Clinical Policy: Tenofovir Alafenamide Fumarate (Vemlidy)

Reference Number: CP.PMN.268
Effective Date: 12.01.21
Last Review Date: 11.25
Line of Business: HIM, Medicaid

Revision Log

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

Description

Tenofovir alafenamide fumarate (Vemlidy®) is a hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor.

FDA Approved Indication(s)

Vemlidy is indicated for the treatment of chronic HBV infection in adults and pediatric patients 6 years of age and older and weighing at least 25 kg with compensated liver 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 Vemlidy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hepatitis B Virus 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 ≥ 6 years and weight ≥ 25 kg;
4. Failure of tenofovir disoproxil fumarate or entecavir at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;^
   **Prior authorization may be required for entecavir*
   ^For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395
5. Dose does not exceed both of the following (a and b):
   a. 25 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 (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace 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: HIM.PA.103 for health insurance marketplace 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 and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Hepatitis B Virus 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. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 25 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 (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace 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: HIM.PA.103 for health insurance marketplace 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 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 and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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
tenofovir disoproxil fumarate (Viread®)	300 mg PO QD	300 mg/day
entecavir (Baraclude®)	0.5 to 1 mg PO QD	1 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): none reported
- Boxed warning(s): post treatment severe acute exacerbation of hepatitis B

Appendix D: General Information
- In April of 2017, the FDA removed Vemlidy's boxed warning regarding lactic acidosis and severe hepatomegaly with steatosis.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HBV infection	25 mg PO QD	25 mg/day

VI. Product Availability

Tablet: 25 mg

VII. References

1. Vemlidy Prescribing Information. Foster City, CA: Gilead Sciences; March 2024. Available at https://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.pdf. Accessed August 11, 2025.
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. 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 11, 2025.
4. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier; Updated periodically. Accessed August 11, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adopted from CP.PCH.33 policy to retire); added legacy Wellcare line of business (WCG.CP.PCH.33 to retire); references reviewed and updated.	08.21.21	11.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	12.10.21	02.22
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section. RT4: updated policy for pediatric extension to ≥ 12 years old.	11.04.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	07.11.23	11.23
RT4: added pediatric extension to ≥ 6 years and weight ≥ 25kg.	04.11.24	
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.10.24	11.24
Per June SDC, removed Commercial line of business. Added step therapy bypass for IL HIM per IL HB 5395.	06.10.25	08.25
4Q 2025 annual review: revised initial approval duration from 6 months to 12 months; references reviewed and updated.	08.11.25	11.25

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.