Clinical Policy: Adefovir

Reference Number: CP.PHAR.142
Effective Date: 08.28.18
Last Review Date: 11.26
Line of Business: HIM/ICHRA, 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 (HBV).

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 HBV infection;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;
3. Age ≥ 12 years;
4. For member with lamivudine-resistant HBV infection: lamivudine is being used in combination with adefovir;
5. Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Pegasys®, entecavir, or tenofovir *(preferred formulation is tenofovir disoproxil fumarate)*;
   **Prior authorization may be required for Pegasys and entecavir*
6. Adefovir is not prescribed concurrently with tenofovir;
7. Dose does not exceed both of the following (a and b):
   a. 10 mg per day;
   b. 1 tablet 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 (health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA and 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: HIM.PA.154 for health insurance marketplace/ICHRA and 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. For member with lamivudine-resistant HBV infection: lamivudine is being used in combination with adefovir;
4. Adefovir is not prescribed concurrently with tenofovir;
5. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 10 mg per day;
   b. 1 tablet 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 (health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

HIM.PA.103 for health insurance marketplace/ICHRA and 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: HIM.PA.154 for health insurance marketplace/ICHRA and 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 – HIM.PA.154 for health insurance marketplace/ICHRA and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALT: alanine aminotransferase
AST: aspartate aminotransferase
FDA: Food and Drug Administration
HBV: hepatitis B virus

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
Pegasys® (peginterferon alfa-2a)	180 mcg SC once weekly for 48 weeks	180 mcg/day
tenofovir disproxil fumarate (Viread®)	300 mg PO QD	300 mg/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 CrCl 30 to 49 mL/min: 10 mg PO Q48H CrCl 10 to 29 mL/min: 10 mg PO Q72H 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-feae-4c5e-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):1560-1599.
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
4Q 2022 annual review: added criterion for patients with lamivudine-resistant HBV to use adefovir in combination with lamivudine per PI; added template generic redirection language for adefovir; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	10.18.22	11.22
4Q 2023 annual review: no significant changes; clarified within criteria that preferred tenofovir formulation is tenofovir disoproxil fumarate; references reviewed and updated.	08.01.23	11.23
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.11.24	11.24
4Q 2025 annual review: removed brand Hepsera from policy as it is no longer available; added generic adefovir to policy for review; removed criteria redirecting brand Hepsera to generic adefovir; revised initial approval duration from 6 months to 12 months; references reviewed and updated.	07.11.25	11.25
4Q 2026 annual review: no significant changes; added ICHRA line of business; references reviewed and updated.	07.07.26	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.

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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.

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