Clinical Policy: Tenofovir Alafenamide Fumarate (Vemlidy)

Reference Number: CP.CPA.253
Effective Date: 02.17
Last Review Date: 11.19
Line of Business: Commercial

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 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 HBV infection;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;
3. Age ≥ 18 years;
4. Failure of tenofovir disoproxil fumarate or entecavir at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 25 mg (1 tablet) per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 25 mg (1 tablet) per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – CP.CPA.09 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
tenofovir disoproxil fumarate (Viread®)	**HBV Infection** 300 mg PO QD	300 mg/day
entecavir (Baraclude®)	**HBV Infection** Nucleoside inhibitor treatment-naive: 0.5 mg PO QD Decompensated liver disease, history of hepatitis B viremia while receiving lamivudine or known lamivudine- or telbivudine-resistant mutations: 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; February 2019. Available at https://www.vemlidyhcp.com. Accessed July 31, 2019.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria created	01.23.17	
Converted to new template. Minor changes to verbiage and grammar. References updated.	06.14.17	11.17
4Q 2018 annual review: no significant changes; added age limit; redirection to generic tenofovir DF included; references reviewed and updated.	07.31.18	11.18
4Q 2019 annual review: added prescriber requirement to align with other HBV policies; references reviewed and updated.	08.27.19	11.19

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.