

# Injectable PrEP Quick Guide

- Screen for acute HIV and PrEP history to assess safety to start injectable PrEP:
  - **Symptoms of acute HIV:** "Have you had any of the following symptoms today or in the past 30 days: a fever with sore throat, rash, swollen lymph nodes, or headache?"
    - If YES: DO NOT start PrEP.
      - o Order 4<sup>th</sup> gen HIV Ag/Ab **AND** HIV RNA Viral Load (qualitative or quantitative)
      - o Consider starting Rapid ART while awaiting results of testing if the patient recently had a likely HIV exposure and acute HIV symptoms.
    - If NO: continue to next question
  - Recent PrEP Use: Have you used any PrEP pills in the past 3 months or PrEP injections in the past 12 months?
    - If NO to both questions: order 4<sup>th</sup> gen HIV Ag/Ab
    - If YES to either question: order 4<sup>th</sup> gen HIV Ag/Ab AND HIV RNA Viral Load (qualitative or quantitative)
- Perform HIV testing if not done in the 7 days prior to PrEP initiation.
  - o Ensure negative result on a laboratory-based 4<sup>th</sup> gen HIV Ag/Ab +/- HIV RNA Viral Load test prior to initial injection
    - Rapid oral fluid HIV tests should be avoided, as they are less sensitive for the detection of acute/recent HIV infection.
- Order remaining lab tests: Injectable PrEP can be initiated while awaiting these labs.
  - STI testing: syphilis serology (RPR/VDRL), GC/CT at all sites of exposure, hepatitis C Ab.
  - Urine pregnancy test (UPT) for patients who can become pregnant. Discuss the benefits vs. risks of PrEP to
    prevent HIV transmission throughout pregnancy if UPT positive and the patient has ongoing risk of acquiring
    HIV.

#### Provide counseling

- Confirm contact information for the patient and whether they give permission to leave voice or text reminders about upcoming labs/injection appointments to help them stay on schedule.
- Prior to initiation, counsel patients about need for monitoring the CAB-LA "tail" after discontinuation with HIV RNA testing every 3 months for 1 year:
  - o CAB-LA levels slowly wane over an average of 10-18 months after injections are discontinued. During this "tail" phase, CAB-LA levels eventually fall below a protective threshold and persist at nonprotective levels, exposing the patient to the risk of HIV acquisition.
  - These lower levels of CAB-LA may also create resistance to CAB or other INSTI medications if HIV is acquired during this time. Infection with INSTI-resistant virus may complicate HIV treatment.
  - Counsel patients on oral PrEP recommendations when there is HIV risk after discontinuation.
- To minimize injection site reactions, patients can take an over-the-counter pain medication within 2 hours before or after the injection and continue as needed for 1-2 days, and/or apply a warm compress or heating pad to the injection site for 15-20 minutes after the injection.
- Administer CAB-LA PrEP injection after confirming lab-based HIV negative test result: Initiation Injections
  - 3 ml suspension of 600 mg IM injected into gluteal muscle at initiation and again after 4 weeks. For BMI <30, a 1.5-inch needle is recommended. For BMI ≥ 30, a 2-inch needle is recommended.



### **Maintenance Injections**

• 3 ml suspension of 600 mg IM injected into gluteal muscle 4 weeks after initiation injection, then every 8 weeks (+/- 7 days)

#### Injection Site

- The preferred injection site is the gluteal muscle using the <u>ventrogluteal approach</u>. The dorsogluteal approach is an acceptable alternative.<sup>1</sup>
- For buttock implants: consider using the <u>vastus lateralis</u> (thigh) <u>site</u> for injections to ensure IM placement. Vastus lateralis injections have been found to achieve equivalent drug levels to gluteal sites.<sup>2</sup>

## **Injectable PrEP Initiation and Follow up Protocol**

	PrEP initiation visit	Follow-up visits (every 3 months)
HIV Status	HIV-1 qualitative (or quantitative) RNA viral load + HIV Ag/Ab test	HIV-1 qualitative (or quantitative) RNA (viral load) + HIV Ag/Ab test
STI and Other Lab Testing	<ul> <li>Syphilis serology (RPR or VDRL)</li> <li>GC/CT at all sites of exposure</li> <li>Consider:</li> <li>O Hep C Ab</li> <li>O Urine Pregnancy Test</li> </ul>	<ul> <li>Repeat STI screen every 4 months</li> <li>Consider repeat:         <ul> <li>O Hep C Ab (annually)</li> <li>O Urine Pregnancy Test (when applicable)</li> </ul> </li> </ul>
Prescription	Provide cabotegravir 3 ml suspension of 600 mg IM injection at initiation visit and again 4 weeks later.	Provide cabotegravir 3 ml suspension of 600 mg IM injection every 8 weeks if HIV test is negative.
Discontinuation		Prior to initiation, counsel about the need for monitoring CAB-LA tail with HIV RNA testing every 3 months for 1 year after discontinuation.  If PrEP is indicated, prescribe daily oral F/TDF or F/TAF beginning within 8 weeks after last injection.  Obtain HIV RNA viral load and HIV Ag/AB quarterly for 12 months after discontinuing injections.

# **Injection Dosing After Missed Injection**

For planned missed doses (such as planned travel), patients can use oral Cabotegravir for up to 2 months or an alternative daily PO regimen, such as F/TDF or F/TAF (particularly if planning on stopping for more than 2 months.) Start oral regimen approximately 2 months after last injection. When resuming CAB-LA, reload according to the manufacturer recs in the table below.

<sup>&</sup>lt;sup>1</sup> https://www.accessdata.fda.gov/drugsatfda\_docs/label/2021/215499s000lbl.pdf

<sup>&</sup>lt;sup>2</sup>https://medinfo.gsk.com/5f95dbd7-245e-4e65-9f36-1a99e28e5bba/e9eaa3fd-ba20-4c6f-b87f-735f830a39de/e9eaa3fd-ba20-4c6f-b87f-735f830a39de viewab le rendition v.pdf



Dose Missed	Time Since Previous Dose	Recommendation
Second Injection	≤ 2 months	Administer dose as soon as possible, then continue every 2-month schedule.
	> 2 months	Restart initiation dosing (2 doses separated by 1 month), followed by every 2-month schedule.
Third injection or after	≤ 3 months	Administer dose as soon as possible, then continue every 2-month schedule.
	> 3 months	Restart initiation dosing (2 doses separated by 1 month), followed by every 2-month schedule.

### **Additional References**

- <u>Preexposure Prophylaxis for the Prevention of HIV Infection in the United States 2021 Update Clinical Practice Guideline</u>
- Ward 86 Long-Acting Injectable Antiretroviral Protocol