Chronic Hepatitis B Drug Therapies: Frequently Asked Questions

1. **What is the funding status for drugs used in the treatment of chronic Hepatitis B infection?**

In Ontario, current treatments for chronic Hepatitis B infection are available for public funding through the Exceptional Access Program (EAP). As part of the Formulary modernization review, an evaluation of these treatments were undertaken to update their funding criteria.

As a result, effective **February 28, 2018**, lamivudine, entecavir, and tenofovir used for the treatment of chronic Hepatitis B infection will be funded under the Ontario Drug Benefit (ODB) Formulary for ODB eligible recipients as Limited Use (LU) benefit.

This changes means that ODB eligible recipients requiring treatment for chronic Hepatitis B infection with lamivudine, entecavir, or tenofovir will not have to apply to the EAP.

In addition, effective **February 28, 2018**, adefovir will no longer be funded through the Exceptional Access Program. Based on available information of clinical and cost-effectiveness, as well as the availability of generic products, adefovir was found to be less efficacious and less cost-effective than other treatments for chronic Hepatitis B infection. Patients who are currently receiving adefovir will continue to receive funding for as long as they require treatment with the drug.

2. **Is a prescription with the appropriate Reason For Use (RFU) code required for patients who were previously approved through Exceptional Access Program (EAP) for lamivudine, entecavir, and tenofovir for the treatment of chronic Hepatitis B infection?**

Existing EAP approvals for lamivudine, entecavir and tenofovir for the treatment of chronic Hepatitis B infection will be honored for the duration of the EAP approval period. A prescription with the correct RFU code will be required when the EAP approval expires.

3. **Will funding be continued for patients on adefovir?**

Effective **February 28, 2018**, adefovir will no longer be funded through EAP.
While new requests for adefovir will no longer be accepted through EAP, recipients who are currently receiving funding for adefovir through EAP will continue to receive funding for the drug for as long as they require treatment.

Ontario

4. Will an Exceptional Access Program (EAP) application be required for lamivudine, entecavir and tenofovir for the treatment of chronic Hepatitis B infection?

No, an EAP application will no longer be required for lamivudine, entecavir, or tenofovir for the treatment of chronic Hepatitis B infection. ODB eligible patients who meet the Reason For Use (RFU) code and associated clinical criteria will be eligible for drug funding.

Effective **February 28, 2018**, new requests for adefovir will no longer be accepted through EAP.

However, those patients who are currently receiving adefovir will continue to receive funding for as long as they require treatment with the drug.

5. What are the Limited Use (LU) Criteria for lamivudine, entecavir and tenofovir in treating chronic Hepatitis B infections?

Reason For Use (RFU) Code and Clinical Criteria

Drug	RFU Code	Clinical Criteria
Lamivudine	502	Confirmed chronic Hepatitis B infection in persons with • HBV DNA ≥ 1000 IU/mL AND • ALT levels > ULN OR • Evidence of fibrosis OR • Documented evidence of cirrhosis LU Authorization Period: 1 year
	503	Patients with chronic Hepatitis B infection currently receiving treatment with lamivudine and requires treatment continuation LU Authorization Period: 1 year
	504	Patients with chronic Hepatitis B infection who are scheduled to undergo chemotherapy or significant immunosuppressive treatment LU Authorization Period: 1 year

Drug	RFU Code	Clinical Criteria
Entecavir	505	Confirmed chronic Hepatitis B infection in persons with • HBV DNA ≥ 1000 IU/mL AND • ALT levels > ULN OR • Evidence of fibrosis OR • Documented evidence of cirrhosis LU Authorization Period: 1 year
	506	For patients with chronic Hepatitis B infection who have a contraindication, intolerance or inadequate response to one or more of the following: lamivudine, tenofovir, adefovir or telbivudine LU Authorization Period: 1 year
	507	Patients with chronic Hepatitis B infection currently receiving treatment with entecavir and requires treatment continuation LU Authorization Period: 1 year
	508	Patients with chronic Hepatitis B infection who are scheduled to undergo chemotherapy or significant immunosuppressive treatment LU Authorization Period: 1 year

Drug	RFU Code	Clinical Criteria
Tenofovir	517	Confirmed chronic Hepatitis B infection in persons with • HBV DNA ≥ 1000 IU/mL AND • ALT levels > ULN OR • Evidence of fibrosis OR • Documented evidence of cirrhosis LU Authorization Period: 1 year
	518	For patients with chronic Hepatitis B infection who have a contraindication, intolerance or inadequate response to one or more of the following: lamivudine, entecavir, adefovir or telbivudine LU Authorization Period: 1 year
	519	Patient is pregnant (2nd trimester or later) with HBV DNA > 1 x 10^6 IU/mL LU Authorization Period: 1 year
	520	Patients with chronic Hepatitis B infection currently receiving treatment with tenofovir and requires treatment continuation LU Authorization Period: 1 year
	521	Patients with chronic Hepatitis B infection who are scheduled to undergo chemotherapy or significant immunosuppressive treatment LU Authorization Period: 1 year

6. What is the funding status for tenofovir used in the treatment of HIV/AIDS?

Tenofovir will continue to be listed as an eligible drug product through the Facilitated Access to HIV/AIDS Drug Products mechanism, but effective **February 28, 2018** a prescription with the RFU code 522 will be required.

Drug	RFU Code	Clinical Criteria
Tenofovir	522	Patients with HIV/AIDS who meet the following criterion: • For the treatment of HIV/AIDS. The prescriber must be approved for the Facilitated Access to HIV/AIDS Drug Products mechanism. LU Authorization Period: 1 year

Additional Information:

For pharmacies:
Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other Health Care Providers and the Public:
Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282