

Reference number(s)
4779-A

SUPPLEMENTAL SPECIALTY PA

BARACLUDGE (entecavir) entecavir

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 Indication

Baraclude is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 2 years of age and older 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 virus reactivation/reinfection prophylaxis
2. Coinfection with chronic hepatitis B virus and human immunodeficiency virus (HIV)

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Chronic hepatitis B virus infection**

Authorization of 6 months may be granted for treatment of chronic hepatitis B virus 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. **Coinfection with chronic hepatitis B virus and HIV**

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

1. Member meets the criteria for approval in Section A, and
2. Member is currently receiving antiretroviral therapy.

C. **Hepatitis B virus reactivation/reinfection prophylaxis**

Authorization of 12 months may be granted for prophylaxis of hepatitis B virus reactivation/reinfection in immunosuppressed members.

III. CONTINUATION OF THERAPY

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A. Chronic hepatitis B virus infection and coinfection with chronic hepatitis B virus and HIV

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for chronic hepatitis B virus infection or coinfection with chronic hepatitis B virus and HIV who achieve or maintain a positive clinical response (e.g., decreased HBV DNA, histologic improvement, ALT normalization, HBeAg seroconversion).

B. Hepatitis B virus reactivation/reinfection prophylaxis

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.
2. Entecavir [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; April 2022.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. <http://micromedex.com/>. Accessed March 1, 2023.
4. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier; 2023 [cited 2023 Mar 1]. Available from: <http://www.clinicalpharmacology.com>.
5. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. *Hepatology*. 2018;67(4):1560-1599. doi: 10.1002/hep.29800.
6. Lexicomp Online, Pediatric and Neonatal Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed March 1, 2023.