

Darunavir

Product:

DARUNAVIR (Prezista®) 300 mg tablet

Class of drugs:

Protease inhibitor

Indication:

Treatment of HIV infection in adult patients

Manufacturer:

Janssen-Ortho Inc.

CED Recommendation

The CED recommended that darunavir (Prezista) 300 mg capsule be listed on the Ontario Drug Benefit (ODB) Formulary via the Facilitated Access mechanism, with specific criteria, for the treatment of HIV infection in treatment-experienced adult patients, on the basis that the product has demonstrated significant improvements in virologic and immunologic markers in patients who did not respond to other protease inhibitors.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer has decided to list darunavir (Prezista) under the Facilitated Access mechanism.

Status

Funding available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Darunavir (Prezista) is a drug used in combination with other drugs known as anti-retroviral medications to treat HIV (Human Immunodeficiency Virus), the virus that causes AIDS (acquired immune deficiency syndrome). It is prescribed for patients when other anti-retroviral drugs have not worked.
- ◆ The Committee considered studies that indicated darunavir (Prezista) combined with optimal antiretroviral therapy, in treatment-experienced patients with HIV, was better at reducing the level of HIV in patients' blood and improving immune function than other comparator anti-retroviral medications.
- ◆ Darunavir (Prezista) costs more than some other reimbursed drugs in the same class but less expensive than tipranavir which is considered through the Exceptional Access Program/ Individual Clinical Review mechanism.
- ◆ **Overall, the Committee noted that darunavir (Prezista), combined with ritonavir, demonstrated significant improvements in reducing viral load and boosting the immune system, in patients not responding to other protease inhibitors.**
- ◆ The CED recommended approving darunavir (Prezista) under the Facilitated Access mechanism, according to specified criteria. (Please refer to the "Detailed Discussion" section for the details of the criteria.)

Background:

Darunavir (Prezista) is a member of a class of drugs called protease inhibitors, used to treat HIV-infected patients. HIV is the virus that causes AIDS. Darunavir (Prezista) works by blocking an enzyme, known as the HIV protease, which the virus needs in order to multiply.

Darunavir (Prezista) is co-administered with another anti-HIV drug called ritonavir, which decreases the breakdown of darunavir (Prezista) thereby increasing the levels of darunavir (Prezista) in the blood. Antiretroviral therapy with drugs like darunavir (Prezista) reduce the amount of HIV in a patient's blood (called the viral load), leading in most cases to an increase in T-helper cells.

T-helper cells are an important part of the immune system. People need T-helper cells, or CD4+ T cells, to maintain an intact immune system that can fight infections. Reducing the amount of HIV in the blood and increasing the T-helper cell count helps to reduce the incidence of opportunistic infections and cancers in patients living with HIV.

Although there is no cure for HIV, antiretroviral drugs can help patients avert the clinical consequences of HIV infection by restoring immune function, improving their quality of life, and reducing HIV-related complications and death.

continued...

Detailed Discussion:

- ◆ The manufacturer, Janssen-Ortho Inc., asked the Ontario Ministry of Health and Long-Term Care to reimburse darunavir (Prezista) in the same way it funds other protease inhibitors listed on the ODB Formulary.
- ◆ The Committee looked at two studies (POWER 1 and POWER 2) comparing darunavir (Prezista) plus ritonavir to other protease inhibitors plus ritonavir on a standard backbone regimen in a total of 235 treatment-experienced patients with HIV infection. At both 24 and 48 weeks, darunavir (Prezista) plus ritonavir therapy resulted in statistically significant improvements in virologic and immunologic markers in patients with evidence of virological failure to other protease inhibitors plus ritonavir. There were no statistically significant differences in quality of life between the groups in the trials.
- ◆ The overall incidence and severity of adverse events were similar in patients treated with darunavir (Prezista) versus other protease inhibitors, except for the incidence of herpes simplex infections and elevated serum triglycerides. Those occurred more often in darunavir (Prezista) -treated patients.
- ◆ Darunavir (Prezista) costs more than most other listed protease inhibitors, but is less expensive than tipranavir, which is reimbursed under the Exceptional Access Program/Individual Clinical Review mechanism.
- ◆ Side-effects for darunavir (Prezista) include diarrhea, nausea, headache, abdominal pain, constipation and vomiting. Less common side effects may include high blood sugar, diabetes, increased bleeding in patients with hemophilia, changes in body fat (lipodystrophy), and immune reconstitution syndrome.
- ◆ Overall, the Committee noted that darunavir (Prezista) boosted with ritonavir reported significant improvements in accepted virologic and immunologic markers, when compared with other protease inhibitors boosted with ritonavir, in treatment-experienced patients with evidence of virological failure to other protease inhibitors.

- ◆ The CED recommended approving darunavir (Prezista) under Conditional Listing via Facilitated Access mechanism, according to the following criteria:
 - In combination with ritonavir, as part of an HIV treatment regimen for treatment-experienced adult patients who have demonstrated failure to at least two protease inhibitors.

CEDAC Recommendation:

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

The Canadian Expert Drug Advisory Committee recommends that darunavir (Prezista) be listed with criteria/conditions.



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

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