

# Implementing Cabotegravir/Rilpivirine (Cabenuva)

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# Disclosures

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No conflicts of interest or relationship to disclose.

# Disclaimer

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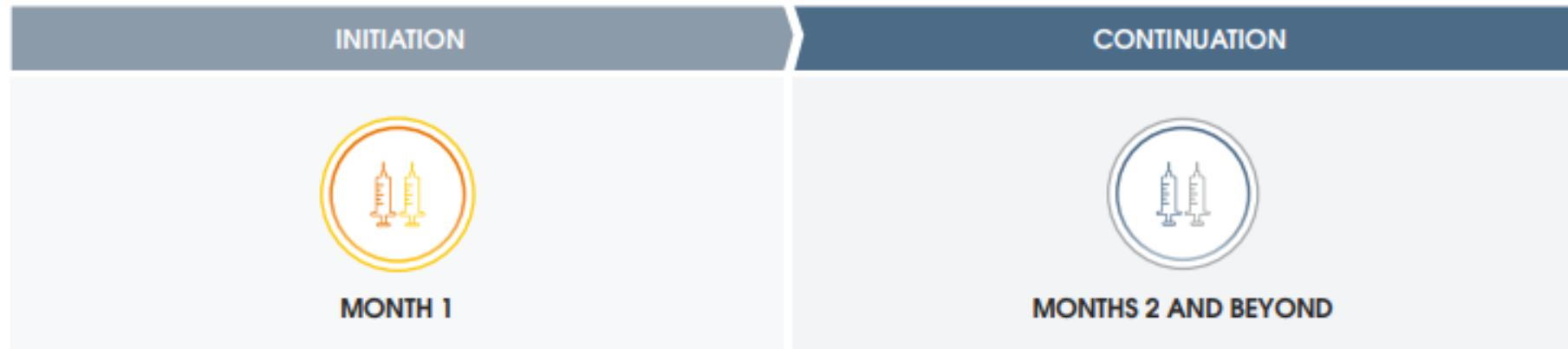
# Cabotegravir/rilpivirine Long-Acting Injections

- Long-acting injectable (LAI) regimen
- Combination of integrase inhibitor (cabotegravir) and NNRTI (rilpivirine)
- Indicated for the treatment for HIV-1 infection
  - For 12 years old and older (at least 35 kg)
  - To replace current ART regimen
  - Must be virologically suppressed on current ART regimen
- Dosing schedule options of monthly or every 2 month injections
- Injections must be administered by a health care provider
- Oral lead-in dosing can be considered prior to initiating the injections
  - Assess tolerability of cabotegravir and rilpivirine
  - Can take up to 1 month



# Dosing Schedule

## Once-monthly dosing schedule



## Every-2-month dosing schedule



# Operational Considerations

- Share decision making with the patient
- Clinical eligibility review
- Insurance coverage
- Drug acquisition
- Preparation and administration of injections
- Adherence monitoring

# Treatment Eligibility Considerations

- Share decision making with the patient on initiating LAI
  - Indication for treatment with cabotegravir/rilpivirine
  - Injections administration requirement
    - Require 2 gluteal injections per dose
    - Administration must be done in clinic
- Complete clinical eligibility
  - Review full HIV treatment history
    - All genotype lab results
    - ART regimen history (ART tx failure, adverse effects, DDI, etc.)
  - Hepatitis B history/immunity
  - Medication and office visit history
  - BMI
  - Comorbidities

# Financial Review

- Financial clearance
  - Benefits investigation
  - Prior authorizations
  - Copay/patient assistance enrollment support
  - Can enroll in ViiV Connect for assistance or can be completed at your facility

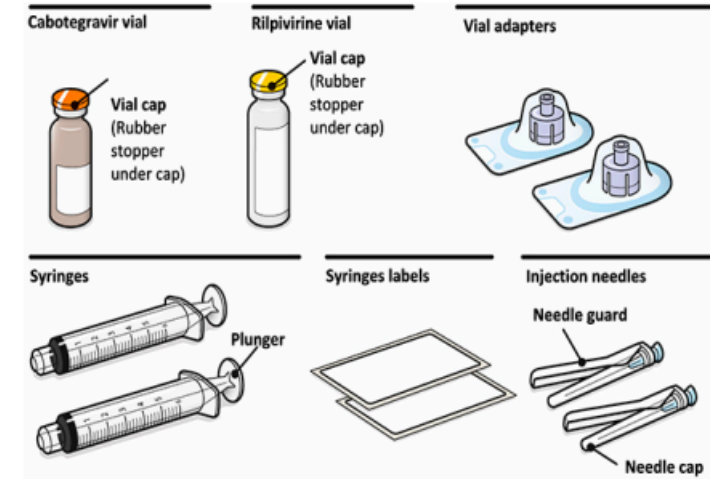


# Medication Access

- Medication Access
  - Buy & Bill
    - Billed under medical benefit
    - Medical facility purchases drug and submits claims to insurance for reimbursement
  - Specialty Pharmacy (“white bagging”)
    - Provider sends prescription to in-network specialty pharmacy (may depend on insurance)
    - Medical facility coordinates with the specialty pharmacy for medication delivery (cannot be sent to patient)
    - May need to ensure administration only billing is submitted to insurance
  - Oral Lead-in
    - Submit request via ViiV Connect enrollment form
    - If opting out of enrolling in ViiV Connect, can send prescriptions directly to TheraCom Specialty Pharmacy (877-654-7812)

# Preparation and Storage

- Cabotegravir/rilpivirine available in 2 dosing kits
    - Cabotegravir/rilpivirine 600mg/900mg (3mL) Kit
      - Cabotegravir 200mg/mL suspension= 600mg (3mL)
      - Rilpivirine 300mg/mL suspension = 900mg (3mL)
    - Cabotegravir/rilpivirine 400mg/600mg (2mL) Kit
      - Cabotegravir 200mg/mL suspension = 400mg (2mL)
      - Rilpivirine 300mg/mL suspension = 600mg (2mL)
    - Injection supplies included in the kit
      - 2 syringes, 2 vial adapters, 2 needles for IM injections (23 gauge, 1½ inch)
      - For individuals with BMI > 30 kg/m<sup>2</sup>, consider 2 inch needles (not included)
    - Storage Requirements
      - Each kit **must** be stored in refrigerator
      - Once the kit is removed from the refrigerator, it must be used or discarded
- \*\*\*Do not remove from the refrigerator until patient ready for injections!



# Administration

- Requires 2 injections for complete dose (1 injection per medication)
- Vials must be at room temperature for 15 minutes before drawn up in syringes
- Vials are good at room temperature for up to 6 hours
  - \*\***Must discard** if not used in 6 hours
- Dose drawn up in syringe is good for up to 2 hours
  - \*\***Must discard** if not used in 2 hours
- Injections are administered to separate gluteal sites
  - Opposite sites or at least 2cm apart
  - Ventrogluteal or dorsogluteal
- In case of post injection reactions, patient should be observed for 10 minutes

# Adherence Monitoring

- Recommend to schedule next appointment for injection before leaving clinic
  - Next target dose date is in 1 month or 2 months (+/- 7 days)
  - Recommend to schedule in 4 or 8 weeks to maintain consistent dosing schedule
- Assign staff to track patients receiving LAI treatment
  - Create patient list or spreadsheet to track injection schedule and due date
  - Coordinate medication supply
  - Track prior authorization approval dates and renewals that may be needed

# What we have learned so far...

- Injection administration
  - Recommend to verifying with the patient that they would like to receive the injection at the visit before removing from refrigerator
  - So far patients have tolerated the injections
  - Reports that rilpivirine injection is little more viscous and requires slower injection
- Insurance related topics
  - Documentation regarding oral lead-in may be needed
  - Documentation on reasons patients cannot take oral medication may be needed
  - Some plans will require “Buy & Bill” or Specialty Pharmacy
  - Prior authorization may take up to 10 business days for initial response
  - Need to track prior authorization approval dates
  - Potential out of pocket costs for copays with the patient

# What we have learned so far...

- Medication Access
  - Verify your facility or institution's policy on clinic-administered injections
  - Oral lead-in supply
    - Usually shipped in 1-2 business days
    - Require verification on insurance approval for the injections, medication list, shipping address
  - Bridge therapy
    - TheraCom will only supply cabotegravir
    - Rilpivirine needs to be filled at retail pharmacy separately
- Other challenges
  - A lot of coordination in all steps of the process
    - Recommend to have a LAI treatment champion to track patients
    - Potential increased workload for many clinic staff
    - May have limited or fluctuating resources in facility due to COVID-19 pandemic

Tell us about your experiences with implementing IM cabotegravir/rilpivirine!

# Resources

- ViiV website for providers (<https://cabenuvahcp.com/resources/>)
  - Dosing & Interactions (<https://cabenuvahcp.com/dosing/>)
  - Access and Patient support page (<https://cabenuvahcp.com/patient-access/>)
    - ViiV Connect Portal enrollment (<https://www.viivconnectportal.com/viivprovider/s/login/>)
    - Access Coordinator (<https://www.viivconnect.com/for-providers/provider-resources/>)
- NASTAD (National Alliance of State and Territorial AIDS Directors)  
<https://nastad.org/resources/adap-provider-administered-long-acting-injectable>



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