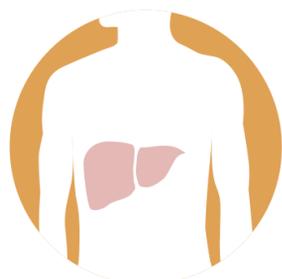


The Ontario Drug Policy Research Network (ODPRN) conducted multiple studies on the effectiveness, safety, and accessibility of treatment for chronic hepatitis B using multiple research methods.

What is chronic hepatitis B (CHB) and who is affected?



Hepatitis B is an infectious viral illness that damages the liver. If untreated, it can lead to serious cirrhosis and liver cancer.

An estimated 600,000 people in Canada are affected. It is especially prevalent amongst newcomers to Canada where the rate of infection is **4 to 6 times higher** than the general population.

There are two kinds of treatments

Oral nucleos(t)ides

Oral medications are the most common treatment. Treatment is often lifelong and continuous. There are five different medications:



*In 70-80% of patients, resistance to lamivudine develops within 5 years, and patients need to be switched to alternative medications, usually tenofovir.

Interferons

There are two available injectables: standard interferon and pegylated interferon.



- The treatment is usually short-term (about 1 year) but has significantly more side effects than oral therapies.
- 25-40% of people who receive injections won't need continued treatment with oral medications.

Selection of treatment is complex and takes into account many factors, such as:



HEALTH OF THE LIVER



PAST TREATMENT



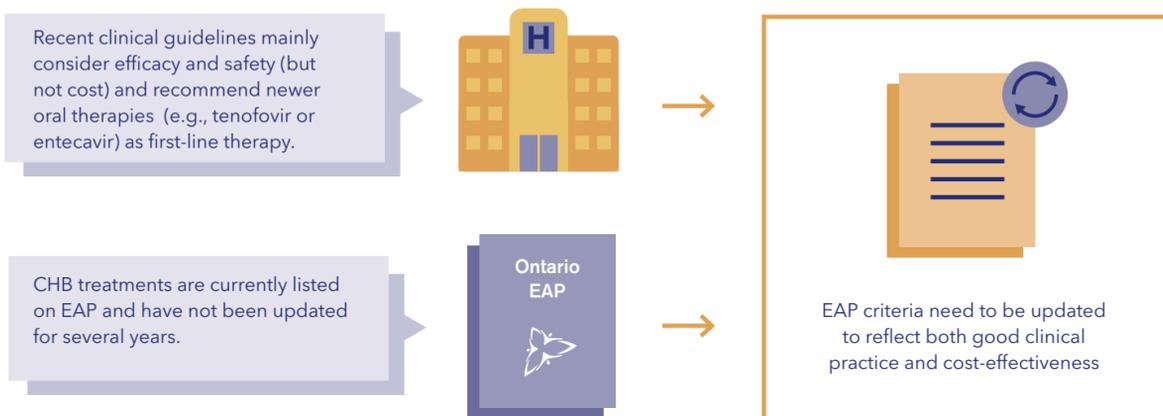
VIRAL LEVELS



AGE

How should the Ontario Public Drug Program cover CHB treatments?

Currently, all CHB treatments (except telbivudine) are available through the Exceptional Access Program (EAP). However this process takes approximately six weeks and isn't ideal for patients needing treatment quickly.



Reimbursement options and monthly cost of drug

Without a generic version of telbivudine, tenofovir, or interferon the cost can be quite high. Currently, since these drugs are not on the formulary, potential generic price savings are not being realized.

Drug name	Monthly cost (brand)	Monthly cost (generic)
entecavir	\$696	\$495
lamivudine	\$149	\$106
adefovir	\$770	\$613
tenofovir	\$594	N/A
interferon alfa-2b	\$1,593	N/A
pegylated interferon 2a	\$1,670	N/A

*Based on costs obtained from McKesson (Accessed: March 27, 2015). Based on a 30 day supply at the lowest recommended dose.

LEGEND FIRST LINE A red outline indicates a drug considered to be the first choice to treat a specific condition. An orange pill indicates potential for generic pricing option upon addition to formulary.

	Exceptional Access Plan	Limited Use
Current listing		
Recommended Option*		

* If cost-savings for entecavir are not realized (25% of the brand cost), then tenofovir and entecavir will remain on EAP.

** Adefovir, entecavir, and lamivudine have generic versions available, but since they are not on the Ontario Drug Benefit Formulary, generic pricing rules (potential cost savings) are not applicable.

Other considerations

- **Recommendation 1:** Evaluate the possible inclusion of pegylated interferon to the Exceptional Access Program as it has advantages over the currently listed standard interferon (only administered once weekly vs. 3 times weekly).
- **Recommendation 2:** Criteria should be re-visited and updated within 4 years or upon genericization of tenofovir. Pricing negotiations with manufacturers based on pricing reductions (approximately 60%) to allow for cost-effective addition of tenofovir should also be considered.
- **Recommendation 3:** Evaluate the possible alteration to current Exceptional Access Program process for patients with decompensated cirrhosis to allow for rapid approval via phone approval.
- **Recommendation 4:** Remove adefovir from the Exceptional Access Program.