CATIE-News

CATIE’s bite-sized HIV and hepatitis C news bulletins.

Biktarvy approved in Canada for HIV treatment

2 August 2018

- Anti-HIV treatment combines two drugs with bictegravir, a new integrase inhibitor.
- Integrase inhibitors reduce HIV in the blood quickly and are generally well tolerated.
- Biktarvy was found similarly effective to other regimens containing dolutegravir.

In July 2018 Health Canada approved the use and sale of a regimen containing the following three anti-HIV medicines:

- bictegravir – 50 mg
- TAF (tenofovir alafenamide) – 25 mg
- FTC (emtricitabine) – 200 mg

These three drugs will be sold in a pill under the brand name Biktarvy. Manufactured by Gilead Sciences, Biktarvy is a complete treatment in one pill. It is taken once daily, with or without food, day or night. Biktarvy will be available for ordering by wholesalers and pharmacies in late August 2018.

About Biktarvy

Of the three drugs in Biktarvy, only bictegravir is new. It belongs to a class of drugs called integrase inhibitors. Over the past six years integrase inhibitors have become the cornerstone of combination therapy for HIV in Canada and other high-income countries. When used as part of HIV treatment, regimens containing an integrase inhibitor usually reduce the amount of HIV in the blood quickly, compared to other regimens. In general, integrase inhibitors are well tolerated.

Effectiveness

In clinical trials with more than 2,000 HIV-positive people, Biktarvy has been found to be similarly effective to other regimens that contain the leading integrase inhibitor dolutegravir (Tivicay and in Triumeq). Biktarvy works well in various groups of people, including women, those using HIV treatment for the first time and those who are treatment experienced.

Safety

Biktarvy was generally safe in clinical trials. Side effects that occurred were usually mild to moderate in intensity and temporary. They included the following:

- headache
- diarrhea
- nausea
- difficulty falling asleep or staying asleep
- abnormal dreams

Note that the people who are typically enrolled in pivotal clinical trials of new HIV treatments are usually young and relatively healthy adults. However, once a treatment is approved and more widely available, it gets used by clinic populations that are usually not in pivotal clinical trials. These people can be older and may have other health issues
(comorbidities)—including cardiovascular disease, liver injury, kidney injury, type 2 diabetes, anxiety, depression—that require medications. As a result, their experience of side effects may be different than those reported in pivotal clinical trials.

Also, as with any newly licensed treatment, the full range of side effects associated with Biktarvy, particularly rare ones, may not be known for at least another five years. However, the data collected so far suggests that Biktarvy is generally safe.

**Special populations**

**Pregnant women**

Although Biktarvy has been tested in HIV-positive women, it has not been formally assessed for its safety in pregnant women, so its effect on the fetus and pregnancy are not known. Gilead Sciences recommends that Biktarvy not be used during pregnancy “unless the potential benefits outweigh the potential risks to the fetus.”

**Older adults (over the age of 65)**

Gilead Sciences states that clinical trials with Biktarvy “did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from patients less than 65 years of age.”

**Pediatrics (under the age of 18)**

Gilead Sciences states: “Safety and efficacy of Biktarvy in pediatric patients less than 18 years of age have not been established.”

**Access**

After Health Canada licenses a treatment, physicians can prescribe it but initially patients must pay for it themselves unless they have a private insurance plan that covers the cost. Usually it takes between three and six months for such coverage to take effect.

If left untreated, HIV infection leads to catastrophic disease that can affect one’s ability to work. HIV treatment is also expensive. Therefore, in Canada, provincial and territorial ministries of health heavily subsidize the cost of anti-HIV medications. Each ministry has a listing for the drugs for which it is prepared to pay. These listings are called formularies.

In the months ahead, Gilead Sciences and provincial and territorial ministries of health will be negotiating the price of Biktarvy. This process might not be completed until the spring of 2019. Check with a pharmacist to find out when Biktarvy is listed on your region’s formulary.

A CATIE factsheet on Biktarvy is in development. Also, additional information on the results of clinical trials with Biktarvy will be available by mid-August in *Treatment Update* 228.

**Resources**

- [Bictegravir vs. dolutegravir](#) – *TreatmentUpdate 222*
- [Bictegravir + TAF + FTC vs. Triumeq](#) – *TreatmentUpdate 222*

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**REFERENCES:**


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.

CATIE provides information resources to help people living with HIV and/or hepatitis C who wish to manage their own health care in partnership with their care providers. Information accessed through or published or provided by CATIE, however, is not to be considered medical advice. We do not recommend or advocate particular treatments and we urge users to consult as broad a range of sources as possible. We strongly urge users to consult with a qualified medical practitioner prior to undertaking any decision, use or action of a medical nature.

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