



## PrEP to Prevent HIV and Promote Sexual Health

### Checklist 1: PrEP Initiation

### Checklist 2: Key Factors in Choice of PrEP Regimen

### Checklist 3: PrEP Follow-Up

May 2022

CHECKLIST 1: PrEP INITIATION	
Confirm PrEP eligibility	<ul style="list-style-type: none"> <li>Discuss HIV risk, including self-reported risk, history of potential exposure, or signs, and assess for signs and symptoms of acute HIV infection</li> <li>If exposure within <math>\leq 72</math> hours, recommend and initiate PEP before PrEP</li> </ul>
Obtain medical history	<ul style="list-style-type: none"> <li>Assess for contraindications or factors that may affect PrEP choice: HIV; HBV; kidney impairment; osteoporosis; potential drug-drug interactions; current or planned pregnancy</li> </ul>
Order baseline laboratory testing and arrange for specimen collection	<ul style="list-style-type: none"> <li>HIV-1/2 Ag/Ab combination immunoassay*</li> <li>HIV RNA assay</li> <li>Serum creatinine and calculated CrCl</li> <li>Serum liver enzymes</li> <li>HBV and HCV serologies</li> <li>HAV serology (MSM and if at risk)</li> <li>Urinalysis</li> <li>Syphilis testing</li> <li>Gonorrhea and chlamydia NAATs (all potential exposure sites)</li> <li>Pregnancy test (if of childbearing capacity)</li> </ul> <p>*Same-day PrEP: Perform rapid and laboratory-based HIV test; ensure laboratory results will be available within 1 week of PrEP start</p>
Review PrEP options and assist patient in making informed choice	<ul style="list-style-type: none"> <li>Explain purpose, benefits, potential risks (including possible adverse effects), and time to protection</li> <li>Discuss available options, including factors and limitations that may influence choice of regimen</li> <li>If injectable PrEP is chosen, decide whether to use oral medication lead-in</li> <li>If on-demand oral PrEP is chosen, ensure understanding of 2-1-1 dosing</li> </ul>
Provide patient education	<ul style="list-style-type: none"> <li>Symptoms of acute HIV infection and recommended response, including who to contact and how</li> <li>Adherence requirements: Dosing, laboratory testing, visit schedule</li> <li>Strategies to address modifiable barriers to access and adherence</li> <li>Possible adverse effects, suggestions for management, and when and how to request assistance</li> </ul>
Counsel on harm reduction	<ul style="list-style-type: none"> <li>Discuss STI prevention, access to contraceptives, access to needle exchange</li> <li>Link to support services as needed</li> </ul>
Arrange for follow-up	<ul style="list-style-type: none"> <li>Obtain and document contact information for remote follow-up (phone, text, email)</li> <li>Review potential adverse effects and how to manage, including when and how to contact care provider</li> </ul>
<p><b>Abbreviations:</b> Ag/Ab, antigen/antibody; CrCl, creatinine clearance; 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.</p>	

<b>CHECKLIST 2: KEY FACTORS IN CHOICE OF PrEP REGIMEN</b>				
<b>Patient Preferences and Regimen Considerations</b>		<b>CAB LA</b>	<b>TDF/FTC</b>	<b>TAF/FTC</b>
Patient's potential risk exposures	Rectal	✓	✓	✓
	Vaginal	✓	✓	
	Penile	✓	✓	✓
	Blood		✓	
Patient's preferred administration method	Pill		✓	✓
	IM injection	✓		
Patient's preferred dosing schedule	Daily		✓	✓
	Before and after sex (2-1-1 dosing)		✓	
	Bimonthly injections (first 2 are 4 weeks apart)	✓		
Required lab testing schedule	At least every 2 months	✓		
	At least every 3 months		✓	✓
Regimen-specific limitations to consider	Renal dysfunction	✓		TGW or MSM
	Osteoporosis or risk of	✓		TGW or MSM
	Chronic HBV infection		Daily only	Daily only
	Generic formulation available		✓	
	Using gluteal fillers (e.g., silicone)		✓	✓
	Pregnant, breastfeeding, or planning pregnancy	ND	✓	ND

**Abbreviations:** CAB LA, long-acting injectable cabotegravir (brand name Apretude); HBV, hepatitis B virus; IM, intramuscular; MSM, men who have sex with men; ND, no data; PrEP, pre-exposure prophylaxis; TAF/FTC, tenofovir alafenamide/emtricitabine (brand name Descovy); TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada); TGW, transgender women.

<b>CHECKLIST 3: PrEP FOLLOW-UP</b>		
<b>INJECTABLE PrEP: CAB LA</b>	If HIV infection is diagnosed	<ul style="list-style-type: none"> <li>• Contact patient immediately to recommend HIV treatment</li> <li>• Obtain baseline laboratory testing including genotype testing</li> <li>• Consult with an experienced HIV care provider regarding an appropriate regimen for immediate ART initiation</li> </ul>
	2 weeks after oral CAB lead-in start	<ul style="list-style-type: none"> <li>• <i>If used</i>, contact patient to address problems with acquiring or taking medications; assess adherence, tolerance, and adverse effects; confirm first injection date</li> </ul>
	Within 1 week of first injection	<ul style="list-style-type: none"> <li>• Contact patient to assess tolerability and advise on adverse effect management if needed</li> <li>• Confirm next injection date</li> </ul>
	Every injection visit	<ul style="list-style-type: none"> <li>• Repeat HIV testing with HIV-1/2 Ag/Ab combination immunoassay and HIV RNA assay</li> <li>• Ask about STI symptoms</li> </ul>
	STI testing every 2 to 4 months regardless of symptoms	<ul style="list-style-type: none"> <li>• Base testing frequency on reported risk</li> <li>• Syphilis screening and NAATs for gonococcal and chlamydial infections at all exposure sites</li> <li>• All MSM and TGW: Perform 3-site testing routinely, regardless of symptoms or sites of reported exposure, unless declined. Self-collected specimens are acceptable</li> </ul>
	At least annually	<ul style="list-style-type: none"> <li>• Obtain serum creatinine and calculated CrCl</li> </ul>
	If injection is missed	<ul style="list-style-type: none"> <li>• If delays are anticipated, arrange for oral bridging medication</li> <li>• If indicated, adjust schedule for next injection</li> </ul>
	If PrEP is discontinued	<ul style="list-style-type: none"> <li>• Recommend oral PrEP for ≥1 year to prevent acquisition of HIV with potential INSTI resistance mutations</li> <li>• <i>If risk is ongoing</i>: Provide risk-reduction counseling and emergency PEP access information</li> <li>• Discuss option of restarting PrEP later</li> </ul>
<b>ORAL PrEP: TDF/FTC or TAF/FTC</b>	If HIV infection is diagnosed	<ul style="list-style-type: none"> <li>• Order baseline laboratory testing including genotype testing</li> <li>• Intensify patient's PrEP regimen to fully suppressive ART or refer the patient to an experienced HIV care provider for ART</li> </ul>
	Within 2 weeks of PrEP start	<ul style="list-style-type: none"> <li>• Contact patient to address problems with acquiring or taking PrEP medications; assess tolerance and adherence; advise on adverse effect management; confirm next visit</li> </ul>
	1 month after PrEP start	<ul style="list-style-type: none"> <li>• Repeat laboratory HIV testing if exposure occurred ≤1 month before PrEP initiation</li> <li>• Ask about adherence; symptoms of acute HIV (repeat HIV testing if reported); STI symptoms (ask at every visit); harm reduction; pregnancy status (test if indicated or requested)</li> <li>• Arrange for laboratory testing at month 3: HIV-1/2 Ag/Ab combination immunoassay; syphilis screening and NAATs for gonococcal and chlamydial infections at all exposure sites; pregnancy testing if indicated or requested (every visit)</li> </ul>
	3 months after PrEP start	<ul style="list-style-type: none"> <li>• Serum creatinine and calculated CrCl (every 6 months thereafter)</li> </ul>
	Every 3 months regardless of symptoms	<ul style="list-style-type: none"> <li>• Assess adherence</li> <li>• Ask about symptoms and test for STIs regardless of symptoms (can decrease frequency based on risk)</li> <li>• For all MSM and TGW, routine 3-site testing for gonorrhea and chlamydia should be performed, unless declined and regardless of sites of reported exposure</li> <li>• Arrange for next laboratory testing</li> <li>• Pregnancy testing if indicated or requested (every visit)</li> </ul>
	Every 6 months	<ul style="list-style-type: none"> <li>• Obtain serum creatinine and calculated CrCl</li> </ul>
	At least annually	<ul style="list-style-type: none"> <li>• Obtain urinalysis and HCV serology for those at risk</li> </ul>
	If PrEP is interrupted	<ul style="list-style-type: none"> <li>• Order laboratory-based HIV testing (HIV-1/2 Ag/Ab combination immunoassay and HIV RNA assay) whenever patient reports PrEP interruption of &gt;1 week within the past month and exposure and whenever patient reports missing PrEP doses during a time of sexual activity and possible HIV exposure</li> </ul>
	If PrEP is discontinued	<ul style="list-style-type: none"> <li>• <i>If risk is ongoing</i>: Provide risk-reduction counseling and emergency PEP access information</li> <li>• Discuss option of restarting PrEP later</li> </ul>
<p><b>Abbreviations:</b> Ag/Ab, antigen/antibody; ART, antiretroviral therapy; CAB, cabotegravir (brand name Vocabria); CAB LA, long-acting injectable cabotegravir (brand name Apretude); CrCl, creatinine clearance; HCV, hepatitis C virus; INSTI, integrase strand transfer inhibitor; MSM, men who have sex with men; NAAT, nucleic acid amplification test; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TAF/FTC, tenofovir alafenamide/emtricitabine (brand name Descovy); TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada); TGW, transgender women.</p>		