



CLINICAL GUIDELINES PROGRAM

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

PrEP to Prevent HIV and Promote Sexual Health: Care Provider Checklists for PrEP Initiation, Regimen Choice, and Follow-Up

May 2022

CHECKLIST 1: PrEP INITIATION	
Confirm PrEP eligibility	<ul style="list-style-type: none"> · Discuss HIV risk, including self-reported risk, history of potential exposure, or signs, and assess for signs and symptoms of acute HIV infection · If exposure within ≤ 72 hours, recommend and initiate PEP before PrEP
Obtain medical history	<ul style="list-style-type: none"> · Assess for contraindications or factors that may affect PrEP choice: HIV; HBV; kidney impairment; osteoporosis; potential drug-drug interactions; current or planned pregnancy
Order baseline laboratory testing and arrange for specimen collection	<ul style="list-style-type: none"> · HIV-1/2 Ag/Ab combination immunoassay* · 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 childbearing capacity) <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"> · Explain purpose, benefits, potential risks (including possible adverse effects), and time to protection · Discuss available options, including factors and limitations that may influence choice of regimen · If injectable PrEP is chosen, decide whether to use oral medication lead-in · If on-demand oral PrEP is chosen, ensure understanding of 2-1-1 dosing
Provide patient education	<ul style="list-style-type: none"> · Symptoms of acute HIV infection and recommended response, including who to contact and how · Adherence requirements: Dosing, laboratory testing, visit schedule · Strategies to address modifiable barriers to access and adherence · Possible adverse effects, suggestions for management, and when and how to request assistance
Counsel on harm reduction	<ul style="list-style-type: none"> · Discuss STI prevention, access to contraceptives, access to needle exchange · Link to support services as needed
Arrange for follow-up	<ul style="list-style-type: none"> · 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 care provider
<p>Abbreviations: 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>	



CHECKLIST 2: KEY FACTORS IN CHOICE OF PrEP REGIMEN				
Patient Preferences and Regimen Considerations		CAB LA	TDF/FTC	TAF/FTC
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.



CHECKLIST 3: PrEP FOLLOW-UP

INJECTABLE PrEP: CAB LA	If HIV infection is diagnosed	<ul style="list-style-type: none"> Contact patient immediately to recommend HIV treatment Obtain baseline laboratory testing including genotype testing Consult with an experienced HIV care provider regarding an appropriate regimen for immediate ART initiation
	2 weeks after oral CAB lead-in start	<ul style="list-style-type: none"> <i>If used</i>, contact patient to address problems with acquiring or taking medications; assess adherence, tolerance, and adverse effects; confirm first injection date
	Within 1 week of first injection	<ul style="list-style-type: none"> Contact patient to assess tolerability and advise on adverse effect management if needed Confirm next injection date
	Every injection visit	<ul style="list-style-type: none"> Repeat HIV testing with HIV-1/2 Ag/Ab combination immunoassay and HIV RNA assay Ask about STI symptoms
	STI testing every 2 to 4 months regardless of symptoms	<ul style="list-style-type: none"> Base testing frequency on reported risk Syphilis screening and NAATs for gonococcal and chlamydial infections at all exposure sites All MSM and TGW: Perform 3-site testing routinely, regardless of symptoms or sites of reported exposure, unless declined. Self-collected specimens are acceptable
	At least annually	<ul style="list-style-type: none"> Obtain serum creatinine and calculated CrCl
	If injection is missed	<ul style="list-style-type: none"> If delays are anticipated, arrange for oral bridging medication If indicated, adjust schedule for next injection
	If PrEP is discontinued	<ul style="list-style-type: none"> Recommend oral PrEP for ≥1 year to prevent acquisition of HIV with potential INSTI resistance mutations <i>If risk is ongoing</i>: Provide risk-reduction counseling and emergency PEP access information Discuss option of restarting PrEP later
ORAL PrEP: TDF/FTC or TAF/FTC	If HIV infection is diagnosed	<ul style="list-style-type: none"> Order baseline laboratory testing including genotype testing Intensify patient's PrEP regimen to fully suppressive ART or refer the patient to an experienced HIV care provider for ART
	Within 2 weeks of PrEP start	<ul style="list-style-type: none"> Contact patient to address problems with acquiring or taking PrEP medications; assess tolerance and adherence; advise on adverse effect management; confirm next visit
	1 month after PrEP start	<ul style="list-style-type: none"> Repeat laboratory 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; pregnancy status (test if indicated or requested) 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)
	3 months after PrEP start	<ul style="list-style-type: none"> Serum creatinine and calculated CrCl (every 6 months thereafter)
	Every 3 months regardless of symptoms	<ul style="list-style-type: none"> Assess adherence Ask about symptoms and test for STIs regardless of symptoms (can decrease frequency based on risk) 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 Arrange for next laboratory testing Pregnancy testing if indicated or requested (every visit)
	Every 6 months	<ul style="list-style-type: none"> Obtain serum creatinine and calculated CrCl
	At least annually	<ul style="list-style-type: none"> Obtain urinalysis and HCV serology for those at risk
	If PrEP is interrupted	<ul style="list-style-type: none"> Order laboratory-based HIV testing (HIV-1/2 Ag/Ab combination immunoassay and HIV RNA assay) whenever patient reports PrEP interruption of >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
	If PrEP is discontinued	<ul style="list-style-type: none"> <i>If risk is ongoing</i>: Provide risk-reduction counseling and emergency PEP access information Discuss option of restarting PrEP later

Abbreviations: 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.