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5.01.057

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

Last Review Date: June 13, 2024

Hepsera

Description

Hepsera (adefovir)

Background
Hepsera (adefovir) is an acyclic nucleotide analog of adenosine monophosphate which is phosphorylated to the active metabolite adefovir diphosphate by cellular kinases. Hepsera inhibits Hepatitis B virus (HBV) DNA polymerase by competing with the natural substrate deoxyadenosine triphosphate and by causing DNA chain termination after its incorporation into viral DNA (1).

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

Related policies
Baraclude

Policy

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

Hepsera may be considered **medically necessary** if the conditions indicated below are met.

Hepsera 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 Hepsera: adefovir) 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

Hepsera (adefovir) is an acyclic nucleotide analog of adenosine monophosphate which is phosphorylated to the active metabolite adefovir diphosphate by cellular kinases. Hepsera inhibits Hepatitis B virus (HBV) DNA polymerase by competing with the natural substrate deoxyadenosine triphosphate and by causing DNA chain termination after its incorporation into viral DNA (1).

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

References

1. Hepsera [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2018.

Policy History

Date	Action
December 2020	Addition to PA. Annual review
June 2021	Annual review
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.01.057
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.