



## Hepatitis B Prior Authorization Guidelines

*In general, the following criteria need to be met to obtain prior authorization approval. In the event of a prior authorization denial, recommended formulary alternatives will be provided to the prescriber based upon the patient's insurance coverage. If a prior authorization and recommended formulary alternatives are denied, our team can provide appeal support services.*

### Standard Requirements

- Diagnosis of acute or chronic hepatitis B episode
  - Requires testing and documentation of serotyping
    - Hepatitis B surface antigen and antibody (HBsAg) (+/-): 2 positive tests 6 months confirms a chronic diagnosis
    - Hepatitis B e antigen and antibody (HBeAg) (+/-)
  - Requires testing a documentation of HBV DNA
    - Threshold for HBeAg positive and negative patients differ:
      - Threshold of > 20,000 U/mL in HBeAg positive patients
      - Threshold of > 2,000 U/mL in HBeAg negative patients
  - Requires testing and documentation of liver function tests, specifically ALT
    - Persistently or elevated ALT may be an indicator of HBV infection
- Documentation of patient's liver function or status
  - The patient does or does not have cirrhosis
  - The patient's cirrhosis is compensated or decompensated
  - The patient has had or is scheduled for a liver transplant
- Documentation of whether the patient is treatment naïve or treatment experienced
  - Documentation of current/failed treatments (drug name, dose, duration, and outcome)
- Patients with acute liver failure, cirrhosis (decompensated or compensate), liver transplant, SOT with hepatitis B positive donor can initiate therapy without HBeAg status or serum ALT levels
- For Entecavir: documented diagnosis of chronic HBV.
  - In patients with decompensated cirrhosis Entecavir is preferred due to the possibility of inducing renal impairment
- For Viread and Vemlidy: documented diagnosis of chronic HBV.
  - Viread: For patients who have renal impairment (CrCl < 50 mL/min) should have frequency of administration adjusted. For CrCl of less than 15 mL/min Viread is contraindicated
  - Viread: Patients at increased risk of bone fracture should have a BMD test conducted

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