

Ramipril/Hydrochlorothiazide

Product:

RAMIPRIL/HYDROCHLOROTHIAZIDE (Altace HCT®) 2.5mg/12.5mg, 5mg/12.5mg, 10mg/12.5mg, 5 mg/25 mg, and 10mg/25mg tablet

Class of drugs:

ACE inhibitor/diuretic

Indication:

Treatment of hypertension (high blood pressure)

Manufacturer:

Sanofi Aventis Canada Inc.

CED Recommendation

The CED recommended that ramipril/hydrochlorothiazide (Altace HCT) be listed on the Ontario Drug Benefit Formulary, on the condition that this line-extension product provides a cost savings to the Ontario Public Drug Programs.

Executive Officer Decision

Based on the CED's recommendation and a subsequent pricing agreement, the Executive Officer decided to list ramipril/hydrochlorothiazide (Altace HCT) on the Ontario Drug Benefit Formulary.

Status

Funding available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Ramipril/hydrochlorothiazide (Altace HCT) is a combination tablet containing two drugs, ramipril and hydrochlorothiazide, used in the treatment of high blood pressure.
- ◆ Both ramipril and hydrochlorothiazide are available as individual agents and both are listed on the Ontario Drug Benefit Formulary.
- ◆ Evidence indicates that ramipril/hydrochlorothiazide (Altace HCT) delivers the medications to the body in the same manner as the combined administration of the separate components.
- ◆ A clinical study reported a greater decrease in blood pressure with ramipril/hydrochlorothiazide (Altace HCT) than with hydrochlorothiazide alone or ramipril alone.
- ◆ **Overall, the Committee acknowledged that this combination product is a reasonable alternative for patients who require both ramipril and hydrochlorothiazide. Therefore, the CED recommended that ramipril/hydrochlorothiazide (Altace HCT) be listed on the Formulary, on the condition that the product provides cost savings to the Ontario Public Drug Programs.**

Background:

High blood pressure affects one in five Canadians. Untreated, high blood pressure can lead to heart attack, stroke or kidney failure. Risk factors include excess weight, lack of exercise, unhealthy diet, stress, and excessive alcohol consumption. Modifying these risk factors is the first approach in managing high blood pressure. Medications are required to manage patients who still have high blood pressure despite lifestyle modifications.

There are several types of medication used to treat high blood pressure. These include diuretics, beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers, calcium channel blockers, alpha-blockers, vasodilators, and central-acting agents. The standard approach is to prescribe one drug at a time. A second drug is usually added only if the first drug was not effective or if the patient experienced side effects at higher doses of the first medication.

Altace HCT is a combination of ramipril (an ACE inhibitor) and hydrochlorothiazide (a diuretic).

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Detailed Discussion:

- ◆ Ramipril and hydrochlorothiazide, as individual agents, are both currently listed on the Formulary.
- ◆ The Committee reviewed bioequivalence data as well as clinical data that compared ramipril/hydrochlorothiazide (Altace HCT) to the individual component medications.
- ◆ The submitted bioequivalence evidence supported that ramipril/hydrochlorothiazide (Altace HCT) is bioequivalent to the combination of ramipril alone and hydrochlorothiazide alone.
- ◆ The pivotal clinical trial (*Genthon R et al. 1994*) reported a statistically significant decrease in diastolic blood pressure for ramipril/hydrochlorothiazide (Altace HCT) versus hydrochlorothiazide alone, and a statistically significant decrease in systolic blood pressure versus ramipril alone. There were no statistically significant differences in serious adverse events or withdrawals between the treatment groups.
- ◆ The clinical study did not assess compliance. It is uncertain whether the use of ramipril/hydrochlorothiazide (Altace HCT) would result in improved adherence compared with the individual agents.
- ◆ Ramipril/hydrochlorothiazide (Altace HCT) is a fixed dose combination product; hence, dosage adjustment is less flexible.
- ◆ Overall, the Committee acknowledged that this line-extension product provides an alternative for patients who require both ramipril and hydrochlorothiazide. The Committee recommended that ramipril/hydrochlorothiazide (Altace HCT) be listed on the Formulary, on the condition that the product provides cost savings to the Ontario Public Drug Program.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that ramipril/hydrochlorothiazide (Altace HCT) not be listed.



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

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