Cabotegravir (CAB) APRETUDE for HIV Pre-exposure Prophylaxis (HIV PrEP) Criteria for Use: June 2022

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 USE 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.

Inclusion Criteria

All of the following criteria must be satisfied for a patient to be a candidate for PrEP with CAB (CABOTEGRAVIR)

☐ Cabotegravir Prescribed by, or in collaboration with, a provider with experience or training in the administration of PrEP (designated facility providers)

☐ Substantial risk of HIV acquisition (sex without condoms, recent or frequent sexually transmitted infections – STI, Sexual relationship with HIV infected partner, injection drug abuse with equipment sharing)

One of the following ADDITIONAL criteria must be satisfied for use of Cabotegravir (CAB):

☐ Intolerance to Truvada or Descovy

☐ CrCl of <60 mL/min or multiple risk factors for significant renal dysfunction

☐ Patient specific factors impacting adherence to daily oral PrEP (e.g., cognitive difficulties, gastrointestinal dysfunction, unstable housing, stigma, or fear of discovery)

☐ Patient at very high-risk for HIV acquisition (e.g. MSM who engage in frequent episodes of condom-less receptive anal intercourse, have repeated episodes of STIs, or high-risk sexual activity with partners who are known or likely to be HIV infected)*

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive Cabotegravir for PrEP

☐ Significant noncompliance with follow-up appointments unless barriers to compliance have been significantly addressed by provider

☐ Drug interactions that preclude administration of CAB (UGT1A1 inducers, Carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifamycin derivatives, St. John's Wort)

Supplemental Information

*The threshold for initiating PrEP in patients should be low. FTC/TDF is the workhorse medication for HIV PrEP, but choice of treatment should be done with shared decision-making between the patient and provider. CAB can provide greater benefit than FTC/TDF in those at the highest risk of acquiring HIV. Things to consider include local incidence of HIV, frequency of episodes of at-risk behaviors and frequent sexually transmitted infections. The CDC/USPSTF Providers supplement to the HIV PrEP clinical guidelines also provide scoring systems that can engage in risk-level assessment.

- Dosing: 600mg IM monthly for 2 months, then every 2 months
- Cabotegravir should be administered in the gluteal muscle as absorption from other sites can be unpredictable
- HIV must be excluded prior to administration of CAB
    - *See Clinical recommendations for additional information on monitoring*

References:

1. Cabotegravir (APRETUDE) National Drug Monograph. National Pharmacy Benefits Management: Department of Veterans Affairs; 2022.
2. APRETUDE, Cabotegravir injection. AMCP Dossier. 2022
3. Centers for Disease Control and Prevention: US Public Health Service: *Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update*: *clinical providers' supplement*. Centers for Disease Control; December 2021.
4. Landovitz RJ, Donnell D, Clement ME, et al. Cabotegravir for HIV prevention in cisgender men and transgender women. *N Engl J Med* 2021;385:595-608.
5. Landovitz R, Li S, Brinsztejn B, et al. Safety, tolerability and pharmacokinetics of long-acting injectable cabotegravir in low risk HIV uninfected individuals. HPTN 077, a Phase 2a randomized, controlled trials. *PlosMedicine* 2018. https://doi.org/10.1371/ournal.pmed.1002690 18 November 2018.
6. Markowitz M, Frank I, Grant R, et al. Safety and tolerability of long-acting cabotegravir injections in HIV-uninfected men (ÉCLAIR): a multicentre, randomised, placebo-controlled, phase 2a trial. *Lancet HIV* 2017;4:e331-40. http://dx.doi.org/10.1016/S2357-3018(17)30068-1 .
7. Mayer K, Molina JM, Thompson M, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. *Lancet* 2020;396:239-54.

Prepared: June 2022. Contact: Kelly.echevarria@va.gov , National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P. Reviewed by Dr. Matthew Goetz, Dr. David Ross, Dr. Marissa Maier, Dr. Pam Belperio and VHA HIV TAG