SENTARA HEALTH PLANS

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 1-800-750-9692**. 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 Sentara #: _____ **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

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- ❑ Member has a diagnosis of Chronic Hepatitis B confirmed by **ALL** of 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 20,000IU/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 2,000IU/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®):

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SECTION II. DRUG CRITERIA

- ❑ Member is 12 years of age or older
- ❑ 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)**

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- ❑ 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)**:

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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)**
- ❑ **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®):

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Medication being provided by Specialty Pharmacy - PropriumRx

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.*

***Approved by Pharmacy and Therapeutics Committee:-~~9/10/2021;~~ 3/16/2023**
REVISED/UPDATED: ~~12/9/2021;~~ ~~12/21/2021;~~~~04/07/2023;~~ **10/26/2023**