

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3097-2
Program	Step Therapy
Medications	Vemlidy® (tenofovir alafenamide)
P&T Approval Date	6/2017, 10/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

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 disoproxil fumarate) 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 12 years of age and older.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 60 mL per minute

(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:
Supply limits may be in place.

4. References:

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2018.
2. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2017.
3. Viread [package insert]. Foster City, CA: Gilead Sciences, Inc.; July 2018.

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.