CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

CICLESONIDE
(Omnaris™ – Nycomed Canada Inc.)

Description:
Ciclesonide is a corticosteroid nasal spray that is approved for the treatment of seasonal allergic rhinitis (SAR), including hayfever and perennial allergic rhinitis (PAR) in adults and adolescents 12 years of age and older.

Dosage Forms:
Metered dose nasal spray containing ciclesonide 50 mcg per spray. The recommended dose is 200 mcg/day administered as two sprays in each nostril once daily.

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that ciclesonide not be listed.

Reasons for the Recommendation:
1. There are no randomized controlled trials (RCTs) comparing ciclesonide with other nasal corticosteroids in patients with SAR or PAR. While there were statistically significant changes observed for ciclesonide patients for the Total Nasal Symptom Scores (TNSS) and Physician-Assessed Nasal Signs and Symptoms (PANS) scores relative to placebo, the differences were small and the clinical significance of these changes is uncertain.

2. At recommended doses, ciclesonide costs $0.70 per day, which is more expensive compared to beclomethasone ($0.49), budesonide ($0.31) and flunisolide ($0.40), other nasal corticosteroids funded by the majority of the participating drug plans.

Summary of Committee Considerations:
The Committee considered a systematic review of six double-blind RCTs in patients with seasonal or perennial allergic rhinitis (N=2750), ranging from 2-52 weeks in duration and all compared ciclesonide to placebo. Two scales used in the trials were the TNSS and the PANS scores, which are unvalidated scales for measuring nasal symptoms. Compared to placebo, ciclesonide resulted in a statistically significant improvement in nasal symptoms relief as assessed by the TNSS after 14 days of treatment in SAR and PAR patients. One trial in SAR patients and two trials in PAR patients showed statistically significant improvements for ciclesonide versus placebo, in Quality of Life as measured by the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ). PANS scores were statistically significantly improved for ciclesonide compared to placebo for one of three trials that measured this outcome.

There were statistically significant changes observed for ciclesonide patients for the TNSS and PANS scores, however, the differences relative to placebo were small and the clinical significance of these changes is uncertain. The changes in RQLQ scores observed in the trials did not reach the established minimum clinically important difference for this outcome measure.

The rates of adverse events were similar in the ciclesonide and placebo treatment arms of the trials.

At recommended doses, ciclesonide costs $0.70 per day, which is similar to the daily cost of mometasone ($0.85), fluticasone ($0.73) and triamcinolone ($0.84) but more expensive compared to beclomethasone ($0.49), budesonide ($0.31) and flunisolide ($0.40).

Of Note:

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

2. The vehicle used in the placebo group in the trials contained hypotonic saline and appeared to result in some improvements to symptom scores. The effectiveness of ciclesonide relative to an inactive placebo group is unknown.

3. The Committee was aware that some drug plans list intranasal corticosteroids that cost more than ciclesonide. Drug plans should consider a drug class review, given the range of costs for these agents.

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.