Canadian Agency for Drugs and Technologies in Health
Agence canadienne des médicaments et des technologies de la santé

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

CICLESONIDE
(Alvesco® - Altana Pharma Inc.)

Description:
Ciclesonide is a corticosteroid that is approved for use by inhalation in the prophylactic management of steroid-responsive bronchial asthma in patients 18 years of age and older.

Dosage Forms:
Metered dose inhalers containing cicelsonide 100 µg and 200 µg per actuation (ex-valve).

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that ciclesonide be listed.

Reasons for the Recommendation:
1. Ciclesonide is similar in efficacy to other inhaled corticosteroids in patients with asthma.

2. The cost of ciclesonide is similar to other inhaled corticosteroids.

Summary of Committee Considerations:
The Committee considered a systematic review of randomized controlled trials (RCTs) comparing ciclesonide with other active therapies for asthma. Sixteen RCTs, ranging in duration from 4-52 weeks, met the inclusion criteria for the systematic review. In general, ciclesonide was similar to fluticasone (10 RCTs), budesonide (3 RCTs) and beclomethasone (3 RCTs) with respect to several measures of pulmonary function including forced expiratory volume in one second (FEV_1), forced vital capacity (FVC) and peak expiratory flow (PEF). There is little information on the relative efficacy of ciclesonide compared with other inhaled corticosteroids on more clinically important outcomes, such as the incidence of asthma exacerbations or the requirement for systemic corticosteroids.

There were no statistically significant differences in the overall incidence of serious adverse events or adverse events in any of the RCTs comparing ciclesonide with other inhaled corticosteroids. However, ciclesonide is a prodrug that is activated by esterases in the lungs to an active metabolite and it is possible that ciclesonide will be associated with less oral candidiasis in comparison to other inhaled corticosteroids. This assumption is supported by the results of two of three RCTs versus fluticasone and one RCT versus beclomethasone that measured this as a secondary outcome.

Ciclesonide 100µg and 200 µg cost $0.35 and $0.57 per dose, respectively. Ciclesonide is similar in cost to approximately equivalent doses of fluticasone, beclomethasone and budesonide.

Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.

Background:

CEDAC provides formulary listing recommendations to publicly funded drug plans. Recommendations are based on an evidence-based review of the medication's effectiveness and safety and an assessment of its cost-effectiveness in comparison to other available treatment options. For example, if a new medication is more expensive than other treatments, the Committee considers whether any advantages of the new medication justify the higher price. If the recommendation is not to list a drug, the Committee has concerns regarding the balance between benefit and harm for the medication, and/or concerns about whether the medication provides good value for public drug plans.