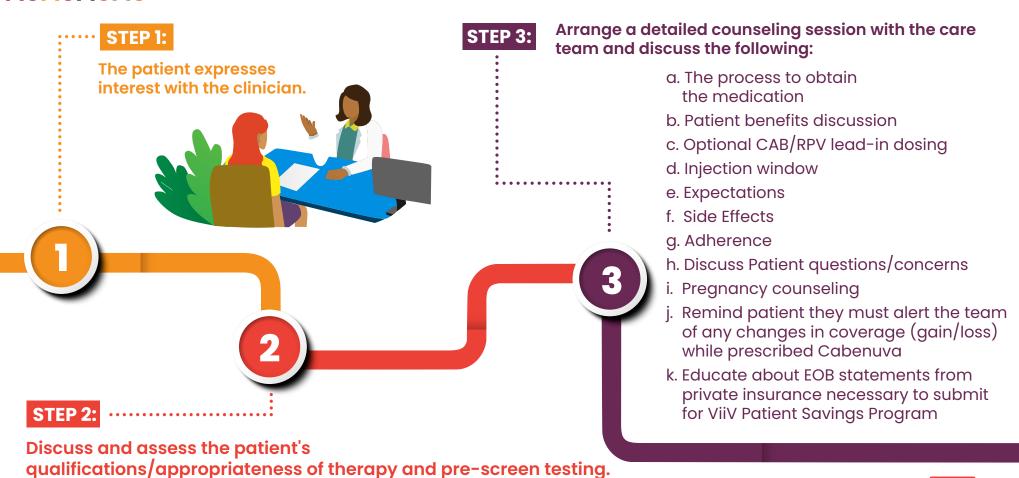


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- a. Amenable to 2 gluteal injections at monthly or every 2 month appointments
- b. Has a suppressed VL (VL < 50 copies/mL) for at least 3 months
- c. Lacks drug resistance mutations to cabotegravir/rilpivirine
- d. Lacks any drug interactions w/ cabotegravir/rilpivirine (eg. PPIs with oral rilpivirine)

- e. Lacks any contraindications to therapy
- f. Lacks HBV coinfection or willing to start alternative hepatitis B treatment
 - i. Must screen for HBV before starting
 - ii. Risk of HBV immune reconstitution inflammatory syndrome or HBV reactivation •
- g. Is not pregnant



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CTED A

Enroll the patient in ViiVConnect.

- a. Assign team member to keep track of PA expiration/benefit approval dates
- b. Coordinate with the specialty pharmacy (SP) or specialty distributor (SD), according to each patient's insurance requirements





STEP 5:

Order the <u>optional</u> oral lead-in medication to be delivered to the patient (Oral)

- a. Oral lead-in of CAB 30 mg plus
 RPV 25 mg once daily with food for at least 28 days
- b. Order by contacting TheraCom via phone (844-276-6299), fax (833-904-1881), or ePrescribe



STEP 6:

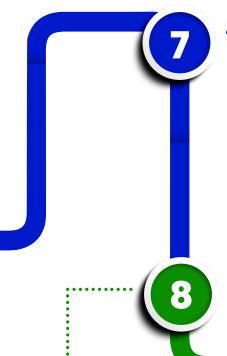
Order the injectable medication to be delivered to the clinic (LAA)

- a. Schedule/confirm 1st injection visit on receipt of medication
 - 1. Schedule first IM injection visit (day 28-30 of optional oral lead-in phase) for at least 60 minutes
- b. Clinic Storage:
 - i. Store medication in refrigerator
 - ii. Document on Cabotegravir/rilpivirine storage log:
 - 1. Date/time received
 - 2. Person accepting
 - 3. Patient name
- 4. Date/time dispensed ····
- 5. Person dispensing





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STEP 7: First Injection Visit (60 min)

- a. Loading dose is CAB 600 mg (3 mL) and RPV 900 mg (3 mL) (day 28-30 of optional oral lead-in)
 - i. Given as two separate injections in separate ventrogluteal sites
- b. RN to take medication out of the fridge when the patient arrives and allow 15 minutes to come to room temperature.
- c. Unopened kit should be labeled with time it was removed from fridge
 - i. The vials may remain in the carton at room temperature for up to 6 hours.

- ii. Medication must be discarded if not used within 6 hours
- d. Administer CAB and RPV at separate gluteal injection sites (on opposite sides or 2 cm apart)
 - i. Use of longer 2-inch needle for BMI ≥30 kg/m2 recommended
- e. Allow 10 to 15 minutes to monitor for adverse effects post-injection
- f. RN to chart against order that Cabenuva dose was given and then document visit
- g. Schedule second injection one month later (+/- 7 day window) from 1st injection

STEP 8:

Second Injection Visit (30min)

- a. Dosing:
 - i. Continuation therapy with monthly CAB 400 mg (2 mL) and RPV 600 mg (2 mL); or
 - ii. Every-2-Month Dosing CAB 600 mg (3 mL) and RPV 900 mg (3 mL)
 - 1. Given as two separate ventrogluteal IM injections
- b. RN to remove medication from refrigerator when the patient arrives and allow 15 minutes to come to room temperature.
- c. Unopened kit should be labeled with time it was removed from fridge
 - i. The vials may remain in the carton at room temperature for up to 6 hours.
 - ii. Medication must be discarded if not used within 6 hours
- d. Schedule follow up in one month for 400/600 mg dosing or 2 months for 600/900 mg dosing





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.. STEP 9: If patient misses appointment for injection (planned):

- a. Patient should begin oral medications at the time the missed injection would be due +/- 7 days
 - i. Patient may receive any fully suppressive oral antiretroviral regimen, or
 - ii. Oral CAB 30 mg plus RPV 25 mg used once daily with food
 - Patient to receive oral medications from Theracomm (or local pharmacy) for up to 2 months
 - 2. ViiV supplies cabotegravir (PO) through TheraCom Pharmacy and
 - 3. Rilpivirine (PO) Rx and copay card (if eligible) must be sent to local pharmacy
- c. Care team must schedule next injection as soon as possible
 - i. If ≤ 1 month since missed target treatment date can continue with monthly maintenance dose (400 mg / 600 mg kit) or Every-2-Month Dosing CAB 600 mg (3 mL) and RPV 900 mg (3 mL) on final day of oral therapy
 - ii. If > 1 month since since missed target treatment date, loading ······ dose (600 mg / 900 mg kit) must be given on final day of oral therapy



STEP 10: If patient misses appointment for injection (unplanned):

- a. Contact patient x 3 and attempt to schedule within one week of missed appt
- b. If unable to schedule within a week period (dependent upon clinical factors), assess patient plan for continuation
 - i. Refill of previous oral therapy sent to patient's preferred pharmacy; <u>or</u>
 - ii. Patient to receive oral medications from TheraComm for up to 2 months
 - iii. Care team must schedule next injection as soon as possible
 - 1. If ≤ 1 month since missed target treatment date can continue with monthly maintenance dose (400 mg / 600 mg kit) or Every-2-Month Dosing CAB 600 mg (3 mL) and RPV 900 mg (3 mL) on final day of oral therapy
 - 2. If > 1 months since missed target treatment date, loading dose (600 mg / 900 mg kit) must be given on final day of oral therapy

STEP 11: Injection Discontinuation

- a. Residual concentrations of CAB/RPV (aka "the tail") may remain in systemic circulation for up to 12 months
- b. Alternative ART needed to preventdrug resistance