

SUPPLEMENTAL SPECIALTY PA

VEMLIDY (tenofovir alafenamide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Chronic hepatitis B virus infection

Authorization of 6 months may be granted for treatment of chronic hepatitis B virus (HBV) when all of the following criteria are met:

- A. Member is HIV-1 negative
- B. Member has compensated liver disease as evidenced by:
 - 1. No evidence of ascites, hepatic encephalopathy, or variceal bleeding
 - 2. INR < 1.5x ULN
 - 3. Total bilirubin < 2.5x ULN
 - 4. Albumin > 3.0 g/dL

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for chronic HBV who achieve or maintain positive clinical response (e.g., decreased HBV DNA level, ALT normalization, HBsAg and/or HBeAg loss and seroconversion) and are HIV-1 negative.

IV. REFERENCES

1. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; February 2019.