# CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

## OLMESARTAN MEDOXOMIL
## (Olmetec® – Schering-Plough Canada Inc.)
## Indication: Mild to Moderate Essential Hypertension

### Description:
Olmesartan is an angiotensin II receptor blocker (ARB) indicated for the treatment of mild to moderate essential hypertension.

### Dosage Forms:
Supplied as 20 mg and 40 mg tablets. The recommended starting dose of olmesartan is 20 mg once daily when used as monotherapy and may be increased to 40 mg daily.

### Recommendation:
The Canadian Expert Drug Advisory Committee recommends that olmesartan be listed in a similar manner as drug plans list other ARBs.

### Reasons for the Recommendation:
1. Results from double-blind randomized controlled trials demonstrate similar reductions in systolic and diastolic blood pressure between olmesartan and other angiotensin receptor blockers.
2. The daily cost of olmesartan is less than or similar to other angiotensin receptor blockers.

### Summary of Committee Considerations:
The Committee considered the results of a systematic review of nine double-blind randomized controlled trials (RCTs) evaluating the effects of olmesartan for the treatment of mild to moderate essential hypertension. Emphasis was placed on six RCTs with full study reports available (N=2779). The focus of the review was olmesartan compared with other ARBs including losartan, valsartan, candesartan and irbesartan. Treatment duration was eight to 12 weeks in five studies and 52 weeks in one study conducted in patients 65 years and older. The primary outcome in all studies was change from baseline in mean diastolic blood pressure. Five studies used a clinic blood pressure measurement and one used ambulatory blood pressure monitoring for assessment of the primary outcome. Change in pulse pressure was not measured and change in heart rate was measured in only one trial. Clinically relevant outcomes such as mortality, morbidity, end-organ damage were either not reported or occurred too infrequently for reliable comparisons between groups.


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Olmesartan resulted in a statistically significantly greater reduction (2 to 3 mm Hg) in mean diastolic blood pressure versus losartan, valsartan, and candesartan. The clinical significance of this difference in diastolic blood pressure lowering is unclear. Reductions in diastolic blood pressure were similar between olmesartan and irbesartan. Reductions in systolic blood pressure were similar between olmesartan and other ARBs in these trials.

The proportion of patients experiencing a serious adverse event or withdrawing due to an adverse event was low and not significantly different between olmesartan and other ARBs or placebo in any study. The proportion of patients who experienced an adverse event was similar between olmesartan and other ARBs in all but one study.

At a daily cost of $0.99, olmesartan is less expensive than other ARBs ($1.03-$2.28). In their economic evaluation, the manufacturer did not consider less expensive comparators such as ACE inhibitors that have similar clinical effects to ARBs. Most angiotensin converting enzyme inhibitors are less expensive than olmesartan.

## Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.
2. Given that most ARBs such as olmesartan are more expensive than most ACE inhibitors, the full potential for cost savings will not be maximized if ARBs are prescribed before ACE inhibitors. Therefore, the Committee suggests that drug plans consider a listing criteria that ARBs only be used in patients who cannot tolerate ACE inhibitors.
3. The manufacturer has reviewed this document and has not requested the removal of any confidential information, in conformity with the CDR Confidentiality Guidelines.

## 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.

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