

Clinical Pharmacy Program Guidelines for Vemlidy

Program	Step Therapy
Medication	Vemlidy (tenofovir alafenamide)
Markets in Scope	Arizona, California, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2017
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

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 2 years of age and older weighing at least 10 kg.³

Vemlidy has a black box warning for hepatitis B exacerbation. Please see full prescribing information for additional details.

2. Coverage Criteria:

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 12 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

- OR-

(b) Patient has a diagnosis of osteoporosis

-OR-

- c. Patient is currently on Vemlidy therapy

Authorization will be issued for 12 months.

3. 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	
Date	Change
6/2017	New step therapy program that requires the use of entecavir or Viread before benefit coverage of Vemlidy.
10/2018	Annual review. Updated references.
10/2019	Annual review. Updated background and references.
10/2020	Annual review. Updated references