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5.01.056

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Anti-Infective Agents	**Original Policy Date:**	January 1, 2021
Subject:	Baraclude	**Page:**	1 of 3

Last Review Date: June 13, 2024

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** if the conditions indicated below are met.

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

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
March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.01.056
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.