

## **BARACLUDE TABLETS (entecavir)**

Baraclude oral solution is not included in this policy

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **Background**

Baraclude (entecavir) is a hepatitis B virus nucleoside analogue reverse transcriptase inhibitor. Baraclude competes with the natural substrate deoxyguanosine triphosphate and functionally inhibits all three activities of the hepatitis B virus (HBV) reverse transcriptase: base priming; reverse transcription of the negative strand from the pregenomic messenger RNA; and synthesis of the positive strand of HBV DNA (1).

#### **Regulatory Status**

FDA-approved indication: Baraclude is indicated for the treatment of chronic hepatitis B virus (HBV) infection (1).

#### **Summary**

Baraclude (entecavir) is a hepatitis B virus nucleoside analogue reverse transcriptase inhibitor. Baraclude competes with the natural substrate deoxyguanosine triphosphate and functionally inhibits all three activities of the hepatitis B virus (HBV) reverse transcriptase: base priming; reverse transcription of the negative strand from the pregenomic messenger RNA; and synthesis of the positive strand of HBV DNA (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Baraclude while maintaining optimal therapeutic outcomes.

#### **References**

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.