UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2285-5
Program	Prior Authorization/Medical Necessity
Medication	Vemlidy® (tenofovir alafenamide)*
P&T Approval Date	8/2022, 11/2022, 11/2023, 2/2024, 5/2024
Effective Date	8/1/2024

1. Background

Vemlidy (tenofovir alafenamide) is a hepatitis B virus (HBV) nucleoside analogue reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 6 years of age and older and weighing at least 25 kg with compensated liver disease.[1]

Entecavir (generic Baraclude) is an HBV nucleoside analogue reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus infection in adults and children at least 2 years of age with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.[2]

Tenofovir disoproxil fumarate (generic Viread) is an HBV nucleoside analogue reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B in adults and pediatric patients 2 years of age and older weighing at least 10 kg.[3]

2. Coverage Criteria[a]:

A. Treatment of Chronic Hepatitis B Infection:

1. **Initial Authorization**

a. **Vemlidy*** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic hepatitis B infection[b]

-AND-

(2) **Both** of the following:

(a) Submission of medical records documenting **one** of the following:

i. Patient has a history of adverse event or intolerance to entecavir (generic Baraclude)

-OR-

ii. Patient is not a suitable candidate for entecavir (generic Baraclude)

-AND-

(b) **One** of the following:

i. Submission of medical records documenting a history of adverse event or intolerance to tenofovir disoproxil fumarate (generic Viread)*

-OR-

ii. Submission of medical records documenting an estimated glomerular filtration rate below 90 mL/min

-OR-

iii. Submission of medical records documenting a diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-scores] with evidence of progressive bone loss on serial DEXA scan

-OR-

iv. Submission of medical records documenting a diagnosis of osteoporosis as defined by a BMD T-score ≤ -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

-OR-

v. Submission of medical records documenting a prior low-trauma or non-traumatic fracture

-OR-

vi. Patient is less than 20 years of age

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vemlidy** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Vemlidy therapy[b]

-AND-

(2) Patient is not a suitable candidate for entecavir (generic Baraclude) or tenofovir disoproxil fumarate (generic Viread).

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] Plans sitused in Nevada are not subject to clinical criteria. Only step therapy may be required.

*Vemlidy and Brand Viread are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2024.
2. Baraclude [package insert]. Princeton, NJ: Brisol-Myers Squibb Company; November 2019.
3. Viread [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2019.

Program	Prior Authorization/Medical Necessity – Vemlidy® (tenofovir alafenamide)
Change Control	
8/2022	New program
11/2022	Updated language for prior use of entecavir and generic Viread.
11/2023	Annual review with no changes to clinical coverage criteria. Updated background and references.
2/2024	Added Nevada footnote.
5/2024	Updated background with expanded indication in patients 6 to 11 years of age weighing at least 25 kg. Updated reference.