

Valsartan / Hydrochlorothiazide – new dosage strengths

Product:

VALSARTAN/HYDROCHLOROTHIAZIDE (Diovan-HCT®) 320mg/12.5mg, 320mg/25mg tablets (new dosage strengths)

Class of drugs:

Anti-hypertensive agent (angiotensin II receptor blocker combined with diuretic)

Indication:

Treatment of hypertension (high blood pressure)

Manufacturer:

Novartis Pharmaceuticals Canada Inc.

CED Recommendation

The CED recommended that valsartan/hydrochlorothiazide (Diovan-HCT) 320mg/12.5mg and 320mg/25mg tablets not be funded. The CED noted that it has been shown to be effective in blood pressure lowering, multiple alternatives are already available on the Formulary and this combination product offers no added therapeutic or cost advantage.

Executive Officer Decision

Based on the CED's recommendation and a subsequent pricing agreement with the manufacturer, the Executive Officer decided to list valsartan/hydrochlorothiazide (Diovan-HCT) 320mg/12.5mg and 320mg/25mg tablets on the Ontario Drug Benefit Formulary.

Status

Funding available through the Ontario Public Drug Program.

Highlights of Recommendation:

- ◆ Valsartan/hydrochlorothiazide (Diovan-HCT) is a combination tablet containing two drugs, valsartan and hydrochlorothiazide, used to treat high blood pressure.
- ◆ The 320mg/12.5mg and 320mg/25mg tablets are new dosage strengths. Three other strengths of the same drug, 80mg/12.5mg, 160mg/12.5mg, and 160mg/25mg are already available on the Ontario Drug Benefit Formulary. The individual components (i.e., valsartan alone and hydrochlorothiazide alone) are also listed separately on the Formulary.
- ◆ The Committee reviewed two studies evaluating the use of valsartan/hydrochlorothiazide (Diovan-HCT) 320mg/12.5mg and 320mg/25mg tablets in blood pressure reduction.
- ◆ In the first study, valsartan/hydrochlorothiazide (Diovan-HCT) 320mg/12.5mg and 320mg/25mg tablets were compared to placebo, valsartan alone, and hydrochlorothiazide alone. The study found that the new combination tablets provided superior blood pressure lowering versus their individual components alone and versus placebo.
- ◆ The second study was conducted in patients with blood pressure not adequately controlled with valsartan 320mg alone. Valsartan/hydrochlorothiazide (Diovan-HCT) 320mg/12.5mg and 320mg/25mg tablets were shown to improve blood pressure reduction compared with valsartan 320mg alone. No major differences in overall safety and tolerability were noted between the combination tablets and valsartan 320mg tablet.
- ◆ The price for valsartan/hydrochlorothiazide (Diovan-HCT) 320mg/12.5mg and 320mg/25mg tablets is \$1.14 per tablet. Lower cost alternatives are available on the Formulary.

- ◆ Overall, the Committee noted that **valsartan/hydrochlorothiazide (Diovan-HCT) 320mg/12.5mg and 320mg/25mg tablets are effective in blood pressure reduction. However, multiple alternatives already exist on the Formulary, and these two new products offer no therapeutic or cost advantage.**

Background:

High blood pressure (hypertension) affects one in five Canadians. Untreated, high blood pressure can lead to heart attack, stroke and kidney failure. Risk factors for hypertension 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 have high blood pressure despite lifestyle changes.

There are many 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 if the first drug was not effective or the patient experienced side effects at higher doses of the first drug.

Valsartan/hydrochlorothiazide (Diovan-HCT) is a combination of two drugs, an angiotensin II receptor blocker and a diuretic, both of which have been proven to reduce mortality and morbidity due to high blood pressure.

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Detailed Discussion:

No additional details. The full CED discussion is as outlined in the Highlights of Recommendation section.

CEDAC Recommendation:

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

The Canadian Expert Drug Advisory Committee (CEDAC) did not review valsartan/hydrochlorothiazide (Diovan-HCT) 320mg/12.5mg and 320mg/25mg tablets.



Ministry of
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