# Clinical Policy: Adefovir

Reference Number: IL.PHAR.142
Effective Date: 1.1.20
Last Review Date: 10.25.26
Line of Business: YouthCare HealthChoice Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Adefovir is a nucleotide analogue and reverse transcriptase inhibitor with activity against human hepatitis B virus.

## FDA Approved Indication(s)

Adefovir is indicated for the treatment of chronic hepatitis B in patients 12 years of age and older with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that adefovir is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Chronic Hepatitis B Infection** (must meet all)**:**

1. Diagnosis of chronic hepatitis B virus infection;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;
3. Age ≥ 12 years;
4. Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: entecavir, or tenofovir;
5. Adefovir is not prescribed concurrently with tenofovir;
6. Dose does not exceed 10 mg per day.

**Approval duration: 6 months**

**B. Other diagnoses/indications** (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Chronic Hepatitis B Infection** (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Hepsera is not prescribed concurrently with tenofovir;
4. If request is for a dose increase, new dose does not exceed 10 mg per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

ALT: alamine aminotransferase

AST: aspartate aminotransferase

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| entecavir (Baraclude®) | 0.5 to 1 mg PO QD | 1 mg/day |
| tenofovir disproxil fumarate (Viread®) | 300 mg PO QD | 300 mg/day |
| Pegasys® (peginterferon alfa-2a) | 180 mcg SC once weekly for 48 weeks | 180 mcg/day |
| Vemlidy® (tenofovir alafenamide fumarate) | 25 mg PO QD | 25 mg/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*
- Contraindication(s): hypersensitivity
- Boxed warning(s): severe acute exacerbations of hepatitis, nephrotoxicity, HIV resistance, lactic acidosis, and severe hepatomegaly with steatosis

*Appendix D: General Information*
- Adefovir labeling warns against coadministration of adefovir with tenofovir-containing products. Adefovir may increase serum concentrations of tenofovir-containing products and vice versa, resulting in additive nephrotoxicity and diminishing therapeutic effect. In the treatment of chronic hepatitis B, tenofovir should not be administered with adefovir to avoid multi-drug resistance. In patients with concomitant HIV and chronic hepatitis B, treatment with tenofovir is sufficient.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Chronic hepatitis B | CrCl ≥ 50 mL/min: 10 mg PO QD<br>CrCl 30 to 49 mL/min: 10 mg PO Q48H<br>CrCl 10 to 29 mL/min: 10 mg PO Q72H<br>Hemodialysis: 10 mg every 7 days following dialysis | 10 mg/day |

## VI. Product Availability
Tablet: 10 mg

## VII. References
1. Adefovir Prescribing Information. Bensalem, PA: Sigmapharm Laboratories; October 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e047f3b2-feae4c5e-9d07-1fefb4c0ec25. Accessed July 7, 2026.

2. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 Hepatitis B Guidance. Hepatology 2018; 67(4):15601599.

3. Ghany MG, Pan CQ, Lok AS, et al. AASLD/IDSA Practice guideline on treatment of chronic hepatitis B. Hepatology. 2026;83(4):974-997.

4. Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection. World Health Organization (WHO). 2024. Available at: https://www.who.int/publications/i/item/9789240090903. Accessed August 13, 2026.

5. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier; Updated periodically. Accessed August 13, 2026.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| New policy created, adapted CP.PHAR.142 Adefovir (Hepsera) policy. | 12.9.19 | 1.7.20 |
| 4Q 2020 annual review: no significant changes; references reviewed and updated. | 12.15.20 | |
| 2Q2022 annual review; no significant changes; references reviewed | 4.1.22 | |
| 4Q 2023 Annual Review: Template changes applied to other diagnoses/indications and continued therapy section. References reviewed and updated. | 10.16.23 | |
| 4Q 2025 annual review: removed brand Hepsera from policy as it is no longer available; added generic adefovir to policy for review; references reviewed and updated. | 10.31.25 | |
| 4Q 2026 annual review: no significant changes; references reviewed and updated. | 10.25.26 | 11.26 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.