

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: Chronic Hepatitis B Treatment Policy

Drug(s): BARACLUDGE (entecavir), EPIVIR-HBV (lamivudine), HEPSERA (adefovir dipivoxil), TYZEKA (telbivudine)

Covered Uses: All FDA-approved indications not otherwise excluded from Part D. All criteria in "other criteria" section must be met for coverage.

Required Medical Information: All requests must be accompanied by complete documentation, which includes chart notes, test results for HBeAg/anti-HBe and HBV DNA (PCR) assay, liver function tests, current HIV status, and liver biopsy report. Medical history.

Age Restrictions: Per package label.

Prescriber Restrictions: N/A

Other Criteria: Hepatitis B oral agents may be considered medically necessary if documentation supports diagnosis of chronic hepatitis B with all of the following:

- Persistent or intermittent elevation in ALT/AST levels defined as 2 times the upper normal limit consistently for at least 6 months, **OR**
- Liver biopsy showing chronic hepatitis with moderate or severe necroinflammation or significant fibrosis, **AND** all of the following:
 - HBsAg positive greater than 6 months,
 - Serum HBV DNA greater than 20,000 IU/ml (105 copies/ml)

Initial approval is up to a maximum of 6 months.

Continued therapy will be considered up to a maximum of 6 month intervals based on demonstrated response supported by documentation of all of the following:

- Member is compliant with therapy as determined by review of prescription drug history,
- Normalization of serum ALT,
- Decrease in serum HBV DNA level by 2 log,
- Loss of HBeAG with or without detection of anti-HBe,
- Stable or improvement in liver histology defined as greater than or equal to a 2-point decrease in Knodell necro-inflammatory score with no worsening of the Knodell fibrosis score. (Using the Ishak Fibrosis Score – improvement is defined as greater than 1 point decrease),
- HBeAg positive chronic hepatitis B patients: continued therapy will be considered for patients with HBeAg seroconversion until 6 months of additional treatment is completed after appearance of anti-HBe,
- HbeAg negative chronic hepatitis B patients: continued therapy will be considered until the patient has achieved HBsAg clearance.

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Exclusion Criteria: Chronic hepatitis B oral agents will not be considered medically necessary for the following:

- Failed to achieve primary response as evidenced by less than 2 log decrease in serum HBV DNA level after at least 6 months of therapy,
- No improvement as evidenced by the above criteria for extension of therapy,
- Inactive HBsAg carrier (persistent HBV infection of the liver without significant, ongoing liver inflammation disease),
- HBeAg positive chronic hepatitis patients for greater than 6 months of treatment after appearance of anti-HBe,
- HBeAg positive with high serum HBV DNA but normal ALT levels,
- Combination therapy of agents identified in this policy except during adefovir transition period (lamivudine will be allowed for short-term use only),
- Greater than 1mg daily of entecavir,
- Greater than 100mg daily of lamivudine-HBV,
- Greater than 10mg daily of adefovir,
- Greater than 600mg daily of telbivudine,
- Previous HBeAg positive chronic hepatitis patients on therapy for 48 weeks or more that have remained seroconverted for at least 6 months,
- Acute hepatitis B

Coverage Duration: Approval for hep B drug naïve members is up to 12 months. Subsequent approvals at 6 month intervals.