

SUPPLEMENTAL SPECIALTY PA

BARACLUE (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

Baraclue is indicated for the treatment of chronic hepatitis B virus (HBV) 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 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 and coinfection with chronic hepatitis virus and HIV**

Authorization of 6 months may be granted for treatment of chronic hepatitis B virus (HBV) 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).
 - ii. Member has histologically active disease.
 - iii. Member has hepatic fibrosis detected by transient elastography or serum markers of fibrosis (e.g., APRI score, FIB-4, FibroSure).
3. Member meets either of the following criteria:
 - i. Member is HIV-1 negative.
 - ii. Member has coinfection with chronic hepatitis B virus and HIV and is currently receiving antiretroviral therapy.

B. **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

Reference number(s)
4779-A

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 HBV infection or coinfection with chronic HBV and HIV who achieve or maintain a positive clinical response (e.g., decreased HBV DNA level, 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® (electronic version). Merative, Ann Arbor, MI. Available at: <http://micromedexsolutions.com/>. (cited: March 4, 2024).
4. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier; 2024 [cited 2024 Mar 4]. 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.
6. Lexicomp Online, Pediatric and Neonatal Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed March 4, 2024.
7. The U.S. Department of Health and Human Services (HHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf>. Accessed March 11, 2024.