UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3097-4
Program	Step Therapy
Medications	Vemlidy® (tenofovir alafenamide)
P&T Approval Date	6/2017, 10/2018, 10/2019, 10/2020
Effective Date	1/1/2021; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try entecavir or Viread® (tenofovir disoproxol fumarte) before providing coverage for Vemlidy® (tenofovir alafenamide).

Entecavir is a hepatitis B virus (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.[1]

Vemlidy is a HBV nucleoside analogue reverse transcriptase inhibitor and is indicated for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease.[2]

Viread is a HBV nucleoside analogue reverse transcriptase inhibitor and is 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-Naïve Chronic Hepatitis B Infection:

1. **Vemlidy** will be approved based on the following criterion:

   a. Patient has a contraindication to entecavir therapy

Authorization will be issued for 24 months

B. Treatment-Experienced Chronic Hepatitis B Infection:

1. **Vemlidy** will be approved based on **one** of the following criteria:

   a. Patient has a history of failure, intolerance or contraindication to entecavir therapy

-OR-

   b. **Both** of the following:

(1) Patient is currently on Viread therapy

-AND-

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

(a) Patient has a creatinine clearance less than 90 mL per minute

-OR-

(b) Patient has a diagnosis of osteoporosis

-OR-

c. Patient is currently on Vemlidy therapy

Authorization will be issued for 24 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.

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. Baraclude [package insert]. Princeton, NJ: Brisol-Myers Squibb Company; November 2019.
2. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2020.
3. Viread [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2019.

Program	Step Therapy – Vemlidy (tenofovir alafenamide)
Change Control	
6/2017	New step therapy program that requires the use of entecavir or Viread before benefit coverage of Vemlidy.
10/2018	Annual review with update to references.
10/2019	Annual review with no changes to coverage criteria. Updated references.
10/2020	Annual review. Modified renal function threshold to less than 90 mL/min for Vemlidy coverage. Updated references