MEDICATION POLICY:

Vemlidy®

Generic Name: Tenofovir Alafenamide

Therapeutic Class or Brand Name: Vemlidy®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 1235208320

Preferred: Entecavir (generic), Tenofovir Disoproxil Fumarate (generic)

Non-preferred: Vemlidy®

Date of Origin: 7/31/2018

Date Last Reviewed / Revised: 8/19/2019

Prior Authorization Criteria

(May be considered medically necessary when criteria I through III are met)

I. Patient is 18 years of age or older and ONE of the following criteria (A - D) is met:

   A. Patient has documented diagnosis of chronic hepatitis B virus infection and has compensated liver disease

   B. Patient is post-liver transplantation with an anti-HBc-positive graft while patient was HBsAg-negative prior to transplant (Note: anti-HBc = antibody to hepatitis B core antigen; HBsAg = hepatitis B surface antigen)

   C. Patient is post-liver transplantation and had documented chronic hepatitis B infection prior to transplant

   D. Patient with prior history of hepatitis B infection who is undergoing immunosuppression related to solid organ transplantation

II. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

III. Patient cannot take entecavir or tenofovir disoproxil fumarate due to prior treatment failure, adverse effects, or contraindications

Exclusion Criteria

- N/A

Other Criteria

- Patient must have a recent documented negative test for HIV-1 infection, unless Vemlidy is being prescribed in combination with other antivirals as part of an HIV-1 co-infection treatment regimen

Quantity / Days Supply Restrictions

- 30 tablets or 630mls per 30 days.

Approval Length

- **Authorization:** 1 year.

- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

REFERENCES

1. https://www.gilead.com/~/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.pdf?la=en .
2. https://aasldpubs.onlinelibrary.wiley.com/doi/10.1002/hep.29800 .
3. Medi-Span®.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
8/19/2019	1. Policy reviewed – no changes.
7/31/2018	1. Policy created.