

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Baraclude (entecavir)

Override(s)	Approval Duration
Prior Authorization Quantity Limits	1 year

Medications	Quantity Limit
Baraclude (entecavir)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Baraclude (entecavir) may be approved for individuals who meet the following criteria:

- I. Individual is 2 years of age or older; **AND**
- II. Individual has a diagnosis of chronic Hepatitis B infection; **AND**
- III. Individual has not been previously treated with lamivudine (AASLD 2018);

OR

- IV. Individual is using as prophylaxis for hepatitis B reactivation in the setting of immune suppression (AGA 2015) or in combination with hepatitis C direct-acting antiviral therapy (AASLD 2018);

OR

- V. Individual is a solid organ transplant recipient and using as prophylaxis for hepatitis B reactivation (AASLD 2018).

Note: Baraclude (entecavir) has black box warnings for severe exacerbations of Hepatitis B, co-infection of HIV and HBV, lactic acidosis, and severe hepatomegaly with steatosis. Hepatic function should be monitored for several months after discontinuation of therapy to assess for severe exacerbation of hepatitis. Therapy for individuals co-infected with HBV and HIV should also include a HAART regimen to avoid potential development of nucleoside reverse transcriptase inhibitors (NRTI) resistance.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Terrault NA, Lok A, McMahon BJ, et al. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. *Hepatology*. 2018; 67:1560-99.

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 29, 2018.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2018. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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