

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Vemlidy® (tenofovir alafenamide fumarate (TAF))

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code: _____

Weight: _____ Date: _____

CLINICAL CRITERIA: Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

Complete SECTION I and SECTION II for Initial Authorization

SECTION I. DIAGNOSIS CRITERIA

- Prescribed by or in consultation with a specialist in gastroenterology, hepatology, infectious disease, or knowledgeable in treating patients with Hepatitis B and disease monitoring

(Continued on next page)

- Member has a diagnosis of Chronic Hepatitis B confirmed by **ALL** the following (**applicable laboratory documentation and results from a Hepatitis B panel must be submitted**):
 - HBsAg positive or negative for at least 6 months
 - There is documented evidence of active viral replication (HBeAg+ and HBV DNA > 100,000 copies/mL)
 - There is documented evidence of active liver disease as demonstrated by persistent elevation in serum alanine aminotransferase (ALT) (greater than 2 times upper limit of normal) or moderate to severe hepatitis on biopsy
- Current levels of alanine aminotransferase (ALT) and Hepatitis B DNA have been measured and meet **ONE** of the following (**must submit lab results**):
 - For serological status of HBeAg-positive, the alanine aminotransferase (ALT) level is found to be 2 or more times greater than the upper limit of normal, and levels of Hepatitis B DNA are greater than 20,000 IU/mL
 - For serological status of HBeAg-negative, the alanine aminotransferase (ALT) level is found to be 2 or more times greater than the upper limit of normal, and levels of Hepatitis B DNA are greater than 2,000 IU/mL
- Clinical markers are outside of those listed above, but at least **ONE** patient variable exists to recommend treatment (**chart notes must be submitted to confirm patient variables**):
 - Age: older age (>40 years) is associated with a higher likelihood of significant histological disease
 - Family history of cirrhosis or HCC
 - Previous treatment history
 - Serological and virological benefits of peg-IFN occur after treatment discontinuation (delayed)
 - Past nucleoside/nucleotide analogue exposure is a risk for drug resistance
 - Presence of extrahepatic manifestations: indication for treatment independent of liver disease severity
 - Presence of cirrhosis
- FOR A DIAGNOSIS OF HUMAN IMMUNODEFICIENCY VIRUS:**

Please provide clinical rationale, medical necessity, and pertinent past medical history as to why Vemlidy[®] be used as a single agent in antiretroviral therapy, and not as part of an existing combination product (i.e., Descovy[®], Biktarvy[®], Genvoya[®], Odefsey[®], Symtuza[®]):

SECTION II. DRUG CRITERIA

- Member is 6 years of age or older and weighs at least 25 kg
- Member has compensated liver disease (**NOTE: laboratory documentation/liver function test results required to confirm that there is no evidence of ascites, hepatic encephalopathy, variceal bleeding, INR <1.5 × ULN, total bilirubin <2.5 × ULN, and albumin >3.0 g/dL**)

- Member has an estimated creatinine clearance ≥ 15 mL/minute
- Treatment with entecavir or tenofovir disoproxil (generic Viread[®]) was ineffective, not tolerated, or is not recommended due to **ONE** of the following:
 - For risk of renal or bone disease: attach documentation presenting precluding patient variables, and documentation of an unsuccessful trial with entecavir
 - The possibility of indefinite therapy recommends the use of Vemlidy[®] (**Provide clinical rationale and/or medical necessity**):

Reauthorization: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Provider please note: a one-time reauthorization is required after initial 12-month approval

- For Chronic Hepatitis B, discontinuation is not appropriate at this time due to **ONE** of the following:
 - Disease state/phase requires ongoing treatment (**attach most recently monitored levels of HBV DNA, ALT, HBeAg status, anti-HBe status**)
 - Seroconversion on nucleoside analog therapy has not yet occurred (**attach most recently monitored levels of HBV DNA, ALT, HBeAg status, anti-HBe status**)

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Please provide clinical rationale, medical necessity, and pertinent past medical history as to why Vemlidy[®] be used as a single agent in antiretroviral therapy, and not as part of an existing combination product (i.e., Descovy[®], Biktarvy[®], Genvoya[®], Odefsey[®], Symtuza[®]):

Medication being provided by Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****
****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****