CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

ESCITALOPRAM OXALATE
(Cipralex® Resubmission – Lundbeck Canada Inc.)

Description:
Escitalopram (S-citalopram), the S-enantiomer of racemic citalopram, is a selective serotonin reuptake inhibitor that is approved for the symptomatic relief of major depressive disorder.

Dosage Forms:
10 mg and 20 mg tablets. The usual dose is 10–20 mg given once daily.

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

Reason for the Recommendation:
1. Citalopram costs $0.88 per day which is less expensive than escitalopram. The manufacturer has requested that the price of escitalopram submitted to the Common Drug Review remain confidential. The Committee concluded that there was insufficient evidence that escitalopram provides clinically important advantages compared to citalopram to justify the price submitted by the manufacturer.

Summary of Committee Considerations:
The Committee considered a systematic review of six randomized controlled trials (RCTs) comparing escitalopram versus citalopram in patients with major depressive disorder. The durations of the trials were four weeks (1 trial), 8 weeks (4 trials) and 24 weeks (1 trial). None of the RCTs included quality of life or days of disability as study outcomes. There were no statistically significant differences in changes in the Montgomery Asberg Depression Rating Scale (MADRS) between escitalopram and citalopram in four RCTs, one RCT did not report on this outcome and one RCT reported a statistically significant greater reduction in the escitalopram group versus citalopram (mean difference of 2.4 points [95% CI 0.20-4.56] on a 70 point scale). Patients in this trial were considered more severely depressed at baseline, with MADRS scores for study inclusion ≥30 compared with the other RCTs (MADRS ≥22).

Remission, which was defined as a MADRS score of <12 or a Hamilton Depression Rating Scale of ≤7, was reported in 4 trials and there were no statistically significant differences in the crude rates of remission between escitalopram and citalopram.

There were no significant differences between escitalopram and citalopram in the incidence of serious adverse events or withdrawals due to adverse events in any of the RCTs.

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 Both published and unpublished data were reviewed and taken into consideration in making this recommendation.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