Etravirine approved in Canada

7 April 2008

On March 27, 2008, Health Canada approved the sale and use of the anti-HIV medication etravirine, formerly called TMC125. To be sold under the brand name Intelence, etravirine is meant for treatment-experienced people with HIV/AIDS (PHAs) who have HIV-1 that is resistant to other medications. Etravirine will be sold by Tibotec, a division of Janssen-Ortho Inc.

In clinical trials with treatment-experienced PHAs, etravirine, when used as part of combination therapy for six months, helped suppress production of HIV and raise levels of important T-cells in the blood. These changes have led to improved health for PHAs. In these trials, etravirine was found to be generally safe.

How etravirine works

HIV uses different enzymes to hijack cells of the immune system and turn them into mini virus factories. Etravirine works by slowing down or inhibiting the effects of one of these enzymes, called RT (reverse transcriptase), and reducing or stopping production of new HIV. Like all other approved HIV medications, etravirine must be taken as part of combination therapy. Etravirine is taken at a dose of 200 mg twice daily, after a meal. Like all other anti-HIV medications, etravirine is not a cure for HIV/AIDS.

Advantage etravirine

Because there is an urgent need for novel anti-HIV therapies, Health Canada conducted an expedited review of etravirine. Currently, there are five classes of approved medications for the treatment of HIV infection, as follows:

- nucleoside analogues (nukes)
- non-nukes or NNRTIs (non-nucleoside reverse transcriptase inhibitors)
- protease inhibitors
- fusion inhibitor
- entry inhibitor

When used in combination, these drugs are usually effective. However, HIV can develop mutations that enable it to resist the effects of these drugs. This is why the ongoing discovery and development of new anti-HIV agents is important.

Etravirine belongs to the family, or class, of anti-HIV drugs called non-nukes. Other members of this group include the following medications:

- efavirenz (Sustiva and in Atripla)
- nevirapine (Viramune)

These drugs are meant for use in the initial treatment of HIV infection. However, etravirine is sufficiently powerful that it was developed to fight strains of drug-resistant HIV that are found in treatment-experienced PHAs.

Side effects

As with all non-nukes, users of etravirine may experience a temporary skin rash. According to Tibotec, in clinical
trials, this rash was generally mild to moderate in intensity. If it occurs, rash appears usually during the first two weeks of therapy and resolves within a week or two. HIV positive people who have previously experienced rash with other non-nukes were not at increased risk for rash when using etravirine.

**Cost**

Etravirine is available for distribution in Canada immediately and pharmacies can order it from Tibotec. The wholesale price is about $21.80 per day, which is also the price in the United States.

**The long and winding road**

Once Health Canada approves a drug, physicians can prescribe it but patients must pay for it unless their private insurance plan provides coverage. HIV/AIDS is a catastrophic disease that affects people’s ability to work and requires expensive care. In many high-income countries, such as Canada, the cost of anti-HIV medications is subsidized by provincial and territorial ministries of health. Each ministry has a listing of drugs for which it is prepared to pay. These listings are called formularies.

After federal approval, each HIV medicine must undergo another review process called Common Drug Review (CDR). As part of this review, recommendations are made as to whether the drug in question should be:

- listed on formularies
- listed on formularies with conditions; its use is restricted
- not listed at all

The CDR may also result in no decision being made as additional information is gathered. With the exception of Quebec, all provinces and territories, the Departments of National Defense and Veterans Affairs, and the Non-Insured Health Benefits plan participate in the CDR.

Etravirine is currently undergoing the CDR process.

**In Quebec**

The Quebec Ministry of Health and Social Services has a committee, Le Conseil du medicament, that reviews new drug applications for the province’s formulary. Tibotec plans to submit an etravirine dossier to this committee shortly. Hopefully, later this year the drug will be listed on the Quebec formulary—Liste des médicaments assurés du Québec.

**Expanded access program for Canada**

In the meantime, Canadian physicians who have patients who may benefit from etravirine can consider enrolling them in the etravirine expanded access program (EAP). This program is currently in place and is being used at major treatment centres across Canada. Tibotec plans to keep the EAP open in each province/territory until it receives formulary approval. Physicians interested in finding out more about the etravirine EAP can contact Tibotec at 1.800.567.3331.

An in-depth CATIE Fact Sheet on etravirine is under development.

—Sean R. Hosein

**REFERENCES:**


Disclaimer

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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