

PharmaCare Coverage for Chronic Hepatitis B Treatments

Effective November 27, 2018, PharmaCare is changing coverage of and criteria for drugs used in the treatment of chronic Hepatitis B (CHB).

The following changes have been made to PharmaCare coverage of CHB treatments:

- Tenofovir disoproxil fumarate (Viread[®] and generics) 300 mg tablet is now covered as a first-line option for treatment-naïve patients with or without compensated cirrhosis, as well as for treatment-experienced, medication-compliant patients who demonstrate lamivudine resistance or who have previously used adefovir and have persistent viremia.
- Entecavir (Baraclude and generics) 0.5 mg tablet is now covered as a first-line option for treatment-naïve patients with or without compensated cirrhosis.
- Adefovir (Hepsera[®] and Apo-adefovair) 10 mg tablet is no longer covered by PharmaCare.
 - Effective November 27, 2018, no new Special Authority (SA) requests for adefovir will be approved.
 - Patients with existing SA approval for adefovir will be automatically granted approval for tenofovir disoproxil fumarate (300 mg tablets, Viread and generics). Coverage is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, as well as the Low Cost Alternative program.
 - Patients with existing Special Authority approval for adefovir will have 6 months to transition to an alternative treatment. Their coverage of adefovir will end on May 29, 2019.
 - A recent [Drug Benefit Council \(DBC\) review of CHB treatments](#) found adefovir to be less efficacious when compared with tenofovir disoproxil fumarate in terms of virologic response, less cost-effective, and associated with higher rates of drug resistance; as such, adefovir is rarely used for the treatment of CHB. The DBC recommended that adefovir be delisted as a PharmaCare benefit for the treatment of CHB.

Detailed criteria for all CHB treatment options are available at www.gov.bc.ca/PharmaCareSpecialAuthority.

Treatment-naïve Patients without Compensated Cirrhosis

Pharmacare-covered options for treatment-naïve CHB patients without compensated cirrhosis include tenofovir disoproxil fumarate, entecavir, lamivudine, and interferon-alfa.

Following their review, the DBC recommended that tenofovir disoproxil fumarate and entecavir be used as first-line agents for both HBeAg positive or negative patients, based on clinical evidence demonstrating that tenofovir disoproxil fumarate and entecavir when compared to lamivudine offer the highest efficacy in terms of virologic response and alanine aminotransferase (ALT) normalization, as well as the lowest rates of drug resistance.

Tenofovir alafenamide (Vemlidy™) is currently under review by the Ministry for potential inclusion as a PharmaCare benefit. This review is targeted for completion in early 2019.

Treatment-naïve Patients with Compensated Cirrhosis

Pharmacare-covered options for treatment-naïve CHB patients with compensated cirrhosis include tenofovir disoproxil fumarate, entecavir, and lamivudine.

Patients with Lamivudine Resistance and/or Adefovir-experienced Patients with Persistent Viremia

The Pharmacare-covered option for treatment-experienced, medication-compliant patients who demonstrate lamivudine resistance or who have previously used adefovir and have persistent viremia is tenofovir disoproxil fumarate.

New SA requests for chronic hepatitis B treatments must be accompanied by lab work, as indicated in the [HLTH 5372: Chronic Hepatitis B Special Authority Request form](#).

In exceptional cases, Pharmacare may consider requests for coverage of patients who do not meet the established criteria, if the physician provides additional documentation supporting the patient's specific clinical need. The Hepatitis Drug Benefit Adjudication Advisory Committee reviews exceptional requests.