



Indiana University Health

LifeCare Cabotegravir / Rilpivirine Injection Standard Work (Q2 Month Dosing Scheme)

**PURPOSE/PROCESS: ACCESS TO CABOTEGRAVIR /
RILPIVIRINE INJECTION**

CABENUVA INJECTION VISIT STANDARD WORK

REVISION # & DATE: V24; 1/12/23

DOCUMENT OWNER: EMILY HUESGEN, KEVIN WALKER

Step	Description:	Reason / Key Point / Image	Position/Who
1	<p><u>Identify Potential Candidate</u></p> <ul style="list-style-type: none"> • Patient expresses interest • Amenable to 2 gluteal injections at months 1 and 2, then every 2 months after (Q2 month appts) • Has a suppressed VL (VL < 50 copies/mL) for at least 3 months • Lacks drug resistance mutations to cabotegravir / rilpivirine • Lacks any drug interactions w/ cabotegravir / rilpivirine • Lacks any contraindications to therapy • Lacks HBV coinfection • Is not pregnant • HIV subtype other than A6/A1 	<p>Patient interest / discussion with provider</p>	<p>NP / PharmD / MSW</p>
2	<p>Discuss patient's candidacy with ALL team members (NP / PharmD / MSW) via appt or Cerner message</p>	<p>Identify potential barriers / Contraindications</p> <p>Examples of barriers:</p> <ul style="list-style-type: none"> • Transportation • Change of job / insurance • Cost • Lack of reliable contact info (e.g. working phone) • Time commitment • Incarceration • DDIs 	<p>NP / PharmD / MSW</p>

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3	Counseling (in-person or phone)	<p>Points of Discussion (Examples):</p> <ul style="list-style-type: none"> • Process • Benefits investigation results • CAB/RPV dosing scheme • Optional OLI (preferences per team / pt discussion) • Appt expectations • Side Effects • Adherence • Review Patient Counseling Section of PI • Patient questions • Pregnancy counseling • Reminder to call PharmD w/ start date if doing OLI • Importance of notifying team of any changes in insurance coverage (gain/loss) while prescribed Cabenuva • Education about EOB statements from private insurance necessary to submit for ViiV Patient Savings Program <p>Verify pt wants to proceed after counseling and document communication in a Cerner message to all team members</p>	PharmD / NP / MSW

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4	<p>Team member who initiates discussion with patient and completes ROI sends Cerner message referral thread to Pharm Tech and team members (NP/PharmD/MSW) to communicate patient candidates for process initiation</p> <p>-Include OLI or DTI preference in Cerner message (as per discussion w/ pt) -Have pt sign ROI -MSW confirms most current insurance card scanned in Cerner (medical and pharmacy benefits) -MSW to check for secondary insurance coverage</p>	<p>To begin enrollment in ViiVConnect portal</p>	<p>NP / PharmD / MSW</p>
5	<p><u>ViiVConnect Patient Enrollment:</u> **All information regarding enrollment status will be communicated to team in Cerner message -PA approvals/denials, benefits investigation results and copay card/virtual debit card will be put in Cerner (scanned/snipped) -All documents will be stored on Y-drive +/- patient folders -Pharm Tech to keep track of PA expiration dates; which are documented in Cerner and in Therigy.</p>	<p>May enroll patient in ViiVConnect Patient Portal to initiate benefits investigation, pre-certs, and patient assistance</p>	<p>Pharm Tech (primary), PharmD</p>

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6.	<p><u>Insurance Approval and Optional OLI:</u> Patient approved and OLI shipped to patient's residence / clinic (location determined by patient's preferences; patient's residence preferred)</p> <ul style="list-style-type: none"> Documentation of approval sent in Cerner message to team and include in Cerner clinical note -> administrative -> cert letters prior authorizations (How to add cert letter prior auth template: -> click on documents ->options) If meds shipped to clinic, PharmD / Pharm Tech to call pt to notify / schedule pick-up date. Store meds in designated area in clinic medication room. If shipped to patient's house, have patient call PharmD when they receive; If no call, call within 3 days to verify receipt of OLI and start date. PharmD to schedule 1st injection visit on receipt of OLI or during pt notification of insurance approval. Schedule first injection visit (day 28-30 of oral lead-in phase) for 60 minutes. Schedule Cerner appt as "LifeCare Cabenuva" visit on RN schedule. Include comment bubble w/ PA authorization # and approval period for all Cabenuva pt appts using medical benefits (for billing dept) 	<ul style="list-style-type: none"> Coordinate delivery of medication to clinic / pt's residence Remind pt to call PharmD with start date Set-up appt for first injection visit <p><u>Clinic Storage:</u></p> <ul style="list-style-type: none"> Store medication in med room cabinet Document on storage log <p><u>Cabotegravir / rilpivirine Storage Log Documentation:</u></p> <ul style="list-style-type: none"> Date/time received Person accepting Patient name Date/time dispensed Person dispensing 	<p>Pharm Tech (primary); PharmD</p> <p>PharmD</p> <p>Following insurance approval process and team notification</p> <p><u>PharmD:</u> Verify start date of optional OLI and schedule 1st injection</p>

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7.	<p><u>Medication Documentation:</u></p> <ul style="list-style-type: none"> Update ART in Cerner (document OLI or injection product by med history) and propose a discontinuation of old ART once OLI has been picked up/received Notify pharmacy to cancel previous ART Update ART in CAREWare Update Cabenuva tracking excel sheet with OLI / DTI and first injection appt date NP enters Cabenuva order set (Q2 month dosing scheme) and RN activates during appt for first injection 	To avoid confusion / medication errors	PharmD / NP
8.	<p><u>Communication:</u> Cerner message (using original referral thread) sent to all team members (NP / PharmD / MSW / Pharm Tech) and RN pool (MH LifeCare Triage) with patient's cabotegravir and rilpivirine (OLI) start date and appt for first injection. Please add Betina to all patients with private insurance for savings card tracking.</p>	<ul style="list-style-type: none"> To alert team Document all conversations with patient in Cerner and include all team members 	PharmD
9.	<p>Phone Follow-Up 1 week post oral lead-in initiation</p> <ul style="list-style-type: none"> If unable to reach, attempt to call q2-3 days for at least 3 attempts Document each attempt in Cerner referral thread 	<p>Discussion Points:</p> <ul style="list-style-type: none"> Tolerability Adherence to PO therapy Administration Medication history Side effects Patient questions Appt reminder for injection date 	PharmD

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10.	<p><u>First Injection Visit</u> (60 min; RN only)</p> <ul style="list-style-type: none"> • RN to pull Cabenuva kit (600/900 mg) from fridge once pt arrives to allow time to warm-up to room temperature (15 min). • Unopened kit should be labeled with time it was removed from fridge (e.g. using sticky note, etc.) <p><u>Breakdown of time:</u> (60 min)</p> <ul style="list-style-type: none"> • Med warm-up (if not pulled from fridge in advance) - needs 15 min at room temp prior to injection • Counseling / prep time for meds (10 min) • 10 to 15 min monitor for adverse effects post-injection* <p>*[e.g. pain, tenderness, hardened mass/lump, swelling, redness, itching/bruising/warmth at injection site, fever, fatigue, HA, muscle/bone pain, nausea, rash, (dyspnea, agitation, abdominal cramping, flushing, sweating, oral numbness, and changes in BP. This occurred in < 1% of subjects in RCTs)]</p>	<ul style="list-style-type: none"> • Give first dose (DTI or day 28-30 of OLI) • Schedule 2nd injection date one month later (+/- 7 day window from 1st injection) • Update Cabenuva tracking excel sheet 	RN

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11.	<p><u>Second Injection Visit</u> (30 min; RN only)</p> <ul style="list-style-type: none"> • Schedule 28 days from initial appt (+/- 7 day window from 1st injection) • RN to pull Cabenuva kit from fridge once pt arrives to allow time to warm-up to room temperature. • Unopened kit should be labeled with time it was removed from fridge (e.g. using sticky note, etc.) • RN to call if patient no-shows appt and communicate to team (NP / PharmD / MSW / Pharm Tech) with Cerner message <p><u>Breakdown of Appt Time:</u> (30 min)</p> <ul style="list-style-type: none"> • Med warm-up (if not pulled from fridge in advance) - needs 15 min at room temp prior to injection • Counseling / prep time for meds (10 min) • 10 to 15 min monitor for adverse effects post-injection* (see Step 10 for side effects to monitor) 	<ul style="list-style-type: none"> • Give 2nd injection • Schedule 3rd injection appt in 2 months w/ NP and SW • Get labwork • Update med history • Update Cabenuva tracking excel sheet 	RN

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12.	<p><u>Third Injection</u> (Full Visit w/ NP/SW)</p> <ul style="list-style-type: none"> • RN to pull Cabenuva kit from fridge once pt arrives to allow time to warm-up to room temperature (15 min). • Unopened kit should be labeled with time it was removed from fridge (e.g. using sticky note, etc.) • RN to call if patient no-shows appt and communicate to team (NP / PharmD / MSW / Pharm Tech) with Cerner message <p>-Attempt to schedule 30 min subsequent and/or concurrent visits with RN, NP and MSW</p>	<ul style="list-style-type: none"> • Review labwork • Tolerability • Insurance status /recerts • Insurance review • Update med history • Schedule next injection appt in 2 months (+/- 7 day window) • Update Cabenuva tracking excel sheet 	NP / MSW / RN
13.	<p><u>Subsequent Visits:</u></p> <ul style="list-style-type: none"> • Pt will receive 2-Month injections with RN • Full visits and lab draws to be scheduled as clinically indicated 	Future appt and lab work requirements will be done PRN	RN

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14. Unplanned Missed Injections:
(> 7 days from injection date and no PO therapy in interim)
- Team has made at least 3 attempts in a 7-day period to reach patient
 - RN to send Cerner message to team on how to best engage patient
 - **Unplanned missed injection > 7 days must be rescheduled w/ team for reassessment** (schedule as consecutive 30 min visits or together based on provider availability)
 - If team has re-evaluated patient and approves of continuation, can continue with injections based on the following timeline:

Team assessment of patient's ongoing candidacy for Q2 Month injections

RN to make call and triage to staff

Missed Injection Visit	Time Since Last Injection	Rec
Injection 2 (Month 2)	≤ 2 months	Give 600/900 mg injections ASAP, then continue Q2 month schedule
	> 2 months	Reinitiate dosing scheme: Give 600/900 mg injections ASAP, then 2 nd injections 1 month later, then Q2 months
	≤ 3 months	Give 600/900 mg injections

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	Injection 3 or Later (Month 4 and later)		ASAP, then continue Q2 month schedule	
> 3 months		Reinitiate dosing scheme: Give 600/900 mg injections ASAP, then 2 nd injections 1 month later, then Q2 months		

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15.	<p><u>Planned Missed Doses:</u></p> <ul style="list-style-type: none"> Pt must alert team in advance if PLANNED missed injection date > 7 days and info must be communicated to team in Cerner message Pt may receive PO CAB/RPV for up to 2 months to replace 1 missed injection visit, or any fully suppressive PO ART may be used until injections are resumed. Pharm Tech to call ViiVConnect for planned missed dose approval if seeking PO CAB/RPV ViiV supplies cabotegravir (PO) through TheraCom Pharmacy and shipped to pt / clinic Rilpivirine (PO) Rx and copay card (if eligible) must be sent to local pharmacy If alternative PO ART is used, send Rxs to patient's pharmacy 	<ul style="list-style-type: none"> Prevent lapse of therapy 1st dose of oral therapy should be taken <u>2 months</u> (i.e. 8 weeks) <u>after last injection</u> and continued until next injection date 	Pharm Tech / NP / PharmD / MSW
16.	<p><u>CAB / RPV Inject Discontinuation:</u></p> <ul style="list-style-type: none"> Route initial patient calls requesting injection discontinuation to NP/PharmD/RN. Send Cerner message notifying all team members + Pharm Tech Initiate an alternative, fully suppressive ART no later than 2 months after final injection <p>If virologic failure is suspected, prescribe an alternative regimen ASAP</p>	<ul style="list-style-type: none"> Residual concentrations of CAB / RPV (aka "the tail") may remain in systemic circulation for up to 12 months Alternative ART needed to prevent drug resistance Pregnancy counseling if applicable 	NP / PharmD / RN / MSW
17.	<p>Drug kit supply will be maintained via Swiss Log (medical benefit) or refills requested by Methodist Retail Pharmacy (pharmacy benefit – clear bagging)</p>	<ul style="list-style-type: none"> To maintain supply 	PharmD / Pharm Tech

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