

Supplemental Specialty Prior Authorization entecavir-Baraclude

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Baraclude	entecavir

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.

FDA-approved Indications^{1,2}

Baraclude is indicated for the treatment of chronic hepatitis B virus 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 (alanine aminotransferase [ALT] or aspartate aminotransferase [AST]) or histologically active disease.

Compendial Uses^{3-5,7}

- Hepatitis B virus reactivation/reinfection prophylaxis
- Coinfection with chronic hepatitis B virus and human immunodeficiency virus (HIV)

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

Coverage Criteria

Chronic Hepatitis B Virus Infection or Coinfection with Chronic Hepatitis B Virus and HIV¹⁻⁴

Authorization of 12 months may be granted for treatment of chronic hepatitis B virus (HBV) when all of the following criteria are met:

- There is evidence of active viral replication (e.g., detectable serum HBV DNA, as measured by the bDNA hybridization or polymerase chain reaction [PCR] assay).
- Member meets any of the following criteria:
 - Member has evidence of persistent elevations in serum aminotransferases (ALT or AST).
 - Member has histologically active disease
 - Member has hepatic fibrosis detected by transient elastography or serum markers of fibrosis (e.g., aspartate aminotransferase to platelet ratio index [APRI] score, Fibrosis-4 [FIB]-4, FibroSure).
- Member meets either of the following criteria:
 - Member is HIV-1 negative.
 - Member has coinfection with chronic HBV and HIV and is currently receiving antiretroviral therapy.

Hepatitis B Virus Reactivation/Reinfection Prophylaxis⁴⁻⁷

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

Continuation of Therapy

Chronic Hepatitis B Virus Infection and Coinfection with Chronic Hepatitis B Virus and HIV^{1,2}

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, hepatitis B e-antigen [HBeAg] seroconversion).

Hepatitis B Virus Reactivation/Reinfection Prophylaxis

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

References

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.
2. Entecavir [package insert]. Carlsbad, CA: Carlsbad Technology, Inc.; June 2024.
3. 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/en/guidelines/adult-and-adolescent-arv>. Accessed March 14, 2025.
4. 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
5. Micromedex (electronic version). Merative; 2025. Accessed March 14, 2025. <https://www.micromedexsolutions.com>
6. Lexi-Drugs. UpToDate Lexidrug. UpToDate Inc. <https://online.lexi.com>. Accessed March 14, 2025.
7. World Health Organization (WHO). Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection. <https://www.who.int/publications/i/item/9789240090903>. Published March 29, 2024. Accessed March 14, 2025.