Injectable PrEP & Related Services at PIMC

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Disclosures

- Nothing to disclose
- The material is the result of work supported with resources and the use of facilities at the Phoenix Indian Medical Center, located in the Phoenix Area of the Indian Health Service
- The contents do not represent the views of the Indian Health Service or the United States Government

Outline

- 1. Introduction
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- 6. Injectable PrEP

- 7. Hepatitis B
- 8. Patient Satisfaction
- 9. SeroPrep
- 10. Acquisition
- 11. Vaccines
- 12. Outreach

About Me









About Me

- Board Certified Clinical Pharmacist (BCPS)
- American Academy of HIV certified (AAHIVP)
- Arizona State Medicaid P&T Committee Member (AHCCCS)
- Love precepting, restaurants, dance clubs, traveling on points, and long walks on the beach
- Go Longhorns!!!

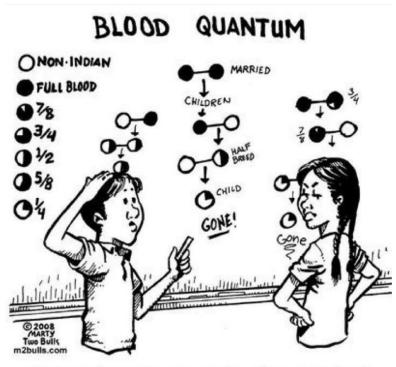


Connection with Native Health



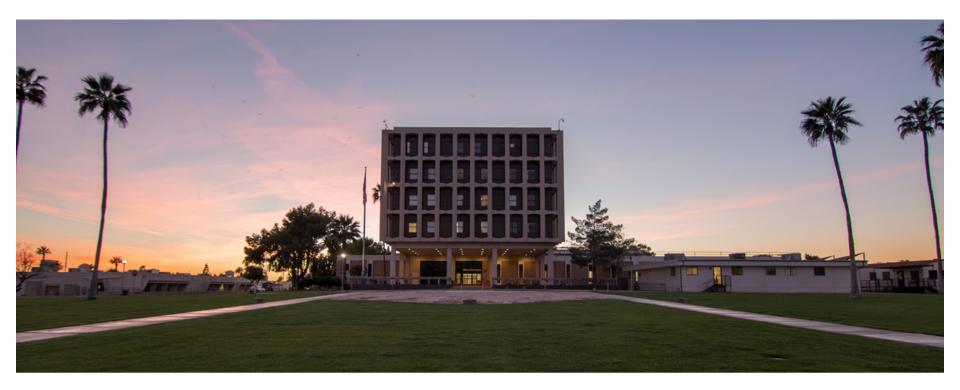


Blood Quantums



Hey wait a minute, we're disappearing!

Our Clinic - HIV Center of Excellence



Our Clinic - HIV Center of Excellence

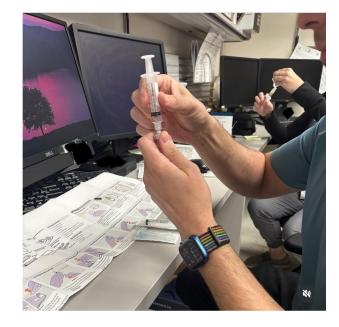


Our Clinic - HIV Center of Excellence

- Primary care for over 400 active HIV+ patients, in addition to chronic diseases
 - HIV, Hep C, STI's, PrEP/PEP/nPEP, Latent Tuberculosis, infectious disease, and more
- Doctors, pharmacists, nurse practitioners, physician assistants, nurses, medical assistants, benefits and resources, behavioral health, etc.
- Community outreach, case management, presentations, housing, etc.
- Medical literature review for hard to find questions
- Teaching students and residents
- Management of drug shortages, find funding of expensive injectables, etc.

Our Clinic - Services

- HIV Primary Care, Case Management
- Clinical Pharmacy
- Prevention, Testing, Counseling, Treatment
- PrEP/PEP/nPEP
- Doxy-PEP
- Hepatitis C, STI's, and Oversee PHN-STI Clinic
- Injectable Medications
- Gender Affirming Care
- Precepting Students & Residents



What our Clinic Pharmacists Do

- PrEP rapid starts
- HIV, HCV, STI, PrEP/PEP/nPEP follow-up and outreach
- HIV chart reviews, genotyping, med history, immunizations, etc.
- Nationwide and internal education presentations
- Case management assistance
- Primary literature research for hard to find questions
- Precepting
- Community engagement
- Much more

Future Goals

- Internal pharmacist provider status
- Integration with pharmacy chronic care clinic
- Universal opt out testing (includes HIV, Hep C, & Syphilis)
- Facility-Wide Transgender Flags
- Expanded Staffing
- Renovations

Three-Site Testing

Extra-genital Self-testing Program at Madison Clinic













STD Prevention Training Center

























Barbee L. Mountain West AIDS Education and Training Center Self-Collected Extra-Genital Gonorrhea and Chlamydia Testing for MSM. https://depts.washington.edu/nwaetc/presentations/uploads/227/selfcollected extragenital gonorrhea and chlamvdia testing for msm.pdf

Three-Site Testing

https://www.uwptc.org/visual-guides

Request Visual Guides

Order Form TestYourself Visual Guides

The UW PTC is happy to provide free, high-quality printable PDFs of our **pharyngeal**, **rectal**, **and vaginal** self-testing visual aids (now available in 21 languages!) for your clinic.

Upon completing the form below you will be redirected to file downloads. The files can be printed in 16"x20" and 8.5"x11" formats. The files are locked to prohibit editing.

Bulk order printing requests available for orders over 200 prints.

NO EDITING OF THESE IMAGES IS PERMITTED - FOR DUPLICATION ONLY



Other STI's and Related Infections

- *M. Genitalium* (Mgen)
- Trichomoniasis
- Herpes
- HPV cancers, warts, polyps, etc.
- Infectious diarrhea
- Urinary Tract Infections (UTI's)
- Mpox
- Scabies, lice, others

Men with recurrent NGU should be tested for *M. genitalium* using an FDA-cleared NAAT. If resistance testing is available, it should be performed and the results used to guide therapy. Women with recurrent cervicitis should be tested for *M. genitalium*, and testing should be considered among women with PID. Testing should be accompanied with resistance testing, if available. Screening of asymptomatic *M. genitalium* infection among women and men or extragenital testing for *M. genitalium* is not recommended. In clinical practice, if testing is unavailable, *M. genitalium* should be suspected in cases of persistent or recurrent urethritis or cervicitis and considered for PID.

Recommended Regimens if *M. genitalium* Resistance Testing is Available

If *macrolide sensitive*: Doxycycline 100 mg orally 2 times/day for 7 days, followed by azithromycin 1 g orally initial dose, followed by 500 mg orally once daily for 3 additional days (2.5 g total)

If macrolide resistant: Doxycycline 100 mg orally 2 times/day for 7 days followed by moxifloxacin 400 mg orally once daily for 7 days

Recommended Regimens if *M. genitalium* Resistance Testing is Not Available

If *M. genitalium* is detected by an FDA-cleared NAAT: Doxycycline 100 mg orally 2 times/day for 7 days, followed by moxifloxacin 400 mg orally once daily for 7 days

Follow-Up

Test of cure is not recommended for asymptomatic persons who received treatment with a recommended regimen. In settings in which *M. genitalium* testing is available, persons with persistent urethritis, cervicitis, or PID accompanied by detection of *M. genitalium* should be treated with moxifloxacin.

Management of Sex Partners

Recent studies report a high concordance of *M. genitalium* among partners of males, females, and MSM; however, no studies have determined whether reinfection is reduced with partner treatment (*940,967,968*). Sex partners of patients with symptomatic *M. genitalium* infection can be tested, and those with a positive test can be treated to possibly reduce the risk for reinfection. If testing the partner is not possible, the antimicrobial regimen that was provided to the patient can be provided.

M. Genitalium Treatment Failure



Mycoplasma genitalium Treatment Failure Registry

The purpose of this form is to collect clinical information on cases of *Mycoplasma genitalium* that fail antimicrobial therapy. All reported information will be maintained in the strictest confidence.

Identifying patient information (e.g., patient name, date of birth, medical record number, social security number) should <u>not</u> be included on the form.

Doxy-PEP

- New and hot right now
- Take within 72 hours of sexual activity to reduce risk of gonorrhea, chlamydia, and syphilis
 - Preferably within 24 hours
- Doxycycline 200 mg orally x 1 for each encounter
 - Take both tablets at the same time do not split up
 - Maximum of 200 mg per day
 - Can theoretically take every single day if patient has risky exposure every day

Doxy-PEP

- Initial studies referenced by CDC in MSM and TGW
 - Chlamydia 70% incident reduction
 - Syphilis 73% incident reduction
 - Gonorrhea No effect seen
- Additional studies have found statistically significant gonorrhea efficacy

MSM = Men who have sex with men TGW = Transgender women

CDC. STI treatment guidelines. Centers for Disease Control and Prevention. Published 2021. https://www.cdc.gov/std/treatment-guidelines/default.htm

Juliana S Grant, Chrysovalantis Stafylis, et al. Doxycycline Prophylaxis for Bacterial Sexually Transmitted Infections, Clinical Infectious Diseases, Volume 70, Issue 6, 15 March 2020, Pages 1247-1253, https://doi.org/10.1093/cid/ciz866

Jean-Michel Molina, Isabelle Charreau, et al. Post-exposure prophylaxis with doxycycline to prevent sexually transmitted infections in men who have sex with men: an open-label randomised substudy of the ANRS IPERGAY trial, The Lancet Infectious Diseases, Volume 18, Issue 3, 2018, Pages 308-317, ISSN 1473-3099, https://doi.org/10.1016/S1473-3099(17)30725-9. https://www.sciencedirect.com/science/article/pii/S1473309917307259.

Doxy-PEP Patient Handout (Front)

Doxy PEP – How to Take : = sex without a condom, including oral sex Two 100 mg pills of doxycycline ideally within 24 hours but no later than 72 hours after condomless oral, anal or vaginal sex Example: Sex on Sat; take dose of doxy by Tues Example: Sex on Thursday; take dose of doxy by Sunday Doxy Doxy Up to 72 hours after sex Up to 72 hours after sex Example 2: Daily (or more) sex Sat-Tues; take daily dose of doxy and last dose within 24 hours but not later than 72 hours after last sex Doxy Doxy Doxy Doxy Up to 72 hours after sex

No more than 200 mg every 24 hours

Doxy-PEP Patient Handout (Back)

Doxycycline PEP Information Sheet

When should I take doxycycline PEP?

 Two 100 mg pills of doxycycline should be taken ideally within 24 hours but no later than 72 hours after condomless sex. Condomless sex means oral, anal or vaginal/front hole sex where a condom isn't used for the entire time.

wi

- What about when I have sex again?
- If you have sex again within 24 hours of taking doxycycline, take another dose 24 hours after your last dose. You can take doxycycline as often as every day when you are having condomless sex but don't take more than 200 mg (two 100 mg pills) every 24 hours.



How should I take doxycycline PEP?

 Take doxycycline with plenty of water or something else to drink so that it does not get stuck when you swallow. If your stomach is upset by doxycycline, taking with food may help.



- Some people are more sensitive to the sun when they take doxycycline, so wear sunscreen.
- Please do not share doxycycline with others.
- Avoid dairy products, calcium, antacides or multivitamins within 2 hours before or after doxy



Reminders

- Let your provider know if you run out of doxycycline, if you are having any side effects, and if you
 think you may have a sexually transmitted infection (STIs)
- Doxy-PEP reduces the risk of syphilis, gonorrhea and chalymdia but these infections can still happen. You should continue to be tested at regular intervals and if you have symptoms
- Doxy-PEP doesn't protect against MPX (monkeypox), HIV, or other viral infections

Doxy-PEP

Table: Quarterly STI incidence by HIV status and by randomization to doxyPEP & control arms

	HIV uninfected MSM/TGW on PrEP		MSM/TGW living with HIV		Total	
	Doxy arm	Control arm	Doxy arm	Control arm	Doxy Arm	Control arm
	N=240	N=120	N=134	N=60	N=374	N=180
Follow up quarters	491	220	266	108	757	328
Participants with an	41	42	24	18	65	60
incident STI (GC, CT						
or syphilis)						
Primary STI	47 (9.6%)	65 (29.5%)	31 (11.7%)	30 (27.8%)	78 (10.3%)	95 (29.0%)
endpoints						
Gonorrhea	40 (8.1%)	45 (20.5%)	21 (7.9%)	20 (18.5%)	61 (8.1%)	65 (19.8%)
Chlamydia	7 (1.4%)	23 (10.5%)	12 (4.5%)	16 (14.8%)	19 (2.5%)	39 (11.9%)
Syphillis	1 (0.2%)	5 (2.3%)	3 (1.1%)	2 (1.9%)	4 (0.5%)	7 (2.1%)

CONCLUSIONS: Doxycycline 200 mg taken within 72 hours after condomless sex significantly reduced STIs in MSM/TGW. Effects on antimicrobial resistance, gut microbiome, and sexual behavior are being assessed as important considerations for this STI prevention strategy.

Doxy-PEP & RPMS

Script one example:

DOXYCYCLINE TAB 100MG

TAKE ONE (1) TABLET BY MOUTH BID WITH MEALS FOR INFECTION , AVOID ANTACIDS,

> DAIRY PRODUCTS AND IRON WITHIN 3 HOURS Quantity: 14 Tablet Days: 7 Refills: 0

Script two example:

DOXYCYCLINE TAB 100MG

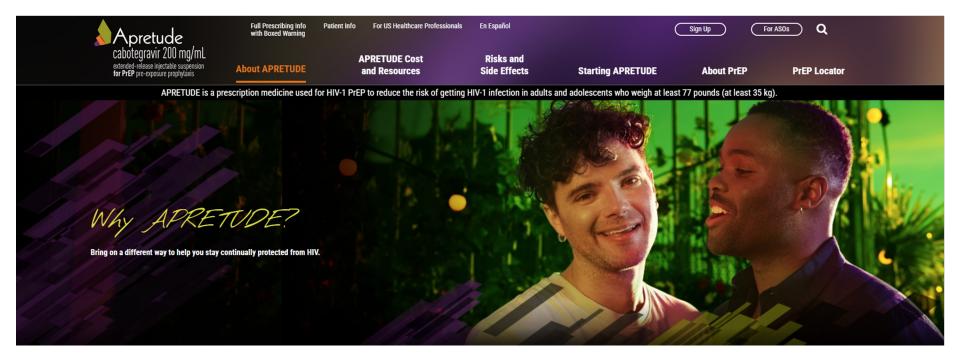
TAKE TWO (2) TABLETS BY MOUTH ONCE IF NEEDED IDEALLY WITHIN 24 HOURS BUT NO LATER THAN 72 HOURS AFTER SEXUAL EXPOSURE FOR INFECTION PREVENTION ***NO MORE THAN 2 TABLETS IN A 24 HOUR PERIOD, AVOID ANTACIDS, DAIRY PRODUCTS AND IRON WITHIN 3 HOURS Quantity: 60 Tablet Days: 30 Refills: 3 *Chronic Med: YES



A new injection to prevent HIV, rather than pills, is a game-changer, scientists say. NPR.org. https://www.npr.org/2021/12/23/1067366345/hiv-aids-injection-fda-approval-cabotegravir-apretude-prep.

Cabenuva HIV Medication. POZ. https://www.poz.com/drug/cabenuva

Apretude (Cab-LA)



See Boxed Warning | What is APRETUDE? | APRETUDE (cabotegravir). apretude.com. Accessed February 29, 2024. https://apretude.com/about-apretude/what-isapretude/?utm_source=google&utm_medium=cpc&utm_term=apretude&gad_source=1&gclid=CjwKCAiAivGuBhBEEiwAWiFmYRmsJSDjnwAEnESrpRL0G4aXnPiqs-IKHUrluaysKhC4aXCFjpRYZBoC4rcQAvD_BwE&gclsrc=aw.ds

Injectable PrEP Overview

- Apretude (Cabotegravir, or Cab-LA)
 - Non-inferiority and superiority trials
 - Unknown exact time to full protection
 - Estimated 7 days to full protection in receptive anal
 - Estimated 21 days to full protection for receptive vaginal (cis-gender women)
 - Counsel on safe sex practices and risk avoidance
 - Monthly x 2 doses, then every other month
 - Only 1 drug estimated less long-term side effects
 - Constant drug level, great safety profile, less drug interactions

Injectable PrEP Guideline

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE

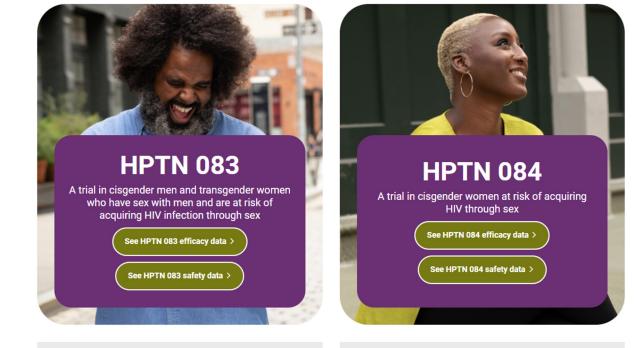
Injectable PrEP Efficacy

Only with APRETUDE:

Superior efficacy with significantly lower incidence of HIV-1 infection vs a daily oral PrEP (TDF/FTC) proven in 2 double-blind clinical trials.

 69% (P=0.0003) and 90% (P<0.0001) lower incidence of HIV-1 infection in HPTN 083 and HPTN 084*[†]





- Noninferiority trial with the prespecified ability to test for superiority
- 43 sites around the world (N=4,566)¹

Gender and sexuality¹:

- 87% of participants were MSM
- 13% were TGW

Age¹:

- 68% were <30 years old

Race¹:

- 50% in the US were Black

- Superiority trial
- 20 sites around sub-Saharan Africa (N=3,224)²

Age²:

- 50% were <25 years old Race²: - 55% had ≥2 sex partners

APRETUDE (cabotegravir 200 mg/mL) Efficacy | HCP Website. apretudehcp.com. Accessed February 29, 2024. https://apretudehcp.com/efficacy/

Injectable PrEP Safety

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED HIV-1 INFECTION

Safety profile established in >2,200 participants in HPTN 083

Adverse drug reactions* of all grades reported in at least 1% of participants receiving APRETUDE

Adverse reactions	APRETUDE (n=2,281)	TDF/FTC (n=2,285)
Injection-site reactions ⁺	82%	35%
Diarrhea	4%	5%
Headache	4%	3%
Pyrexia [‡]	4%	<1%
Fatigue [§]	4%	2%
Sleep disorders ^{II}	3%	3%
Nausea	3%	5%
Dizziness	2%	3%
Flatulence	1%	1%
Abdominal pain ⁴	1%	1%

Injectable PrEP Dosing

Table 1. Recommended Dosing Schedule (with Oral Lead-In) for Pre-Exposure Prophylaxis in Adults and Adolescents Weighing at Least 35 kg

Oral Lead-In		Intramuscular (Gluteal)	
(at Least 28 Days)	Intramuscular (Gluteal)	Continuation Injection	
(Month Prior	Initiation Injection	(Month 4 and	
to Starting Injections)	(Month 1 and Month 2)	Every 2 Months Onwards)	
Oral cabotegravir 30 mg by	APRETUDE ^a	APRETUDE ^b	
mouth once daily for 28 days	600 mg (3 mL)	600 mg (3 mL)	

^a Should be administered on the last day of oral lead-in or within 3 days thereafter.

^b Individuals may be given APRETUDE up to 7 days before or after the date the individual is scheduled to receive the injections.

Table 2. Recommended Dosing Schedule (Direct to Injection) for Pre-Exposure

Prophylaxis in Adults and Adolescents Weighing at Least 35 kg

Intramuscular (Gluteal)	Intramuscular (Gluteal)	
Initiation Injection	Continuation Injection	
(Month 1 and Month 2)	(Month 4 and Every 2 Months Onwards)	
APRETUDE ^a	APRETUDE ^a	
600 mg (3 mL)	600 mg (3 mL)	

^a Individuals may be given APRETUDE up to 7 days before or after the date the individual is scheduled to receive the injections.

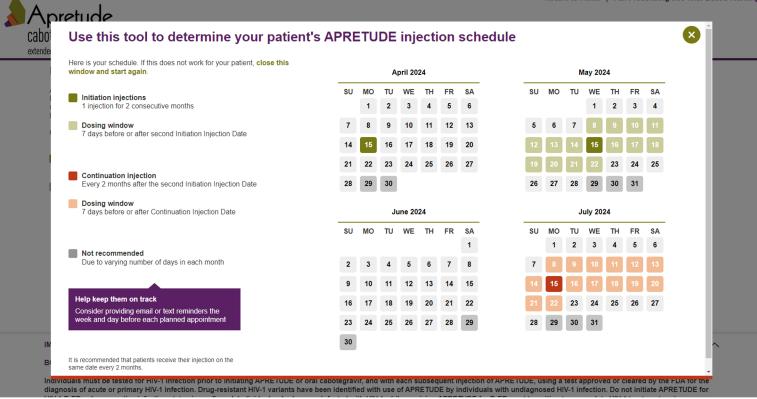
Injectable PrEP Initiation

Table 1b: Summary of Clinician Guidance for Cabotegravir Injection PrEP Use

	Sexually-Active Adults	Persons Who Inject Drugs ¹	
Identifying substantial risk of acquiring HIV infection	 Anal or vaginal sex in past 6 months AND any of the following: HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) Bacterial STI in past 6 months² History of inconsistent or no condom use with sexual partner(s) 	HIV-positive injecting partner OR Sharing injection equipment	
Clinically eligible	ALL OF THE FOLLOWING CONDITIONS ARE MET: Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection No signs/symptoms of acute HIV infection No contraindicated medications or conditions		
Dosage	 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle Initial dose Second dose 4 weeks after first dose (month 1 follow-up visit) Every 8 weeks thereafter (month 3,5,7, follow-up visits etc) 		

Injectable Target Dates





Converting from Oral Cabotegravir to Injectable PrEP

CAB PREP INITIATION VISIT

In the clinical trials of CAB injections for PrEP, patients were provided oral CAB 30 mg tablets daily for 5 weeks prior to receiving the first injection.¹⁴⁷ Because there were no safety concerns identified during this lead-in period or during the injection phase of the studies, an oral lead-in is not required when initiating CAB PrEP. It may be optionally used for patients who are especially worried about side effects to relieve anxiety about using the long-acting CAB injection. However, continued daily oral CAB is not recommended or FDA-approved for PrEP.

Converting from Oral FTC/TDF or FTC/TAF to Injectable PrEP

CAB PREP INITIATION VISIT

Patients who have been taking daily oral PrEP, can initiate CAB injections as soon as HIV-1 RNA test results confirm that they remain HIV negative.

Injectable PrEP **Planned** Missed Injections

If an individual plans to miss a scheduled every-2-month continuation injection visit by more than 7 days, take daily oral cabotegravir for up to 2 months to replace 1 missed scheduled every-2-month injection. The recommended oral daily dose is one 30-mg tablet of oral cabotegravir. The first dose of oral PrEP should be taken approximately 2 months after the last injection dose of APRETUDE. Restart injection with APRETUDE on the day oral dosing completes or within 3 days; thereafter, as recommended in Table 3. For oral PrEP durations greater than 2 months, an alternative oral regimen is recommended.

Contact Viiv to order oral Vocabria (cabotegravir) to ship to patient or clinic directly, and at no cost

Injectable PrEP Unplanned Missed Injections

If a scheduled injection visit is missed or delayed by more than 7 days and oral dosing has not been taken in the interim, clinically reassess the individual to determine if resumption of injection dosing remains appropriate [see Warnings and Precautions (5.1)]. If the injection dosing schedule will be continued, see Table 3 for dosing recommendations.

Injectable PrEP Missed Injections

Table 3. Injection Dosing Recommendations after Missed Injections

Time since Last Injection	Recommendation
If second injection is missed and	
time since first injection is:	
Less than or equal to 2 months	Administer 600-mg (3-mL) gluteal intramuscular injection
	of APRETUDE as soon as possible, then continue to
	follow the every-2-month injection dosing schedule.
Greater than 2 months	Restart with 600-mg (3-mL) gluteal intramuscular
	injection of APRETUDE, followed by a second 600-mg
	(3-mL) initiation injection dose 1 month later. Then
	continue to follow the every-2-month injection dosing
	schedule thereafter.
If third or subsequent injection	
is missed and time since prior	
injection is:	
Less than or equal to 3 months	Administer 600-mg (3-mL) intramuscular injection of
	APRETUDE as soon as possible, then continue with the
	every-2-month injection dosing schedule.
Greater than 3 months	Restart with 600-mg (3-mL) gluteal intramuscular
	injection of APRETUDE, followed by the second 600-mg
	(3-mL) initiation injection dose 1 month later. Then
	continue with the every-2-month injection dosing schedule
	thereafter.

Injectable PrEP Initiation Labs

TESTING NOT INDICATED ROUTINELY FOR CAB PREP PATIENTS

Based on the results of the CAB clinical trials,^{12, 147, 148} the following laboratory tests are NOT indicated before starting CAB injection or for monitoring patients during its use: creatinine, eCrCl, hepatitis B serology, lipid panels, liver function tests.

Screening tests associated with routine primary care and not specific to the provision of CAB for PrEP are discussed in the primary care section (see Table 8)

Injectable PrEP Followup Labs

Table 7	Timing of	CAB PrEP-associated Laboratory	Tests
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Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	Х	Х	Х	Х	Х	Х	Х
Syphilis	Х			MSM^/TGW~ only	Heterosexually active women and men only	х	MSM/TGW only
Gonorrhea	Х			MSM/TGW only	Heterosexually active women and men only	Х	MSM/TGW only
Chlamydia	Х			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

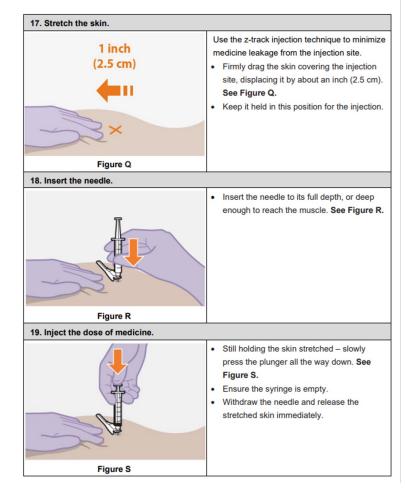
* HIV-1 RNA assay

X all PrEP patients

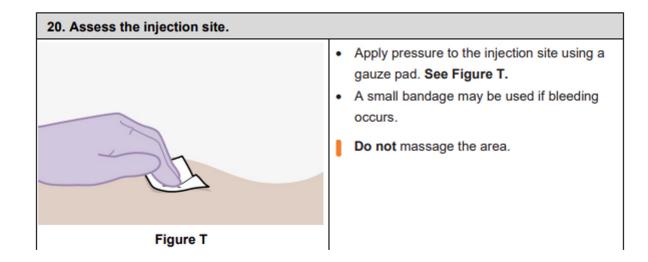
^ men who have sex with men

~ persons assigned male sex at birth whose gender identification is female

Injectable PrEP Administration



Injectable PrEP Administration

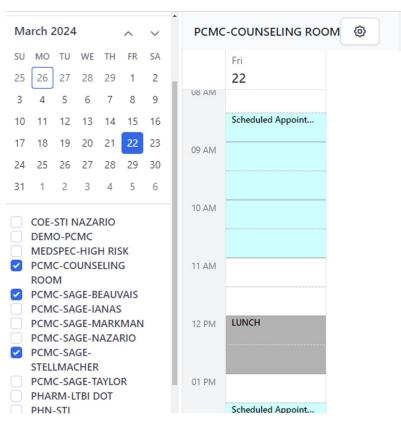


Injectable PrEP Follow Up

Follow-up care	At follow-up visit 1 month after first injection
	 HIV Ag/Ab test and HIV-1 RNA assay
	At follow-up visits every 2 months (beginning with the third injection - month 3) provide the following:
	 HIV Ag/Ab test and HIV-1 RNA assay
	 Access to clean needles/syringes and drug treatment services for PWID
	At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:
	 Bacterial STI screening² for MSM and transgender women who have sex with men² – oral, rectal, urine, blood
	At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:
	 Bacterial STI screening¹ for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood
	At follow-up visits at least every 12 months (after the first injection) provide the following:
	 Assess desire to continue injections for PrEP
	 Chlamydia screening for heterosexually active women and men – vaginal, urine
	At follow-up visits when discontinuing cabotegravir injections provide the following:

 Re-educate patients about the "tail" and the risks during declining CAB levels
 Assess ongoing HIV risk and prevention plans
 If PrEP is indicated, prescribe daily oral F/TDF or F/TAF beginning within 8 weeks after last injection
 Continue follow-up visits with HIV testing quarterly for 12 months

Injectable PrEP Follow Up



Pt arrived to clinic to receive second injection of Cab-LA for HIV PrEP.

-Confirmed HIV lab results negative, including not detected VL (seen in SQ). New labs completed today, will monitor results.
-Pt agrees to discontinue oral PrEP, last dose was yesterday. Notified pt exact timeframe to full protection is not known, but estimated to be 7 days. Agrees to use condoms consistently for at least 7 days, longer if desired.
-Sexual habits/safe sex discussed.
-Given FDA patient handout prior to administration, pt read & confirmed they would like to initiate Cab-LA for HIV PrEP today.
-Pt hep B immune, though testing not indicated for Cab-LA per CDC & Manufacturer.
-Managing injection site reactions per MFR recommendations.
**OTC pain soon prior to or after injection for 1-2 days PRN.
**Warm compresses or heating pad for 15-20 min after arriving home.

-Need for HIV combo & HIV VL testing prior to each injection, ordered in EHR for release on 2/28, pt would like to complete prior to visit.

- -Seven day +/- window for injections with option to use oral CAB bridge up to 2 months, importance of on-time injections to prevent sero-conversion & delayed recognition of seroconversion associated w/ Cab-LA.
- -CBC, chem, Hep B, lipid panel, and liver enzymes NOT ordered NOT indicated for Initiation nor monitoring of Cab-LA per CDC and manufacturer.
- -Pt agrees to follow up in 1 month, will complete HIV labs and be assessed for s/sx of acute HIV infection.

Future Planning per 2021 CDC PrEP guidelines: -At each bi-monthly visit, will assess for s/sx of acute HIV infection, administer Cab-LA, and respond to new questions. -At least every 4 months - Evaluation as above + bacterial STI screening (pt is MSM), and typical 3-site testing (sooner if indicated). -Every 12 months (beginning at 5th injection) - Tests as above + assess desire to continue Cab-LA.

Vaccines: -Up to date, no additional vaccines recommended at this time.

ICD: Z29.81 - Encounter for HIV Pre-Exposure Prophylaxis

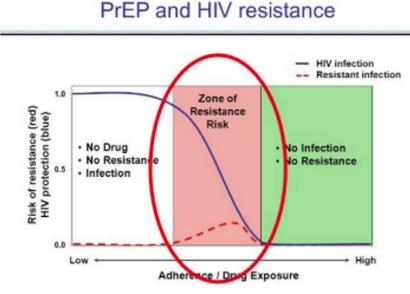
Activity Time: 30 Minutes

Medication is paid for by the patient assistance program by the manufacturer VilV and NOT billed through PIMC. Medication is filled by an outside pharmacy and delivered to Phoenix Indian Medical Center and administered in the clinic.

Indication: Z29.81

Injectable PrEP Follow Up / Discontinuation

Figure 7 The trade-off of PrEP drug levels and risk of HIV infection with resistant virus



Slide modified from John Mellors, FDA 201

Discontinuing Injectable PrEP

- Stop after provider evaluation of HIV risk
- Discuss how to safely discontinue
- Consider use of oral PrEP for 12 months after discontinuation
 - If patient remains at risk for HIV
 - Drug levels will remain and are subtherapeutic
 - Drug levels are high enough to cause resistance

Hepatitis B

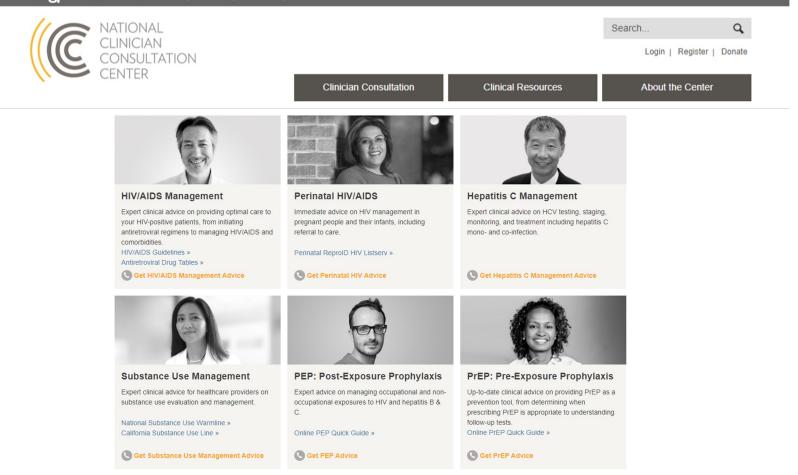
Test and Result	Interpretation	Action			
HBsAg—Positive Total anti-HBc — Positive IgM anti-HBc — Positive Anti-HBs — Negative	Acute infection	Link to hepatitis B care			
HBsAg — Positive Total anti-HBc — Positive IgM anti-HBc — Negative ¹ Anti-HBs — Negative	Chronic Infection	Link to hepatitis B care			
HBsAg — Negative Total anti-HBc — Positive Anti-HBs — Positive	Resolved Infection	Counsel about HBV infection reactivation risk			
HBsAg — Negative Total anti-HBc — Negative Anti-HBs — Positive ²	Immune from receipt of prior vaccination (if documented complete series)	If no documentation of full vaccination, then complete vaccine series per ACIP recommendations.			
HBsAg — Negative Total anti-HBc — Positive	Only core antibody is positive. See possible interpretations and corresponding actions:				
Total anti-HBc — Positive Anti-HBs — Negative	Resolved infection where anti-HBs levels have waned	Counsel about HBV infection reactivation risk			
	Occult Infection	Link to hepatitis B care			
	Passive transfer of anti-HBc to an infant born to an HBsAg-positive gestational parent	No action			
	A false positive, thus patient is susceptible	Offer HepB vaccine per Advisory Committee on Immunization Practices (ACIP)			
	A mutant HBsAg strain that is not detectable by laboratory assay	Link to hepatitis B care			
HBsAg — Negative Total anti-HBc — Negative Anti-HBs — Negative ³	Susceptible, never infected (if no documentation of HepB vaccine series completion)	Offer HepB vaccine per ACIP recommendations			

CDC. Interpretation of Hepatitis B Serologic Test Results | CDC. www.cdc.gov. Published March 3, 2023. https://www.cdc.gov/hepatitis/hbv/interpretationOfHepBSerologicResults.htm

Patient Reports

- Patient satisfaction in clinic at PIMC
 - Soreness & local pain x 2-3 days
 - No discontinuations so far
 - Great adherence with keeping appointments
 - No other complaints

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UCSF SeroPrEP

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The SeroPrEP Study

SeroPrEP is a study for people who may have acquired HIV after receiving pills or injections for PrEP.

The SeroPrEP study is being done to better understand why some people acquire HIV while taking oral PrEP or CAB LA. We enroll participants and support sample collection from all 50 U.S. states and Puerto Rico.

→ If you are **PrEP client** who may have acquired HIV infection while taking PrEP, you may complete the participant consent form.

→ If you are a clinician who has a patient who may have acquired HIV infection while taking PrEP, you may refer your patient using the link for clinicians.

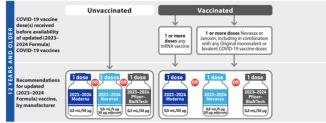
Funding and Acquisition

- Patient Assistance delivers directly to PIMC pharmacy
- Have patients wet sign paperwork in clinic if any doubt about funding
 - PAP is extremely efficient at verifying patient coverage, saves time
- AHCCCS has published prior authorization criteria online
- Insurance Companies may cover under medical or pharmacy coverage
 - Sometimes require outside pharmacy or specific contracted companies
 - Creates complexity with out-of-pocket costs and deductibles
- Can request facility P&T assistance

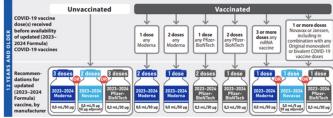
Vaccines

Immunizations for <mark>HIV (non-pregnant adult)</mark>	Immunizations for PrEP (non-pregnant adult)
Junneos: 2 doses, 4 weeks apart, offer if at risk (MSM, recent STI, etc.) *Consider hold if CD4 < 200 unless at significant risk, non-replicating*	Jynneos: 2 doses, 4 weeks apart, offer if at risk (MSM, recent STI, etc.).
MCV4: 2 doses, 2 months apart then every 5 years. Men8: Rarely need, CDC routine indications (16-23 ygs, microbiologist, asplenia, shared decision, etc.).	MCV4: 2 doses, 2 months apart for CDC routine (college student, travel, asplenia, etc.). Men8: Rarely need, CDC routine indications (16-23 vrs, microbiologist, asplenia, shared decision, etc.).
Shingrix: Need positive varicella titers first - 2 doses, 2-6 months apart regardless of age.	Shingrix: 2 doses, 2-6 months apart for age 50 +
COVID-19: See table on back of sheet. If recent covid infxn, can get when symptoms resolve, or hold x 3 months. Consider immunocompromised recommendations if in severe condition.	COVID-19: See table on back of sheet. If recent covid infxn, can get when symptoms resolve, or hold x 3 months. Consider immunocompromised recommendations if in severe condition.
Flu: annual (high dose if CD4 < 200 and/or age 65 + preferred, but give whatever is in stock).	Flu: annual (high dose if age 65 + preferred, but give whatever is in stock).
Hep A: Titers first. If negative, repeat with 2 doses > 6 months apart, repeat titers 1-2 months after dose #2.	Hep A: 2 doses, > 6 months apart documented.
Heb B: Titers first. If negative, 2 doses of <u>heplisay</u> 4 weeks apart, repeat titers 1-2 months after second dose. For non-responders, consider annual boosters.	Heb B: Complete series documented, will vary by brand (2 doses <u>heplisay</u> , 3 doses <u>engerix</u> b/ <u>prehevrio</u> , or incomplete series finalized w/ <u>heplisay</u>).
HPV9: 3 doses at 0, 1-2, and 6 months. < 46 <u>vrs</u> or w/ shared decision, <u>Consider</u> repeat HPV9 even if previously completed w/ HP4 or HPV2.	HPV9: 3 doses at 0, 1-2, and 6 months. < 46 <u>yrs</u> or w/ shared decision, <u>Consider</u> repeat HPV9 even if previously completed w/ HP4 or HPV2.
Tdap: once as adult, then Td/Tdap every 10 years.	Tdap: once as adult, then Td/Tdap every 10 years.
Pneumo: Most need 1 dose PCV20 5 years after last PPSV23/PCV20, review latest CDC immunocompromised guideline.	Pneumo: Most need 1 dose PCV20, review latest CDC routine recommendations (alcoholism, chronic heart/lung/kidney dx, DM, malignancy, etc.).
MMR: Review titers, if any individual titer is "negative or equivocal," repeat series of 2 doses, 4 weeks apart. Document immune, do not repeat titers. *Contraindicated if CD4 < 200*	MMR: CDC routine – At least 1 documented dose (Hold if born before 1957 or positive titers/immunity documented).
Varicella: Titers first & repeat series if negative with 2 doses, <mark>3 months</mark> apart. Need positive first before <u>shingrix</u> at any age. Document immune. *Contraindicated if CD4 < 200 *	Varicella: CDC routine 2-doses, 4 weeks apart (hold if hx of medically diagnosed chickenpox, documented 2-dose series, positive titer, born before 1980, etc.)
RSV: 1 dose if 60 + years old or if 32-36 weeks pregnant	RSV: 1 dose if 60 + years old or if 32-36 weeks pregnant

COVID-19 Non-Immunocompromised adult as of 10/13/23



COVID-19 Moderate/Severe Immunocompromised adult as of 10/13/23



Pneumococcal Vaccines for most patients 19-64 w/ HIV



Unique Pneumococcal names in E.H.R Immunization <u>Package</u> **Pneumo-PS = PPSV23 **Pneumo-NOS = Pneumococcal vaccine, not otherwise specified **PCV-NOS = PCV conjugate, not otherwise Specified

Last Reviewed 1/5/24 - Full references available, derived from mixture of CDC, ACIP, and clinic experience.

Last Reviewed 1/5/24 - Full references available, derived from mixture of CDC, ACIP, and clinic experience.

Outreach - Challenges

- Referrals and consults for PrEP/PEP/nPEP
 - STI clinic, urgent care, ED, primary care, inpatient, outside facilities, etc.
- Community outreach, decreasing stigma
- Funding, state medicaid
- Transportation, mobility issues
- Refill automation, shipping to remote areas
- Patient social issues, substance use disorders
- Staffing with increased patient load

Outreach - Barriers to Care

The Washington Post	
Democracy Disc in Dealmose	

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Democracy Dies in Darkness

HEALTH Health Care Medical Mysteries Science Well+Being

Sober homes promised help and shelter. Some delivered fraud, officials say.



By <u>David Ovalle</u>

September 18, 2023 at 6:00 a.m. EDT

Ovalle D. Sober homes promised help and shelter. Some delivered fraud, officials say. Washington Post. Published September 18, 2023. https://www.washingtonpost.com/health/2023/09/18/sober-homes-arizona-medicaid-fraud/

Outreach - Education



Outreach - Education

Native STAND is a comprehensive sexual health curriculum for Native high school students that focuses on sexually transmitted infections, HIV/AIDS, and teen pregnancy prevention, while also covering drug and alcohol use, suicide, and dating violence. Twenty-seven sessions support healthy decision-making through interactive discussions and activities that promote diversity, self-esteem, goals and values, team building, negotiation and refusal skills, and effective communication. The 1.5 hour lessons contain stories from tribal communities that ground learning in cultural teachings.

AGE GROUP DESIGNED FOR: High School

LGBT INCLUSIVE: Yes

TRAUMA INFORMED: Yes

PROGRAM SETTING: Flexible

HEALTH TOPICS COVERED: Healthy Relationships, Other Healthy Life-Skills, Sexual Health

DURATION: 27 sessions (90 minutes each)

COST TO PURCHASE: Free (plus cost of materials for class activities, roughly \$500)

Outreach - Research

National Native HIV/AIDS Awareness Day is March 20

Celebrate by learning about HIV prevention!

- Get tested! CDC recommends that everyone between the ages of 13 and 64 get tested for HIV at least once as part of routine health care.
- PrEP (Pre-Exposure Prophylaxis) is a once-daily pill that is 99% effective at preventing HIV, and
- PrEP is available at PIMC! Talk to a provider for more information or you can make your own appointment to start HIV prevention by calling 602-263-1541 and leaving your contact information and that you are interested in starting PrEP. A team member will get back to you within 1 business day.





Outreach - Community Service & Fundraising



Outreach - Creative Strategies

- New PHN-STI clinic has provider rapid-starting patients
- Very flooded with PrEP management
 - Considering possible exclusive case manager
 - Asking PCP's to take more active role
 - Small handful of other department providers comfortable with managing
- Incentive gift card at the moment but currently limited to HIV patients only, available through national program.
 - Looking into similar programs for PrEP

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