

Prior Authorization Approval Criteria

Baraclude (entecavir)

Generic name:	Entecavir
Brand name:	Baraclude
Medication class:	Antiviral agent
FDA-approved uses:	Treatment of hepatitis B in adults and children 2 years and older with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases or histologically active disease.

Criteria for approval (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosed chronic hepatitis B with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases or histologically active disease.
- Must be 2 years of age or older.

Caution:

- A black box warning is present in the entecavir prescribing information, as with lamivudine and adefovir, regarding the occurrence of lactic acidosis and severe hepatomegaly with steatosis with the use of nucleoside analogs.

Approval Duration:

- Indefinite

Benefit Type:

- Pharmacy

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 6/13/07

Revised: 12/14/16

The criteria listed above applies to Fallon Health Plan and its subsidiaries.