UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2285-6
Program	Prior Authorization/Medical Necessity
Medication	Vemlidy® (tenofovir alafenamide)*
P&T Approval Date	8/2022, 11/2022, 11/2023, 2/2024, 5/2024, 5/2025
Effective Date	8/1/2025

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.

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.

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.

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.
5/2025	Annual review with no changes.