Cabotegravir/Rilpivirine (CAB/RPV) CABENUVA
Criteria for Use
June 2021

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.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive CAB/RPV.

- ☐ Known hypersensitivity to any component of the treatment regimen
- ☐ Coadministration with strong UGT1A1 and/or CYP3A4 inducers (e.g. rifamycins, dexamethasone, anticonvulsants that induce UGT/CYP)
- ☐ Baseline resistance mutations to either CAB or RPV
- ☐ History of significant INSTI or NNRTI resistance associated mutations (with the exception of K103N)
- ☐ Prior virologic failure to any previous antiretroviral regimen (defined as HIV-1 RNA >400 copies per mL after initial viral suppression)*
- ☐ Pregnant or planning to become pregnant
- ☐ Active hepatitis B virus (HBV) infection not on active HBV therapy
- ☐ Unable to discontinue use of PPI therapy while on **ORAL** RPV induction/bridge therapy

Inclusion Criteria

The answers to all of the following must be fulfilled in order to meet criteria.

- ☐ Virologically controlled (HIV-1 RNA<50 copies/mL) on a stable oral standard antiretroviral regimen for ≥ 6 months with two or more HIV-1 RNA labs<50 copies/mL in the past 12 months (one in the previous 6-12-months, and one 0-6 months)
- ☐ A specific indication for CAB/RPV injection exists, SUCH AS difficulty managing oral medication (e.g., cognitive deficits, homelessness), concern for oral absorption of antiretrovirals, or concern for severe stigma with discovery of oral medications
- ☐ Documented history of adherence to HIV-related clinic appointments for the past year
- ☐ Provider documents that the patient agrees to reliably show up for clinic injections and understands that failure to do so will impact clinic schedules and MAY result in changing back to an oral regimen

Supplemental Information

**A change in a prior antiretroviral regimen due to adverse events, safety concerns, ease or convenience is NOT considered evidence of virologic failure, as long as patients remained suppressed through the change.*

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