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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Anti-Infective Agents	**Original Policy Date:**	January 1, 2021
Subject:	Baraclude	**Page:**	1 of 3

Last Review Date: March 12, 2021

Baraclude tablets

Description

Baraclude (entecavir) tablets

Baraclude oral solution is not included in this policy

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).

Related policies
Hepsera

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Baraclude may be considered **medically necessary** for patients with Hepatitis B infection who have had an inadequate response, intolerance, or contraindication to the generic.

Baraclude may be considered **investigational** for all other diagnoses.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Hepatitis B (HBV) infection

a. Patient **MUST** have tried the preferred product (generic Baraclude: entecavir) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.

Policy History

Date	Action
December 2020	Addition to PA. Annual review
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.