to be comparable to other inhaled corticosteroids listed on the Formulary with respect to its efficacy, safety and costs. Moreover, ciclesonide (Alvesco) may be associated with less oral candidiasis.** Therefore, the Committee recommended ciclesonide (Alvesco) be listed on the Ontario Drug Benefit Formulary.

Background:

Ciclesonide (Alvesco) is a drug in the class known as corticosteroids. It is taken via an inhaler to treat asthma. This medication is prescribed for patients 18 or older, as a first-line treatment for patients with persistent symptoms.

Asthma is a chronic disease that affects the airways. The walls of the airways swell, making them sensitive and irritable, especially when they come in contact with allergens. When the airways react, they narrow, restricting the air that flows to the lungs. This causes wheezing, coughing, tightness in the chest and difficulty breathing.

Asthma attacks cause muscles around the airways to tighten, increasing the swelling and making it hard to breathe. Asthma is treated with two kinds of medications: medications to relieve asthma symptoms and long-term control drugs to prevent symptoms. Drugs like ciclesonide (Alvesco) help prevent asthma attacks.

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Detailed Discussion:

- ◆ Data from randomized controlled trials (RCTs) indicate that ciclesonide (Alvesco) has comparable efficacy to fluticasone, budesonide, and beclomethasone in terms of forced expiratory volume in one second (FEV1), forced vital capacity (FVC), and the need for rescue medication in the treatment of asthma.
- ◆ Available RCT evidence also indicates no significant differences in incidence of adverse events when ciclesonide (Alvesco) was compared to fluticasone, budesonide, or beclomethasone.
- ◆ Because ciclesonide (Alvesco) only becomes activated when it reaches the lungs, it is possible that this product may be associated with less oral candidiasis in comparison to other inhaled corticosteroids. However, there are insufficient clinical trial data to support or refute this possible advantage.
- ◆ The Committee noted that FEV1 was used as the primary measure of efficacy in most studies. It would have been useful if the relevant trials reported the incidence of asthma exacerbations, using clear, predefined criteria.
- ◆ A large number of studies involving ciclesonide (Alvesco) were unpublished. Methodology was often poorly reported, making analysis of their results difficult.
- ◆ Ciclesonide (Alvesco) appears to be similar in cost to fluticasone; however the dose equivalency between these two products is unclear. The cost of ciclesonide is approximately \$0.35 per 100mcg dose and the cost of fluticasone is approximately \$0.30 per 125mcg dose.
- ◆ Overall, the Committee felt that ciclesonide (Alvesco) is comparable to other inhaled corticosteroids currently listed on the formulary in terms of efficacy, safety, and tolerability. Ciclesonide (Alvesco) may be associated with less oral candidiasis. Although dose equivalency to other comparators is unclear, ciclesonide (Alvesco) appears to be priced similarly to other listed inhaled corticosteroids.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that ciclesonide (Alvesco) be listed.



Ministry of
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