Ramipril

**Product:**
RAMIPRIL (Altace®) 15 mg capsule

**Class of drugs:**
Angiotension Converting Enzyme (ACE) inhibitor

**Indication:**
Treatment of high blood pressure

**Manufacturer:**
sanofi aventis Canada Inc.

**Highlights of Recommendation:**
- Ramipril (Altace) is a drug used to treat mild to moderate high blood pressure. It is also given to patients who have suffered a heart attack to improve their survival and reduce hospitalizations.
- Ramipril (Altace) 1.25 mg, 2.5 mg, 5 mg and 10 mg capsules are already listed on the ODB Formulary.
- There was no evidence from any studies that showed better results in reducing blood pressure with the 15 mg formulation of ramipril (Altace), compared with combining the formulations already being reimbursed.
- There are several generic products available that are less expensive than the brand name product (Altace).

**Background:**
High blood pressure affects one in five Canadians. Excess weight, lack of exercise, unhealthy diet, stress, smoking, and excessive alcohol consumption increase the risk for high blood pressure. Some patients, however, still develop high blood pressure despite modifying their lifestyle, and require medication to control their blood pressure.

Several types of medications are used to treat high blood pressure. These include alpha-blockers, angiotensin II receptor blockers, angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, calcium channel blockers, central-acting agents, diuretics, and vasodilators.

The Ontario Public Drug Programs list many of these medications to treat high blood pressure.

The standard approach to treating high blood pressure is to prescribe one drug at a time; a second drug is usually added only if the first drug was not effective or the patient experienced side effects at the higher doses.

Ramipril (Altace) is an ACE inhibitor. It works by relaxing the blood vessels and helping the heart pump blood more efficiently. Doctors also prescribe this drug for secondary prevention to patients who have had heart attacks.

**CED Recommendation**
The CED recommended that ramipril (Altace) 15 mg capsule not be listed on the Ontario Drug Benefit (ODB) Formulary on the basis that there is no proven clinical need for the 15 mg format and the generic forms of ramipril are less expensive.

**Executive Officer Decision**
Based on the CED's recommendation, the Executive Officer decided not to list ramipril (Altace) 15 mg capsule.

**Status**
No funding through Ontario Public Drug Programs.
Detailed Discussion:

- The manufacturer, sanofi aventis Canada, asked the Ontario Ministry of Health and Long-Term Care to consider funding a new 15-mg line extension of ramipril (Altace) on the Ontario Drug Benefit Formulary. sanofi aventis proposed that the new extension product would save the Ministry money.

- The Committee noted that there is efficacy evidence from clinical trials that supports ramipril (Altace) for the management of hypertension, but there was no comparable evidence submitted showing that the new 15-mg capsule works any better at reducing blood pressure. Therefore, the Committee is unable to determine the clinical advantage in blood pressure reduction of the new format versus the multiple strengths of ramipril (Altace) currently reimbursed on the Formulary.

- The Committee questioned the clinical need for the new extension format, because patients have access to other strengths of ramipril (Altace) they may combine to achieve a 15 mg daily dose.

- Ramipril (Altace) has become generic, with two companies asking the Ministry to consider reimbursing their generic form of ramipril at half the price of the brand name product (Altace). The Committee noted that because of these generic ramipril products, the cost savings claim for ramipril (Altace) 15mg will not materialize.

- Overall, the Committee noted a clinical need for the ramipril (Altace) 15-mg capsule formulation was not demonstrated. Furthermore, the manufacturer’s claims for cost savings for the new extension format will not materialize because multiple strengths of the generic form of ramipril have been introduced in Ontario, at half the cost.

CEDAC Recommendation:

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

The Canadian Expert Drug Advisory Committee did not review ramipril (Altace) 15mg capsules.

For more information, please contact:

Ministry of Health and Long-Term Care
Ontario Public Drug Programs
415 Yonge Street, Suite 1601
Toronto, Ontario  M5B 2E7
or click: www.moh.on.gov.ca/dss/ced