



Prior Authorization Approval Criteria

Baraclude (entecavir)

Generic name:	Entecavir
Brand name:	Baraclude
Medication class:	Antiviral agent
FDA-approved uses:	Treatment of hepatitis B in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases or histologically active disease.
Available dosage forms:	0.5 mg and 1 mg tablets and 0.05 mg/ml oral solution
Usual dose range:	0.5 mg once daily in nucleoside naïve patients 1 mg once daily in patients with a history of hepatitis B viremia while receiving lamivudine or with known lamivudine-resistance mutations Dose reduction recommended in patients with decreased renal function.
Duration of therapy:	Optimal duration of treatment is unknown.
Cost (based on AWP 2007):	\$800 per month

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

- 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 16 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.

Monitoring:

- Periodic monitoring of hepatic function is recommended.
- CBC, differential, platelets
- LFTs, RFTs
- Urinalysis

Contraindications:

- Patients with any hypersensitivity to entecavir or any component of the product.

Not approved if:

- Does not meet the above stated criteria
- Have any contraindications to the use of entecavir

Special considerations:

- Entecavir appears at least as effective as lamivudine and retains promising activity in patients who are refractory to lamivudine therapy.
- Most studies were done comparing entecavir to lamivudine.
- Ongoing studies are being conducted comparing entecavir and adefovir.
- The most common adverse effects reported in clinical trials were headache, fatigue, dizziness, and nausea.
- Tier and cost comparison of oral drugs for hepatitis B:
 - Adefovir (Hepsera) Tier 3, PA required \$23.89/ tablet
 - Entecavir (Baraclude) Tier 3, PA required \$26.67/tablet
 - Lamivudine (EpiVir) Tier 2 \$9.29/tablet
 - Telbivudine (Tyzeka) Tier 3, PA required \$20.29/tablet

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 6/13/07