JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS099
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	Subject **Vemlidy**	*Revision Date*	07/21/2021
		Page	1 of 2

This document applies to the following Participating Organizations:

Priority Partners

Keywords: vemlidy

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
	A. Vemlidy	**1**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**1**
IV.	**EXCLUSIONS**	**2**
V.	**REFERENCES**	**2**
VI.	**APPROVALS**	**2**

I. POLICY

A. Vemlidy (tenofovir alafenamide) will require prior authorization to ensure appropriate use. It will require prior authorization for outpatient prescription drug benefit coverage to ensure this medication is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Vemlidy** may be approved for patients meeting all the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing the following:
      a. Diagnosis of chronic hepatitis B virus infection
      b. Patient has compensated liver disease, supported by all the following:
         I. No evidence of ascites, hepatic encephalopathy, or variceal bleeding
         II. INR <1.5x ULN
         III. Total bilirubin <2.5x ULN
         IV. Albumin >3.0 mg/dL
      c. Baseline serum creatinine, estimated creatinine clearance, urine glucose, and urine protein have been assessed
         I. *In addition to these measures, serum phosphorus is required for patients with chronic kidney disease (CKD)
      d. Baseline testing showing that the patient is negative for HIV-1 infection
      e. Requested quantity is not greater than the FDA recommended dose of 1 tablet per day
      f. Prescriber is, or has consulted with, a gastroenterologist, infectious disease specialist, or hepatologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 12 months of therapy.

B. Approval for continuation of therapy can be extended in 12-month intervals with clinical documentation showing beneficial patient response, as well as all the following:
   1. Patient has been retested for HIV-1 infection and remains negative
   2. Patient does not have evidence of ascites, hepatic encephalopathy, or variceal bleeding
   3. Documentation showing on-treatment monitoring of serum creatinine, estimated creatinine clearance, urine glucose, and urine protein (*also serum phosphorus, if patient has CKD)

IV. EXCLUSIONS

A. Vemlidy will **NOT** be approved for the following:
   1. Patients with any of the following:
      a. Co-infection with HBV and HIV-1
      b. End stage renal disease (estimated creatinine clearance below 15 mL per minute) and not being treated with hemodialysis
      c. Decompensated hepatic impairment (Child-Pugh Class B or C)
   2. Any other use that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Vemlidy: Prescribing Information. Foster City, CA: Gilead Sciences, Inc. March 2021

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
01/19/2017	New policy developed per P&T recommendation
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
07/21/2021	Clarified clinical criteria and reauthorization requirements

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