

Tenofovir alafenamide fumarate (Vemlidy®)**Criteria for Use****March 2017**

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES. The Product Information should be consulted for detailed prescribing information. See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or <http://vawww.pbm.va.gov> for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive tenofovir alafenamide fumarate.*

Patient prescribed combination product containing tenofovir disoproxil fumarate or tenofovir alafenamide fumarate for HBV and/or HIV infection

Inclusion Criteria *The answers to one of the following must be fulfilled in order to meet criteria.*

One of the following:

Patient with calculated CrCl or eGFR of 15-59 mL/min or has end stage renal disease (ESRD) and is receiving dialysis*

OR

Patient prescribed concomitant nephrotoxic medications (*eg: ACE-inhibitors, calcineurin inhibitors, certain chemotherapy agents, diuretics, etc.*)

OR

Patient at risk of fracture or with evidence of bone mineral destruction (*including, but not limited to: active treatment for osteoporosis or osteopenia, history of stress fracture, oral glucocorticoid use within past 3 months at a prednisolone dose \geq 7.5 mg daily, currently smoking, etc.*)

Dosage and Administration

One 25 mg tablet orally once daily taken with food

Issues for Consideration

*No dose adjustment is needed for patients with a CrCl 15-59 mL/min OR CrCl <15mL/min AND receiving hemodialysis. Not recommended in patients with ESRD (CrCl < 15 mL/min who are NOT receiving dialysis)

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Prepared: December 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, VA Pharmacy Benefits Management Services