Clinical Policy: Tenofovir Alafenamide Fumarate (Vemlidy)

Reference Number: IN.CP.PMN.268
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Commercial 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 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.

I. Initial Approval Criteria

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

1. Diagnosis of chronic HBV infection;
    a. Compensated liver disease
    b. Negative HIV status
    c. Creatinine clearance > 15 mL/minute
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 clinically significant adverse effects are experienced or both are contraindicated;
   **Prior authorization may be required for entecavir*
5. Dose does not exceed 25 mg (1 tablet) per day.

Approval duration:
Medicaid – 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

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. If request is for a dose increase, new dose does not exceed 25 mg (1 tablet) per day.

Approval duration:
Medicaid– 12 months

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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III. Use: 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.

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®)	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 2021. Available at https://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.pdf. Accessed August 8, 2021.
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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/.

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
Policy revised to meet IN Medicaid State Moratorium	12.2021	01.2022