Virginia Ryan White HIV/AIDS Part B (RWHAP B)

STANDARD OPERATING PROCEDURE

Accessing the Long Acting Injectable Antiretroviral (LARV) Cabenuva for Direct VA MAP Clients

Effective Date: August 24, 2021

Revised Date: Not Applicable

General Medication Information to Consider Before Ordering

1. The provider must determine if a client is clinically eligible to receive Cabenuva.
2. The provider should ensure that clients who are interested in the Cabenuva treatment regimen agree to the required monthly dosing schedule and counsel them on the importance of adherence to scheduled dosing visits.
3. The provider must perform a health history specific to the administration of Cabenuva.

Ordering Cabenuva for Direct VA MAP Clients

1. The prescriber must complete a Viiv Connect Long Form for each client. This will serve as the first prescriber communication to VA MAP for purposes of this procedure.
    a. Visit the VIIV Connect website to access the form: www.viivconnect.com/injectable/enrollment/ or
    b. Click here to go directly to the Long Form: CABENUVA (cabotegravir; rilpivirine) Enrollment Form (viivconnect.com)
    c. A ViiV Access Coordinator is available at 1-844-588-3288 Monday through Friday, 8:00 am to 11:00 pm for assistance.
2. The prescriber must submit the completed Viiv Connect Long Form to Viiv Connect and the Virginia Department of Health's Division of Pharmacy Services (DPS). *Virginia's Board of Pharmacy allows the completed long form to serve as the legal prescription for the client.*
    a. **The prescriber should check the boxes for both the initiation dose and the continuation dose with refills on the form.**
    b. Fax the form to DPS at 804-371-0236.
3. Once the manufacturer receives the Viiv Connect Long Form, it will ship the oral lead-in medication to the Prescriber's Office, Patient's home address or other, designated in section 4 of the form by Viiv specialty drug distributor TheraCom.

Dosing and Administration

1. The client will begin with the initial oral lead-in, i.e., daily dose of one 30mg tablet of Vocabria (cabotegravir) and one 25mg tablet of Edurant (rilpivirine), for a 30-day period.
2. If client is tolerating the oral regimen, the prescriber should complete and fax a Cabotegravir/ Rilpivirine Order Form for the initiation injection to DPS 14 days after beginning oral regimen.
3. If client is tolerating the initiation injection of Cabenuva and wants to continue therapy, the prescriber should complete and fax a Cabotegravir/ Rilpivirine Order Form for the continuation

injections to DPS 14 days after the initial injection. If the prescriber did not originally order the continuation injection on Viiv Enrollment Form, the prescriber will need to fax or electronically submit a prescription to DPS.

4. If client wants to continue with the monthly maintenance regimen of Cabenuva, a new Cabotegravir/ Rilpivirine Order Form must be completed and faxed to DPS 14 days after each injection. If there are no refills remaining on the current order, fax or electronically submit a prescription to DPS.
5. Clinician's may give Cabenuva up to seven days before or after the date of the patient's scheduled monthly injections.
6. In the event the client misses their monthly injection date, the provider will observe the missed dose Cabenuva injection protocol in the next section.
7. If client requires oral rilpivirine for missed injection therapy, the prescriber should fax a Cabotegravir/ Rilpivirine Order Form to DPS and contact Viiv Access Coordinator to initiate shipment of Vocabria to patient at no additional fee. The prescriber will need to fax or electronically submit a prescription to DPS.
8. The practitioner will utilize the Administration Logs to capture data for client medication administration, and keep it in the client chart or upload into electronic records. Use the links below to access the administration logs.
   Administration Log Rilpivirine
   Administration Log Cabotegravir

Missed Injections

The manufacturer strongly recommends adhering to the monthly injection-dosing schedule. Patients who miss injection visits will need clinical reassessment to ensure resumption of therapy remains appropriate.

1. **Planned Missed Injections:** If a patient plans to miss a scheduled injection visit by more than seven days, the provider must communicate the patient's planned missed injection with DPS and Viiv Access Coordinator, so DPS can facilitate the shipment of rilpivirine and Vocabria through Viiv's distributor, TheraCom. The patient can take daily oral therapy to replace up to two consecutive monthly injection visits. Patients should take the first dose of oral therapy approximately one month after the last injection dose of Cabenuva and continue it until the day injection dosing restarts.
2. **Unplanned Missed Injections:** If a patient misses a monthly injection or experiences a delay of more than seven days and has not taken oral therapy in the interim, clinically reassess the patient to determine if resumption of injection dosing remains appropriate.

Injection Dosing Recommendations after Missed Injections

1. **< 2 months since last injection:** Resume with Cabenuva continuation dose of cabotegravir 400mg/rilpivirine 600mg IM monthly injections as soon as possible.
2. **>2 months since last injection:** Reinitiate with Cabenuva initiation dose of cabotegravir 600mg/rilpivirine 900mg IM then continue to follow the cabotegravir 400mg/rilpivirine 600mg IM monthly dosing schedule.

Use this link to view **Contraindications and Side effects**

Eligibility Requirements for Provider/Administration Site

1. Providers must be able to meet cold chain storage requirements with the ability to store medication refrigerated at 2℃ - 8℃ (36℉ - 46℉) **AND** have a procedure for receiving and storing cold chain medications in a timely manner.
2. Administration sites must have a current Controlled Substance Registration (CSR) on file with DPS or have a pharmacy that can receive and store this medication.
3. Providers must have an adequate environment and supplies for injection administration including:
    a. A private room for administration, preferably with an exam table allowing clients to lie down for injection.
    b. Licensed staff properly trained in Z-track injection administration in gluteal muscles (ventro-gluteal recommended).
    c. An emergency supply kit in case of anaphylaxis reaction including epinephrine.
    d. Adequate qualified staff to accommodate increase in appointments, as per treatment regimen.

Medication Shipment, Handling and Storage

Before shipping, DPS must verify that the administration site has a current Controlled Substance Registration (CSR) on file with DPS or that it has a pharmacy that can receive and store this medication. Prescribers can follow this link to Controlled Substance Registration (CSR) Application.

1. Injection medication must be stored in the refrigerator at 2℃ - 8℃ (36℉ - 46℉). Do not freeze this medication.
2. Medication must be at room temperature prior to administration.
3. Drug components may remain in the syringe up to two hours.
4. If client does not receive an injection, the administration site should return the product to the pharmacy under cold chain (include the medication's declared value), shipping only on Monday, Tuesday or Wednesday. The injection will then be returned to stock for dispensing.

Virginia Department of Health Pharmacy Services (DPS)
101 N 14th Street
Richmond, VA 23219
Tele (804) 786-4326
Fax (804) 371-0236

If there is a problem with medication shipment

- If the administration site receives a damaged product in its shipment, it should contact DPS for instructions on how to return it. Site will need to provide documentation of damage including a photo.

Failure to finish the lead-in

- If client does not finish the oral lead-in regimen for any reason, it is the prescriber's clinical responsibility to prescribe the patient an alternate antiretroviral regimen to prevent gaps in medical care.

HRSA Performance Measure: None

Guidance:

Ryan White HIV/AIDS Program (RWHAP) ADAPs play a key role in providing access to medications for people with HIV and in meeting the goals of the Ending the HIV Epidemic: A Plan for America. HRSA recommends RWHAP ADAPs consider adding long-acting ARVs to their formularies once these medications are available.

Exceptions: None

If you are interested in the clinical trial results, please go to https://cabenuvahcp.com/clinical-trials/

References:

www.viivconnect.com/injectable/enrollment/

www.cabenuva.com

Cabenuva drug insert

https://clinicalinfo.hiv.gov/en/drugs/cabotegravir-rilpivirine/kit#nlm34068-7

HRSA's Long-acting Antiretroviral (ARV) Medication Guidance and Ryan White HIV/AIDS Program, December 4, 20019 at https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters