BRITISH COLUMBIA
CENTRE *for* EXCELLENCE
in HIV/AIDS

St. Paul's Hospital
608-1081 Burrard Street
Vancouver, BC
Canada V6Z 1Y6

Tel 604.806.8477
Fax 604.806.8464
www.bccfe.ca

22 September 2023 *(with updated recommendations May 2024)*

RE: Cabotegravir and Rilpivirine extended-release injectable suspensions

Cabotegravir and rilpivirine extended-release injectable suspensions (Cabenuva®) are available through the BC-CfE Drug Treatment Program (DTP) on a case-by-case basis, as an alternative, complete regimen for the treatment of HIV-1 infection in individuals who are at least 12 years of age and >35 kg, and are virologically stable and suppressed (HIV-1 RNA <40 copies/mL) on standard oral antiretroviral therapy, and who meet clinical eligibility criteria based on studies of efficacy and/or safety.

Clinical eligibility includes all of the following:

- ≥12 years of age and weighing ≥35 kg
- HIV plasma viral load suppressed (<40 copies/mL) ideally ≥6 months on stable oral antiretroviral therapy
- Confirmed HIV-1 (not subtype A1/A6)
- No evidence of HIV resistance to integrase inhibitors or NNRTIs (with the exception of isolated K103 substitution)
- Caution if BMI >30 kg/m^2
- Does not require treatment for hepatitis B (HBsAg negative)
- No contraindications to intramuscular injections (e.g. needle phobia, bleeding disorder, anticoagulant therapy)
- No previous allergy or intolerance to rilpivirine or cabotegravir
- Not taking any contraindicated medications (e.g. carbamazepine, phenytoin, rifampin, rifabutin, systemic dexamethasone)
- Not pregnant, breast-feeding, or planning pregnancy
- Client willing and able to attend regular clinic appointments (every 4 or 8 weeks +/- 7 days) for injections

Requesting prescribers must be experienced in the management of persons living with HIV, and have the capacity and ability to provide the required logistical support, clinical care and follow-up to support the treatment.

Providence Health Care
How you want to be treated.

Logistical support includes:

- Secure medication fridge in clinic that maintains internal temperature 2-8 °C.
- Clinic has support to coordinate client injection appointments, schedule medication delivery, and promptly handle refrigerated medication deliveries upon receipt.
- Clinic has private area to provide gluteal IM injections.
- Ability to support product administration by healthcare provider every 4 or 8 weeks (i.e. 2 large volume gluteal IM injections per dose via Z-track method, within product stability parameters).
- Support for contingency planning of injections and/or oral bridging for travel, transitions in care, late injections, missed appointments, etc.

Prior to submitting a request, careful consideration should be made to ensure the client understands and is able to adhere to the injection dosing schedule requirements. They should be aware that late or missed injections, or unplanned treatment discontinuation may result in a prolonged period of low drug concentrations in the body, and a potential risk of viral rebound, development of resistance to integrase inhibitor and/or NNRTI medications, and possible loss of future treatment options.

The product is not recommended, nor is Health Canada approved, as an alternative treatment amongst individuals with detectable plasma viral load while on oral HIV treatment and/or who have adherence challenges.

Requests for the product can be made by submitting a BC-CfE Drug Treatment Program HIV/AIDS Drug Request Prescription Form and Cabenuva® Request Form with accompanying documentation supporting the request, including the reason(s) why the client is unable to take a preferred oral antiretroviral regimen available in BC. Each request will be subject to a case-by-case clinical review.

Updated Recommendations (May 2024)

As of May 2024, evidence is accumulating on the use of CAB-RPV LA injections in PLWH with viremia. However, much of the evidence is preliminary and is limited to observational cohort data including <300 PLWH. In addition, data are very limited (N ~30) regarding the efficacy of this two-drug regimen in PLWH with high viral loads (>100,000 copies/mL).

The CDET therefore has revised its recommendation as follows:

When supported by intensive follow-up and case management services, injectable CAB-RPV without prior oral lead-in may be considered for PLWH with persistently detectable viral load who meet the following criteria (Grade C)

- Unable to take oral ART consistently despite extensive efforts and clinical support
- High risk of HIV disease progression (CD4 cell count <200/µL or history of AIDS)

Other BC-CfE eligibility criteria for CAB-RPV LA still apply, including:

- ≥12 years of age and weighing >35 kg
- not HIV subtype A1/A6
- no resistance to integrase inhibitors or NNRTIs (with the exception of K103 substitution)
- not pregnant or planning pregnancy
- no relevant drug interactions
- caution if BMI >30 kg/m2