CANADIAN COORDINATING OFFICE FOR HEALTH TECHNOLOGY ASSESSMENT

OFFICE CANADIEN DE COORDINATION DE L'ÉVALUATION DES TECHNOLOGIES DE LA SANTÉ

CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

OMALIZUMAB
(Xolair® - Novartis Pharmaceuticals Canada Inc.)

Description:
Omalizumab is a humanized monoclonal antibody to IgE approved for use in adults and adolescents (≥12 years of age) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

Dosage Forms:
150 mg vial for subcutaneous injection

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

Reasons for the Recommendation:
1. The committee considered five double-blind, placebo-controlled, randomized controlled trials (RCTs), and one open-label RCT. Three of the four blinded RCTs reported no statistically significant improvement in acute asthma exacerbations leading to hospitalizations, emergency department visits or physician visits. One trial reported statistically significant improvement in the rates of hospitalization and physician visits.

2. Current recommended therapy for patients with severe persistent asthma includes at least the use of an inhaled steroid plus a long-acting beta-2 agonist, if symptoms persist despite the use of an inhaled steroid alone. Only one of the RCTs required that patients be on both of these therapies and this trial did not find that omalizumab decreased acute asthma exacerbations leading to hospitalizations, emergency department visits or physician visits.

3. All trials reported that omalizumab improved quality of life, as assessed by the Asthma Quality of Life Questionnaire (AQLQ).

4. The rate of serious adverse events was not increased by omalizumab compared to placebo, however, close monitoring for anaphylaxis at the time of injection is recommended.

5. Omalizumab costs approximately $1200 per patient per month. The pharmacoeconomic model submitted by the manufacturer reported a mean incremental cost-effectiveness ratio of approximately $63,000 per Quality Adjusted Life Year (QALY), with a sensitivity analysis range of $35,000 to $219,000 per QALY. However, the pharmacoeconomic model, which was based on rates of asthma exacerbation, overstated the benefits of omalizumab by using the number of exacerbations for all patients rather than the number of patients who experienced an exacerbation. The Committee felt that this significantly overestimated the clinical effectiveness of omalizumab and that the true cost-effectiveness of omalizumab is likely to be much less favourable. The Committee felt that omalizumab was not cost-effective at the current price.

Of Note:

1. Since omalizumab is dosed according to IgE levels and requires expert assessment for response, it requires significant clinical expertise in asthma to prescribe and monitor.

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