CANADIAN COORDINATING OFFICE FOR HEALTH TECHNOLOGY ASSESSMENT

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

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

ERLOTINIB
(Tarceva - Hoffmann – La Roche Limited)

Description:
Erlotinib is a human epidermal growth factor receptor type 1/epidermal growth factor receptor (HER1/EGFR) tyrosine kinase inhibitor. It is indicated for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen, and whose EGFR expression status is positive or unknown.

Dosage Forms:
100 and 150 mg tablets.

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that erlotinib be listed for patients with NSCLC after failure of at least one prior chemotherapy regimen, and whose EGFR expression status is positive or unknown.

Reasons for the recommendation:

1. The Committee based its recommendation on one double-blind randomized controlled trial (RCT) comparing erlotinib with placebo in patients with NSCLC who had failed on one (almost all platinum-based) or two prior chemotherapy regimens. Compared to placebo, erlotinib increased median survival from 4.7 to 6.7 months and the percentage of patients surviving at one year from 21.5 to 31.2%. The survival benefit was not found in the subgroup of patients with tumours testing EGFR response negative.

2. The survival benefit was achieved without significant decrease in quality of life, most notably cough, dyspnea or pain, as measured on approximately two-thirds of the subjects.

3. Rash and diarrhea were the most common adverse effects of erlotinib in the RCT and dose reduction due to these effects was required in 12 and 5% of patients, respectively.

4. Erlotinib costs $80 per day at the recommended dose of 150 mg daily. Based on a pharmacoeconomic model submitted by the manufacturer, the Committee considered erlotinib to be cost-effective compared to docetaxel and to have an incremental cost-effectiveness of $71,000 per life year gained compared to best supportive care.

Of Note:

1. In the RCT, EGFR status could only be determined in 47.4% of patients (positive in 27.6%, negative in 19.8%). The Committee recommends that EGFR status be determined on as many patients as possible and that further studies be done to evaluate the relationship between erlotinib effectiveness and EGFR status.