

CHECKLIST 1: Key Factors in Choice of PrEP Regimen						
Individual Preferences and Regimen Considerations		SC LEN	CAB LA	TDF/FTC	TAF/FTC	
	Rectal	~	~	~	~	
Individual's poten-	Vaginal	V	~	V	~	
tial risk exposures	Penile	V	~	~	~	
	Blood			~		
Individual's	Pill			~	~	
preferred administration method	IM injection		~			
	SC injection	~				
	Daily			V	V	
Individual's pre- ferred dosing schedule	Before and after sex, 2-1-1 (rectal or penile exposures) or 2-1-1-1 (vaginal exposure)			~		
	Bimonthly injections (first 2 are 4 weeks apart)		~			
	Every 6 months	V				
	At least every 2 months		~			
Required lab test- ing schedule	At least every 3 months			V	~	
	At least every 6 months	V				
Regimen- specific limitations to consider	Renal dysfunction	V	~		~	
	Osteoporosis or risk of	V	~		~	
	Chronic HBV infection			Daily only	~	
	Generic formulation available			~		
	Using gluteal fillers (e.g., silicone)	V		~	V	
	Pregnant, breast/chestfeeding, or planning pregnancy	~	~	~	~	

Abbreviations: CAB LA, long-acting injectable cabotegravir (Apretude); HBV, hepatitis B virus; IM, intramuscular; PrEP, pre-exposure prophylaxis; SC LEN, subcutaneous lenacapavir (Yeztugo); TAF/FTC, tenofovir alafenamide/emtricitabine (Descovy); TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (Truvada).



CHECKLIST 2: Assessment and Counseling Before PrEP Initiation

- ✓ Assess the patient's <u>health literacy</u> and ensure that the purpose, benefits, and risks of PrEP are understood.
- ✓ Individualize the decision of which medication to initiate for PrEP by weighing the benefit of reducing the patient's risk of acquiring HIV against the potential adverse effects of the medication as well as the patient's preferences.
- ✓ Make clear that PrEP efficacy is highly dependent on adherence, assess for readiness and willingness to adhere to PrEP and recommended follow-up care, and assess for barriers to adherence.
- ✓ Assess interest in and eligibility for injectable PrEP, including the ability to adhere to visits every 2 months for IM injections or every 6 months for SC injections.
- ✓ Assess for relative contraindications for injectable PrEP, including the presence of gluteal fillers for IM injections and for significant medication interactions with SC LEN.
- ✓ Obtain thorough sexual and drug use histories, identify current risk-taking behaviors, and encourage safer sex practices in addition to PrEP and safer drug injection techniques, if applicable.
- ✓ Ask whether the patient has a sex partner (or partners) with known HIV; if yes, ask if the partner's viral load status is known.
- ✓ Discuss with patients in HIV-serodifferent partnerships the benefits and risks of relying on their partner's undetectable viral load achieved with ART versus adding PrEP to prevent sexual transmission of HIV.
- ✓ Counsel HIV-serodifferent couples who are considering using PrEP during attempts to conceive about the utility, safety, and possible risks of the medication and other approaches to safer conception.
- ✓ Perform a psychosocial assessment and refer for appropriate social and psychological support services, as indicated, to minimize HIV risk and support maintenance in care.
- ✔ Partner with other care providers as needed to provide services that may include mental health and substance use treatment, case management, navigation and linkage services, housing assistance, and income/benefits assessments.

Resources:

- Tufts Medicine <u>Health Literacy Tool Shed (funded by the National Library of Medicine)</u>
- · AHRQ Short Assessment of Health Literacy—Spanish and English
- AHRQ Rapid Estimate of Adult Literacy in Medicine—Short Form
- AHRQ Short Assessment of Health Literacy for Spanish Adults
- NYSDOH AI GOALS Framework for Sexual History Taking in Primary Care and Substance Use Harm Reduction in Medical Care
- NYSDOH <u>Expanded Syringe Access Program (ESAP)</u>: Overview of the <u>Law and Regulations</u> and <u>Directory of New York State Syringe Exchange Programs</u>

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; ART, antiretroviral therapy; PrEP, pre-exposure prophylaxis; SC LEN, subcutaneous lenacapavir.



CHECKLIST 4: PrEP Initiation				
Confirm PrEP eligibility	 Discuss HIV risk, including self-reported risk and history of potential exposure, and assess for signs and symptoms of acute HIV infection. If exposure occurred within ≤72 hours, recommend and initiate PEP before PrEP. 			
Obtain medical history	 Assess for contraindications or factors that may affect PrEP choice: HIV infection, HBV infection, kidney impairment, osteoporosis, potential drug-drug interactions, current or planned pregnancy. 			
Order baseline lab testing and arrange for specimen collection	 HIV 1/2 Ag/Ab combination immunoassay (for same-day initiation, perform rapid and lab-based HIV test; ensure lab results available within 1 week of PrEP start) HIV RNA assay Serum creatinine and calculated CrCl Serum liver enzymes HBV and HCV serologies HAV serology (MSM and if at risk) Urinalysis Syphilis testing Gonorrhea and chlamydia NAATs (all potential exposure sites) Pregnancy test (if of child-bearing capacity) 			
Review PrEP options and assist individual in making informed choice	 Explain purpose, benefits, potential risks (including possible adverse effects), and time to protection. Discuss available options, including factors that may influence regimen choice. If CAB LA is chosen, decide whether to use the oral medication lead-in. If on-demand oral PrEP is chosen, ensure understanding of 2-1-1 or 2-1-1-1 dosing. 			
Provide education	 Explain symptoms of acute HIV infection and recommended response, including who to contact and how. Outline adherence requirements: dosing, lab testing, visit schedule. Discuss strategies to address modifiable barriers to access and adherence. Explain possible adverse effects, suggestions for management, and when and how to request assistance. 			
Counsel on harm reduction	 Discuss STI prevention and access to contraceptives and needle exchange. Offer doxy-PEP to individuals at risk of bacterial STIs. Link to support services as needed. 			
Arrange for follow-up	 Obtain and document contact information for remote follow-up (phone, text, email). Review potential adverse effects and how to manage, including when and how to contact a care provider. Schedule follow-up appointments, including injection appointments. 			

Abbreviations: Ag/Ab, antigen/antibody; CAB LA, long-acting injectable cabotegravir; CrCl, creatinine clearance; doxy-PEP, doxycycline post-exposure prophylaxis; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; MSM, men who have sex with men; NAAT, nucleic acid amplification test; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.



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PrEP to Prevent HIV and Promote Sexual Health





CHEC	KLIST 5: PrEP Fo	now up		
Injectable PrEP: CAB LA	If HIV infection is diagnosed	Contact individual immediately to recommend HIV treatment. Obtain baseline lab testing, including genotype testing. Immediately initiate a PI-based ART regimen.		
	2 weeks after starting oral CAB lead-in (if used)	 Contact individual to address problems with acquiring or taking medication; assess adherence, tolerance, and adverse effects; and confirm first injection date. 		
	Within 1 week of first injection	 Contact individual to assess tolerability and advise on adverse effect management if needed. Confirm next injection date. 		
	Every injection visit	Repeat HIV testing with HIV-1/2 Ag/Ab combination immunoassay. Ask about STI symptoms. Offer contraception to individuals of childbearing potential who wish to avoid pregnancy while using PrEP.		
	STI testing every 2-6 months regardless of symptoms	Base testing frequency on reported risk. Perform syphilis screening and NAATs for gonococcal and chlamydial infections at all exposure sites. For all MSM and transgender women, routine 3-site testing should be performed regardless of symptoms or sit of reported exposure, unless declined. Self-collected specimens are acceptable.		
	At least annually	Obtain serum creatinine and calculated CrCl.		
	If injection is missed	If delays are anticipated, arrange for oral bridging medication. If indicated, adjust schedule for next injection.		
	If PrEP is discontinued	 If risk is ongoing, recommend oral PrEP be started 2 months after the last injection and continued for ≥1 year to prevent acquisition of INSTI-resistant HIV, and provide risk-reduction counseling and information on accessing emergency PEP. Discuss option of restarting PrEP in the future. 		
Injectable PrEP:	If HIV infection is diagnosed	Contact individual immediately to recommend HIV treatment. Obtain baseline lab testing, including genotype testing. Immediately initiate an INSTI-based ART regimen.		
C LEN	Within 1 week of first injection	Contact individual to assess tolerability and advise on adverse effect management if needed. Confirm next injection date.		
	Every injection visit	Repeat HIV testing with HIV-1/2 Ag/Ab combination immunoassay. Ask about STI symptoms. Offer contraception to individuals of childbearing potential who wish to avoid pregnancy while using PrEP.		
	STI testing every 3–6 months regardless of symptoms	 Base testing frequency on reported risk. Perform syphilis screening and NAATs for gonococcal and chlamydial infections at all exposure sites. For all MSM and transgender women, routine 3-site testing should be performed regardless of symptoms or of reported exposure, unless declined. Self-collected specimens are acceptable. 		
	At least annually	Obtain serum creatinine and calculated CrCl.		
	If injection is missed	If delays are anticipated, arrange for oral bridging medication. If indicated, adjust schedule for next injection.		
	If PrEP is discontinued	 If risk is ongoing, recommend oral PrEP be started 6 months after last injection and continued for another 6 months to prevent acquisition of capsid inhibitor—resistant HIV, and provide risk-reduction counseling and in mation on accessing emergency PEP. Discuss option of restarting PrEP in the future. 		
)ral	If HIV infection is diagnosed	Order baseline lab testing, including genotype testing. Intensify PrEP regimen to fully suppressive ART or refer individual to an experienced HIV care provider.		
PrEP: TDF/FTC or TAF/FTC	Within 2 weeks of initiation	 Contact individual to address problems with acquiring or taking PrEP medications, assess tolerance and adherence, advise on adverse effect management, and confirm next visit. 		
	1 month after initiation	 Repeat lab HIV testing if exposure occurred ≤1 month before PrEP initiation. Ask about adherence, symptoms of acute HIV (repeat HIV testing if reported), STI symptoms (ask at every visit) harm reduction, and pregnancy status (test if indicated or requested). Offer contraception to individuals of childbearing potential who wish to avoid pregnancy while using PrEP. Arrange for lab testing at month 3: HIV-1/2 Ag/Ab combination immunoassay; syphilis screening and NAATs gonococcal and chlamydial infections at all exposure sites; and pregnancy testing if indicated or requested (every visit). 		
	3 months after initiation (and every 6-12 months thereafter)	Obtain serum creatinine and calculated CrCl.		
	Every 3 months regardless of symptoms	 Assess adherence. Ask about symptoms and test for STIs (can decrease frequency based on risk). For all MSM and transgender women, routine 3-site testing for gonorrhea and chlamydia should be performed regardless of sites of reported exposure, unless declined. Self-collected specimens are acceptable. Arrange for next lab testing. Perform pregnancy testing if indicated or requested (every visit). 		
	At least annually	Obtain urinalysis and HCV serology for those at risk.		
	If PrEP is interrupted	 Order lab-based HIV testing (HIV-1/2 Ag/Ab combination immunoassay and HIV RNA PCR) whenever individude reports PrEP interruption of >1 week within the past month and possible HIV exposure or reports missing PrE doses during a time of sexual activity and possible HIV exposure. 		
	If PrEP is discontinued	If risk is ongoing, provide risk-reduction counseling and information on accessing emergency PEP. Discuss option of restarting PrEP in the future.		