

## SUPPLEMENTAL SPECIALTY PA

### BARACLUDE (entecavir) entecavir (generic)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### A. FDA-Approved Indications

Baraclude is indicated for the treatment of chronic hepatitis B virus infection in adults and children at least 2 years of age with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

###### B. Compendial Uses

1. Hepatitis B reactivation prophylaxis
2. Coinfection with Chronic Hepatitis B and HIV

All other indications are considered experimental/investigational and not medically necessary.

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. **Chronic Hepatitis B Infection**

Authorization of 6 months may be granted for treatment of chronic hepatitis B when all of the following criteria are met:

1. There is evidence of active viral replication (e.g., detectable serum HBV DNA, as measured by the bDNA hybridization or PCR assay).
2. Member meets any of the following criteria:
  - i. Member has evidence of persistent elevations in serum aminotransferases (ALT or AST), or
  - ii. Member has histologically active disease or hepatic fibrosis is detected on transient elastography.

###### B. **Hepatitis B Prophylaxis**

Authorization of 6 months may be granted for prophylaxis of hepatitis B reactivation in immunosuppressed members.

###### C. **Coinfection With Chronic Hepatitis B and HIV**

Authorization of 6 months may be granted for treatment of coinfection with chronic hepatitis B and HIV when all of the following criteria are met:

1. Member meets the criteria for approval in Section A, and
2. Member is currently receiving highly active antiretroviral therapy (HAART).

##### III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for the indications listed in Section II who achieve or maintain a positive clinical response (e.g., decreased HBV DNA, histologic improvement, ALT normalization, HBeAg seroconversion).

#### IV. REFERENCES

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.
2. Entecavir [package insert]. Waterford, Ireland: EirGen Pharma Ltd.; September 2017.
3. Baraclude. Micromedex Solutions. Greenwood Village, CO: Truven Health Analytics. <http://micromedex.com/>. Accessed March 7, 2022.
4. Clinical Pharmacology [Internet]. Tampla (FL) Elsevier. C2021- [cited 2022 March 7]. Available from <http://www.clinicalpharmacology.com>
5. Terrault, N.A., Lok, A.S., McMahon, et al. (2018), Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology, 67: 1560-1599. <https://doi.org/10.1002/hep.29800>