Canadian Agency for Drugs and Technologies in Health
Agence canadienne des médicaments et des technologies de la santé

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

RAMIPRIL/HYDROCHLOROTHIAZIDE
(Altace® HCT Resubmission – Sanofi-Aventis Canada Inc.)

Description:
Altace® HCT is a fixed dose combination of ramipril and hydrochlorothiazide. It is approved for the treatment of essential hypertension in patients for whom this combination therapy is appropriate. Altace® HCT is not indicated for initial therapy and patients should be titrated to a stable dose of the individual components prior to initiation of therapy with Altace® HCT.

Dosage Forms:
Tablets containing ramipril/hydrochlorothiazide in the following ratio: 2.5 mg/12.5 mg, 5 mg/12.5 mg, 5 mg/25 mg, 10 mg/12.5 mg, 10 mg/25 mg.

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Altace® HCT be listed.

Reasons for the Recommendation:
1. Altace® HCT costs $0.38 (2.5 mg/12.5 mg, 5 mg/12.5 mg, 5 mg/25 mg strengths) or $0.48 per day (10 mg/12.5 mg, 10 mg/25 mg strengths), which is slightly less costly compared to equivalent doses of generic ramipril and hydrochlorothiazide.

Summary of Committee Considerations:
The Committee considered the results of a systematic review of randomized controlled trials (RCTs) of the fixed-dose combination of ramipril and hydrochlorothiazide in patients with essential hypertension. One RCT of 660 subjects with mild to moderate hypertension, comparing Altace® HCT (ramipril 2.5 mg/HCT 12.5 mg) with each of the individual components, met the inclusion criteria for the systematic review. Altace® HCT resulted in a statistically significant decrease in diastolic blood pressure compared with hydrochlorothiazide and a statistically significant decrease in systolic blood pressure compared with ramipril. There were no statistically significant differences in serious adverse events or withdrawals between treatment groups. The study did not assess adherence with therapy as an outcome. As such, it is uncertain if the use of Altace® HCT would result in improved adherence compared with the individual agents.

Of Note:

1. With the introduction of Altace® HCT and generic formulations of angiotensin converting enzyme inhibitors (ACEI), drug plans should review formulary listing policies for this class of drug.

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.