

Blue Cross Blue Shield of Vermont and The Vermont Health Plan

Hepsera™ (Adefovir dipivoxil)

Prior Approval Guidelines

- Description:** Adefovir dipivoxil is a prodrug of adefovir, a nucleotide analog of adenosine monophosphate, with activity against human hepatitis B virus (HBV). Adefovir inhibits HBV DNA polymerase (reverse transcriptase) and causes chain termination, thus inhibiting viral DNA replication.
- Indications:** For the treatment of chronic hepatitis B in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. This indication is based on histological, virological, biochemical and serological responses in adult patients with HBeAg-positive & HBeAg-negative chronic Hep-B with compensated liver function, & in adult patients with clinical evidence of lamivudine-resistant hepatitis B virus with either compensated or decompensated liver function.
- Reasons for Prior Authorization:** Cost Potential for misuse Toxicity
- Criteria for Approval:**
- 1) Patient has active HBV replication as evidenced by:
 - Persistent elevations in aminotransaminases (ALT or AST)
 - Persistence of HBsAg for longer than 6 months
 - Detection of HBeAg AND/OR HBV-DNA
 - Biopsy
 - 2) Unresponsive or resistance to previous therapy with lamivudine suspected.
 - 3) Patient is not a candidate for interferon or lamivudine therapy.
 - 4) Prescriber is a gastroenterologist, infectious disease specialist or physician. experienced in treating Hepatitis B.
 - 5) HIV status of the patient is known.
- Reasons for Denial of Benefit:**
- 1) Patient has any of the following **contraindications**
 - History of hypersensitivity to any components of the product
 - 2) Patient does not meet criteria for approval
 - 3) HIV status of the patient is unknown.
- Renewal Criteria:** Demonstrated response to Hepsera therapy as demonstrated by reassessment of Hepatitis B serology at 12 and 24 weeks (i.e., reductions in HBV DNA serum levels, decreases in ALT/AST, appearance of HBeAb, decreased levels of HBeAg)
- Benefit Approval:**
- Initial Approval:** 6 months, additional approval for 12 month periods will be granted based on reassessment of Hepatitis B viremia for patients demonstrating response to therapy.
- Quantity limits:** 30 tablets per RX apply as the recommended dose is 10mg once daily.
- References:**
- 1) Hepsera™ Prescribing Information, Gilead Sciences, Inc.; Foster City, CA. September 2002. <http://www.hepsera.com>
 - 2) Isada CM, Kasten BL, Goldman MP, et al. Antimicrobial Therapy & Diagnostic Tests/Procedures 3rd Edition. 1996;435-437.
 - 3) Rivkina A, Rybalov S. Chronic Hepatitis B: Current and Future Treatment Options. Pharmacotherapy 2002;22(6):721-737.
 - 4) Gilbert DN, Moellering RC, Sande MA. Sanford Guide to Antimicrobial Therapy 2002 32nd Edition. Merck: 102-103.