MEDICATION POLICY

Generic Name: Entecavir

Therapeutic Class or Brand Name: Baraclude®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Entecavir tablets (generic)

Non-Preferred: Baraclude® tablets, Baraclude® oral solution

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/1/17

GPI Code: 1235203000

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

I. Documented diagnosis of Chronic Hepatitis B virus infection with evidence of active viral replication and ONE of criteria A OR B is met:
   A. Evidence of persistent elevations in serum aminotransferases (ALT or AST).
   B. Histologically active disease.

II. Minimum age requirement: 2 years old.

III. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

IV. Non-preferred products (i.e. Baraclude® tablets, Baraclude® oral solution) require a documented clinical reason containing details as to why generic entecavir is not appropriate or is contraindicated.

Exclusion Criteria:

- N/A

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 30 tablets or 630mls per 30 days.

Approval Length:

- **Authorization:** 1 year.

- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://onlinelibrary.wiley.com/doi/10.1002/hep.28156/epdf.
2. http://www.aasld.org/sites/default/files/guideline_documents/ChronicHepatitisB2009.pdf.
3. http://www.fchp.org/~/media/Files/FCHP/Imported/Baraclude_entecavir.pdf.ashx.
4. Medi-Span.
5. http://packageinserts.bms.com/pi/pi_baraclude.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
12/1/2017	1. Policy reviewed: no changes made.
9/13/2016	1. **Added** "http://onlinelibrary.wiley.com/doi/10.1002/hep.28156/epdf" **under References**.
2/24/2015	1. **Changed** "N/A" **to** "Preferred: Entecavir tablets (generic); Non-Preferred: Baraclude® tablets, Baraclude® oral solution" **under Applicable Drugs (if Therapeutic Class)**. 2. **Changed** "Minimum age requirement: 16 years old" **to** "Minimum age requirement: 2 years old" **under Prior Authorization Criteria**. 3. **Added** "Non-preferred products (i.e. Baraclude® tablets, Baraclude® oral solution) require a documented clinical reason containing details as to why generic entecavir is not appropriate or is contraindicated" **under Prior Authorization Criteria**. 4. **Changed** "30 tablets or 600ml per 30 days" **to** "30 tablets or 630mls per 30 days" **under Quantity/Days Supply Restrictions**. 5. **Added** "http://www.aasld.org/sites/default/files/guideline_documents/ChronicHepatitisB2009.pdf" **under References**.
2/13/2014	1. **Adapted policy to new format.** 2. **Added GPI Code**. 3. **Changed criterion I under Prior Authorization Criteria from:** "Documented diagnosis of Chronic Hepatitis B virus infection" **to:** "Documented diagnosis of Chronic Hepatitis B virus infection with evidence of active viral replication and ONE of criteria A OR B is met: A. Evidence of persistent elevations in serum aminotransferases (ALT or AST); B. Histologically active disease". 4. **Updated references** to include Medi-Span.