CEDAC Final Recommendation and Reasons for Recommendation
Plain Language Version

Raltegravir (Isentress™ – Merck Frosst Canada Ltd.)
Indication – HIV Infection

The information contained within this plain language version of the Canadian Expert Drug Advisory Committee (CEDAC) Final Recommendation and Reasons for Recommendation about this drug is based on the information found within the corresponding technical version of the CEDAC Final Recommendation and Reasons for Recommendation. Health care professionals and those requiring more detailed information are advised to refer to the technical version found at www.cadth.ca.

Drug

Raltegravir, commonly known as Isentress, is a drug for the treatment of HIV-1 infection. It works by preventing more copies of the HIV virus from being made within the body of an infected person. The drug has received a Notice of Compliance with Conditions from Health Canada. This means that Health Canada has approved this drug on the basis of promising evidence and on the condition that more studies confirm that Isentress is helpful in the treatment of HIV infection. Isentress is approved for the treatment of HIV-1 in adults who have already been treated for the infection but, because their HIV-1 infection is resistant to several of the drugs used, the HIV virus continues to multiply inside their body.

Dose

The recommended dose is one 400 mg tablet taken twice each day.

CEDAC Recommendation

CEDAC recommended that Isentress be listed for coverage by Canada's publicly funded drug plans for patients with HIV infection who have not been adequately controlled because the HIV virus is resistant to at least three of the drugs that have been previously used.

Reasons for the Recommendation

- Studies show that Isentress improves control of HIV infection in patients who have failed other HIV-1 treatments.
- Isentress costs about the same as or less than other drugs currently listed for coverage by Canada's publicly funded drug plans for patients who have failed other treatments.

Summary of CEDAC Considerations

- CEDAC considered three studies of Isentress in the treatment of patients with HIV-1 infection. The studies compared optimized therapy for HIV plus, either Isentress or a tablet that had no active medication – called a placebo. The treatments were given to patients who had failed treatment and were resistant to different types of drugs used to treat HIV.
- The Committee focused on two of the three studies. These two key studies were identically designed, both lasting for 48 weeks and included a total of 699 patients. They compared Isentress plus optimized therapy for HIV with placebo plus optimized therapy.
- The two key studies showed that Isentress plus optimized therapy resulted in improvements in measures of HIV infection. (These measures included the number of patients with HIV-1 RNA levels less than 400 copies/mL or 50 copies/mL and the average increase in CD4 cell count.)
- When combined with optimal therapy for HIV infection, there were no differences between Isentress and placebo in serious side effects, or the number of patients quitting the studies because of side effects.
- Isentress costs $27 per day. This is similar to or less than other drugs used to treat patients with HIV who are not responding to other treatments.

Of Note:

- Once further studies are available on how well Isentress works, the publicly-funded drug plans may wish to seek further advice from CEDAC about Isentress.

Background

The Canadian Expert Drug Advisory Committee (CEDAC) is a committee of the Canadian Agency for Drugs and Technologies in Health (CADTH). The Committee is made up of drug evaluation experts and public members. CEDAC provides recommendations about whether or not drugs should be listed for coverage by the participating publicly funded drug plans; however, the individual drug plans make their own decision about whether or not to cover a drug.

In making its recommendations, CEDAC decides if the drug under review ought to be covered by the participating public drug plans based on an evidence-informed review of the medication's effectiveness and safety, and based on an assessment of its cost-effectiveness in comparison with other available treatment options.

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The manufacturer has reviewed this document and has not requested the deletion of any confidential information.