

Irbesartan/Hydrochlorothiazide

Product:

IRBESARTAN/HYDROCHLOROTHIAZIDE (Avalide®) 300/25mg combination tablet

Class of drugs:

Angiotensin II receptor blocker (ARB)/Diuretic

Indication:

High blood pressure

Manufacturer:

sanofi-aventis Canada Inc.

CED Recommendation

The CED recommended irbesartan/hydrochlorothiazide (Avalide) 300/25mg fixed combination tablet be listed on the Ontario Drug Benefit Formulary, on the basis that the product provides enhanced blood pressure management for patients whose blood pressure is not adequately controlled with lower strengths of the medication.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided to list irbesartan/hydrochlorothiazide (Avalide) 300/25mg tablet on the Ontario Drug Benefit Formulary.

Status

Funding available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Irbesartan/hydrochlorothiazide (Avalide) is a combination product used to treat high blood pressure.
- ◆ Irbesartan/hydrochlorothiazide (Avalide) 150/12.5mg tablets and 300/12.5mg tablets are currently available as General Benefits on the Ontario Drug Benefit (ODB) Formulary.
- ◆ Priced at \$1.14 for each tablet, irbesartan/hydrochlorothiazide (Avalide) is more expensive than similar combination drugs, which range from \$1.02 to \$1.07 per tablet, as well as angiotensin-converting enzyme inhibitors, which run from \$0.65 to \$0.77 per tablet.
- ◆ The CED noted that the product could help people who are using 300/12.5mg tablets but who require greater blood pressure control provided by 300/25mg tablets.
- ◆ **Overall, the Committee agreed that this new product is a reasonable addition to the Formulary as there may be a clinical need for this product for patients who require enhanced management of their blood pressure.** As such, the Committee recommended irbesartan/hydrochlorothiazide (Avalide) 300/25mg tablet be listed on the ODB formulary.

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 classes of blood pressure 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. Different types of blood pressure medications work differently to lower blood pressure. Irbesartan is an angiotensin II receptor blocker and hydrochlorothiazide is a diuretic (a type of drug that increases urine output).

Angiotensin II is the name of a peptide, or string of amino acids (proteins) involved in maintaining blood pressure and volume.

The Ontario Public Drug Programs funds many of the above mentioned 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 has experienced side effects at the higher doses.

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Detailed Discussion:

- ◆ The manufacturer, sanofi-aventis Canada Inc., asked the Ministry of Health and Long-Term Care to consider listing irbesartan/hydrochlorothiazide (Avalide) 300/25mg tablet on the Ontario Drug Benefit Formulary.
- ◆ A study by M. Kochar, R. Guthrie & J. Triscari J, published in the *American Journal of Hypertension* (1999;12:797-805), confirmed the additional reduction of blood pressure offered by the irbesartan/hydrochlorothiazide 300/25mg tablet when compared to 300/12.5mg tablet. The trial suggests an additional mean reduction of 6.5 mm of Hg in systolic and 4.4 mm of Hg in diastolic blood pressure comparing irbesartan/hydrochlorothiazide (Avalide) 300/25mg tablet vs. irbesartan/hydrochlorothiazide (Avalide) 300/12.5mg tablet.
- ◆ Irbesartan/hydrochlorothiazide has been evaluated for one year or more in 968 patients with essential hypertension. Headaches and dizziness were the most frequent adverse events requiring intervention, which occurred in 0.7 per cent of cases.
- ◆ It remains unknown whether irbesartan/hydrochlorothiazide (Avalide) 300/25mg tablet is a better blood pressure reducing agent than other combination products, such as eprosartan/hydrochlorothiazide, telmisartan/hydrochlorothiazide, and candesartan/hydrochlorothiazide, since no trials making a direct comparison have been published.
- ◆ However, the CED agreed that there may be a clinical need for this new line extension product for patients who require enhanced blood pressure control that smaller dosage versions of irbesartan/hydrochlorothiazide (Avalide) cannot provide.

CEDAC Recommendation:

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

The Canadian Expert Drug Advisory Committee (CEDAC) did not review irbesartan/hydrochlorothiazide (Avalide) 300/25mg tablet.



Ministry of
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