



HIV Pre-exposure Prophylaxis

STATEWIDE PLAN AND GUIDANCE



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I. DHEC's Role

The South Carolina Department of Health and Environmental Control (DHEC) HIV Pre-exposure Prophylaxis (PrEP) Statewide Plan and Guidance (The Plan) has been developed by DHEC as an element of the PrEPMeSC initiative. The Plan provides evidence-based guidance about procedures for increasing PrEP acceptance, PrEP prescribing, PrEP referrals, and diagnostic testing for participating providers.

The Plan will include but not be limited to the following subjects:

- a. Mission and purpose of the pre-exposure prophylaxis plan
- b. Clinical guidance for prescribing pre-exposure prophylaxis
- c. Referral guidance for clients who are screened as potential candidates
- d. Pre-screening guidance for clinicians to assess client readiness
- e. Payment options for clients

The SC DHEC STD/HIV and Viral Hepatitis division of the Bureau of Communicable Diseases and Prevention will be responsible for maintaining current guidance in The Plan and will serve as a source for technical assistance and education. The division will utilize CBA (capacity building assistance) to further enhance the capacity of funded and unfunded entities to effectively implement the pre-exposure prophylaxis plan.

The STD/HIV and Viral Hepatitis division will provide basic procedures for engaging a client, scheduling an appointment, developing a referral process, and providing general procedures for required testing.

The STD/HIV and Viral Hepatitis division will implement PrEP referral services in local health departments to address awareness and knowledge surrounding PrEP services. Clients can receive low-cost STI and HIV testing at local health departments. Social workers and disease intervention specialists (DIS) will also provide risk reduction and STI prevention counseling.

II. Goal of PrEP Therapy¹

The goal of PrEP is to reduce the acquisition of HIV infection with its resulting morbidity, mortality, and cost to individuals and society. Therefore, clinicians initiating the provision of PrEP should:

- Prescribe medication regimens that are proven safe and effective for uninfected persons who meet recommended criteria to reduce their risk of HIV acquisition.
- Educate clients about the medications and the regimen to maximize their safe use.
- Provide support for medication adherence to help clients achieve and maintain protective levels of medication in their bodies.
- Provide HIV risk-reduction support and prevention services or service referrals to help clients minimize their exposure to HIV and other STIs.
- Provide effective contraception to women who are taking PrEP and who do not wish to become pregnant.
- Monitor clients to detect HIV infection, medication toxicities, and levels of risk behavior in order to make indicated changes in strategies to support clients' long-term health.

III. Referral Process

When screening, clients should be prioritized according to those who are at the highest risk. Clients who are seeking the following services should be assessed for possible PrEP services or referrals: HIV testing, STI screening, family planning, partner services or general inquiry. The priority populations, according to South Carolina epidemiological data of high HIV incidence and/or risk factors, should be assessed. This includes:

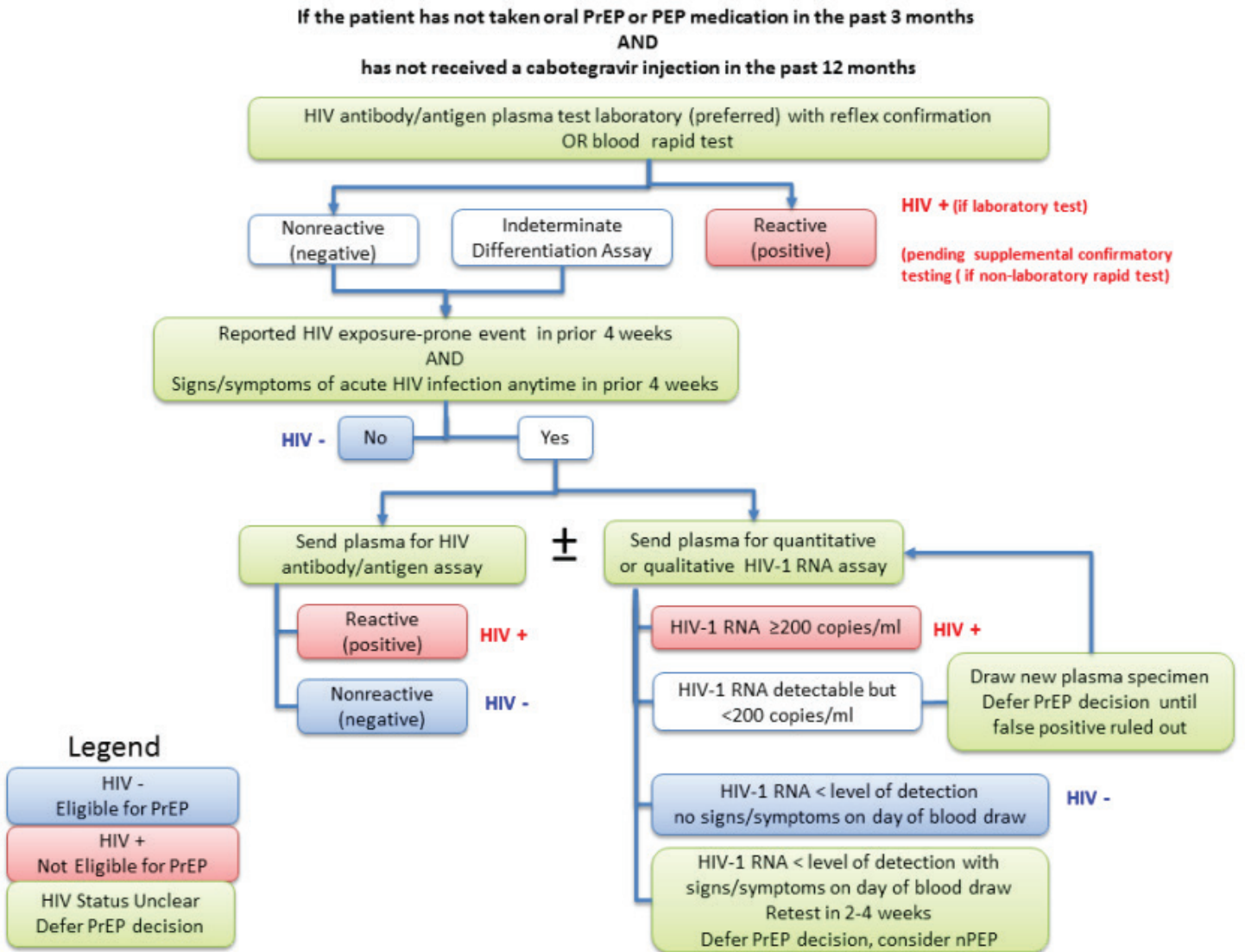
- Persons who have a HIV-positive sexual partner (especially if partner has an unknown or detectable viral load).
- Persons who have tested positive for bacterial STI in the past 6 months.
- Persons who have inconsistent condom use with sexual partner(s).
- Persons who inject drugs with HIV-positive injecting partner or sharing injection equipment.

It's recommended that a designated position either social worker, disease intervention specialist, case manager, linkage coordinator, nurse, clinician, or physician who has, at a minimum, basic knowledge of pre-exposure prophylaxis provide PrEP navigation.

Positions appointed to conduct the screening may also refer to or familiarize themselves with the [PrEPMeSC: Quick Guide \(CR-012206\)](#), which includes basic PrEP information and questions to ask that will gauge readiness or interest in PrEP services.

- Clients who are pre-screened (may include taking a sexual history) and are interested in moving forward should:
 - ▶ Be referred to a PrEP coordinator/navigator or someone designated to assess potential PrEP clients for initial assessment.
 - ▶ If PrEP services are not offered at your clinic, clients should be provided with a list of providers in their area by accessing them at one of the 4 options:
 - HIV.gov: locator.aids.gov
 - PrEP Locator: prelocator.org
 - SC Providers: gis.dhec.sc.gov/HIVLocator
 - PrEPMeSC PrEP Directory: scdhec.gov/sites/default/files/Library/CR-012460.pdf

IV. Clinician Determination of HIV status for PrEP Provision to Persons with Recent or Ongoing Antiretroviral Prophylaxis Use¹



V. Laboratory Testing¹

HIV Ab/Ag screening (4th generation preferred)

- ▶ HIV-1/HIV-2 testing and documented negative results are required prior to prescribing PrEP medications. For patient safety, HIV testing should be repeated at least every 3 months (before prescriptions are refilled or reissued). **Note:** *Rapid tests that use oral fluid should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests. Clinicians should not accept patient-reported test results or documented anonymous test results.*

HIV-1 RNA (Viral Load)

- ▶ HIV-1 RNA assay is recommended within one week of initiation (or collected at initiation) and follow-up due to the long duration of drug exposure with injectable PrEP. This is the most sensitive test to exclude acute HIV in clients receiving the injectable PrEP.

Serum Creatinine

- ▶ Renal function screening should be assessed for clients receiving oral PrEP (F/TDF or F/TAF). Therefore, all persons considering oral PrEP should have a serum creatinine test performed, and an eCrCL should be calculated utilizing the Cockcroft-Gault formula. Any person with an **eCrCl of <60 ml/min** should not be prescribed Truvada or TDF/FTC. If **eCrCl <30 ml/min**, Descovy is not recommended. Serum phosphorous is recommended in patients with chronic kidney disease.

Hepatitis B Ab/Ag Screening

- ▶ Vaccination against HBV is recommended for all adolescents and adults at substantial risk for HIV infection, especially for MSM. Therefore, HBV infection status should be documented prior to PrEP being prescribed. Those clients found to be HBsAg positive should be evaluated for possible treatment either by the clinician providing PrEP care or by linkage to an experienced HBV care provider.
- ▶ HBV infection is not a contraindication to PrEP use. Both TDF and FTC are active against HBV. HBV-mono-infected clients taking TDF or FTC, whether as PrEP or to treat HBV infection, who then stop these medications must be closely monitored for severe acute exacerbations of hepatitis B.

Hepatitis C antibody

- ▶ Serologic testing for HCV is recommended for persons who have ever injected drugs. MSM at substantial risk for HIV infection being started on PrEP have been shown to have a high prevalence of HCV infection. Therefore, MSM starting PrEP should be tested for HCV infection as a part of baseline laboratory assessment.
- ▶ Clients with active HCV infection (HCV RNA+ with or without anti-HCV seropositivity) should be evaluated for possible treatment because TDF/FTC does not treat HCV infection. When the clinician providing PrEP care is not able to provide HCV care, the patient should be linked to an experienced HCV care provider.

Lipid Panel

- ▶ Higher rates of triglyceride elevation and weight gain was noted among F/TAF users. Persons being prescribed F/TAF should receive annual (every 12 months) triglyceride and cholesterol level monitoring.

Sexually Transmitted Infections—Syphilis and GC/CT (3-point testing)

- ▶ **Syphilis** — Tests to screen for syphilis are recommended for all adults prescribed PrEP, both at initiation and follow-up screening visits.
- ▶ **Gonorrhea/Chlamydia** — Tests to screen for gonorrhea and chlamydia are recommended for all sexually active adults prescribed PrEP, both at initiation and follow-up screening visits. NAAT testing is preferred.

Pregnancy testing, if applicable

- ▶ T/TDF is approved for PrEP use in pregnant and breastfeeding women. Data in the Antiretroviral Pregnancy Registry does not have any evidence of adverse effects among fetuses exposed to medication during pregnancy. Women who become pregnant while taking PrEP should seek prenatal care as soon as possible.

VI. Medication

Prescription: FFDA-approved medications (as of 9/1/2022)

Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg; FTC/TDF (Truvada)¹ tablet PO daily (30-day supply); up to 2 refills. Note: no refills with initiation. Patients should return to clinic 1 month after initiation^{1,2}.

Emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets; F/TAF (Descovy)¹ tablet PO daily (30-day supply); up to 2 refills. Note: no refills with initiation. Patients should return to clinic 1 month after initiation. Descovy is not approved for cisgender women (women who identify with their assigned gender at birth)^{1,3}.

Cabotegravir 600 mg (Apretude) intramuscular injection (gluteal muscle) every 2 months^{1,4}.

Optional Cabotegravir 30 mg, 1 tablet PO daily for a 4-week lead-in prior to initial injection. Note: no refills with initiation. Patients should return to clinic 1 month after initiation to receive injection^{1,4}.

Also, clinicians should consider acute HIV infection^{1,2,3,4}:

1. If the client reports the condom broke during sex with an HIV-positive partner or relapse to injection drug use etc.
2. If the client describes any nonspecific signs and symptoms of a viral infection during the past month or on the day of visit.

Protection — maximum intracellular concentrations of TFV-DP (activated form of medication) achieved in the following durations¹:

- **Rectal tissue** — 7 daily doses
- **Cervicovaginal tissue** — 20 daily doses
- **Blood (peripheral blood mononuclear cells)** — 7 daily doses

Data is not currently available for to estimate the maximum protection against HIV infection in F/TDF or F/TAF in penile tissue or injectable PrEP¹.

VII. Side Effects

Common Side Effects

- **“Start-up syndrome”** — usually resolves within the first month of taking PrEP. Discuss with client about the use of over-the-counter medication to assist with temporary side effects¹.
 - ▶ Headache
 - ▶ Nausea
 - ▶ Abdominal discomfort
- Weight loss reported with F/TDF use².
- Weight gain was reported with F/TAF use¹.
- **Injection Site Reactions** — Inform clients these reactions are common and transient. Clients can take over-the-counter medication prior to (1-2 hours) or after receiving injection or apply a warm compress or heating pad to injection site for 15-20 minutes after injection¹.
 - ▶ Pain
 - ▶ Tenderness
 - ▶ Induration

Adverse Effects

Oral Medications^{2,3}

- **Renal Failure** — FTC and TDF are eliminated by the kidneys. Renal impairment, including cases of acute renal failure and Fanconi syndrome associated with TDF^{2,3}.
- **Decrease bone mineral density (BMD) — only observed in 3–4% of HIV-infected individuals taking medications with TDF.** In clinical trials TDF was associated with slightly greater decreases in BMD and increases in biochemical markers of bone metabolism. Also, parathyroid hormone and 1,25 Vitamin D levels were also higher with TDF users. Unclear if it would be seen in HIV-uninfected individuals taking fewer antiretroviral meds^{2,3}.
- **Severe Acute Exacerbations of Hepatitis B in clients with HBV.**
- **Lactic Acidosis and Severe Hepatomegaly**
- **Serum Lipid** changes reported with F/TAP³

Injection Medication

- **Hepatotoxicity** was reported in a limited number of individuals⁴.
- **Depressive Disorder** (including depression, depressed mood, major depression, persistent depressive disorder, suicide ideation or attempt).

Additional Counseling

- Clients discontinuing the injection, should be informed about the long “tail” of gradually declining drug levels and the risk for developing a drug-resistant strain if HIV infection is acquired during that time⁴.

VIII. Data Collection

SC DHEC is working to improve data collection regarding PrEP uptake in the state. For those who are funded by SC DHEC, you should use the following modalities to input data regarding PrEP:

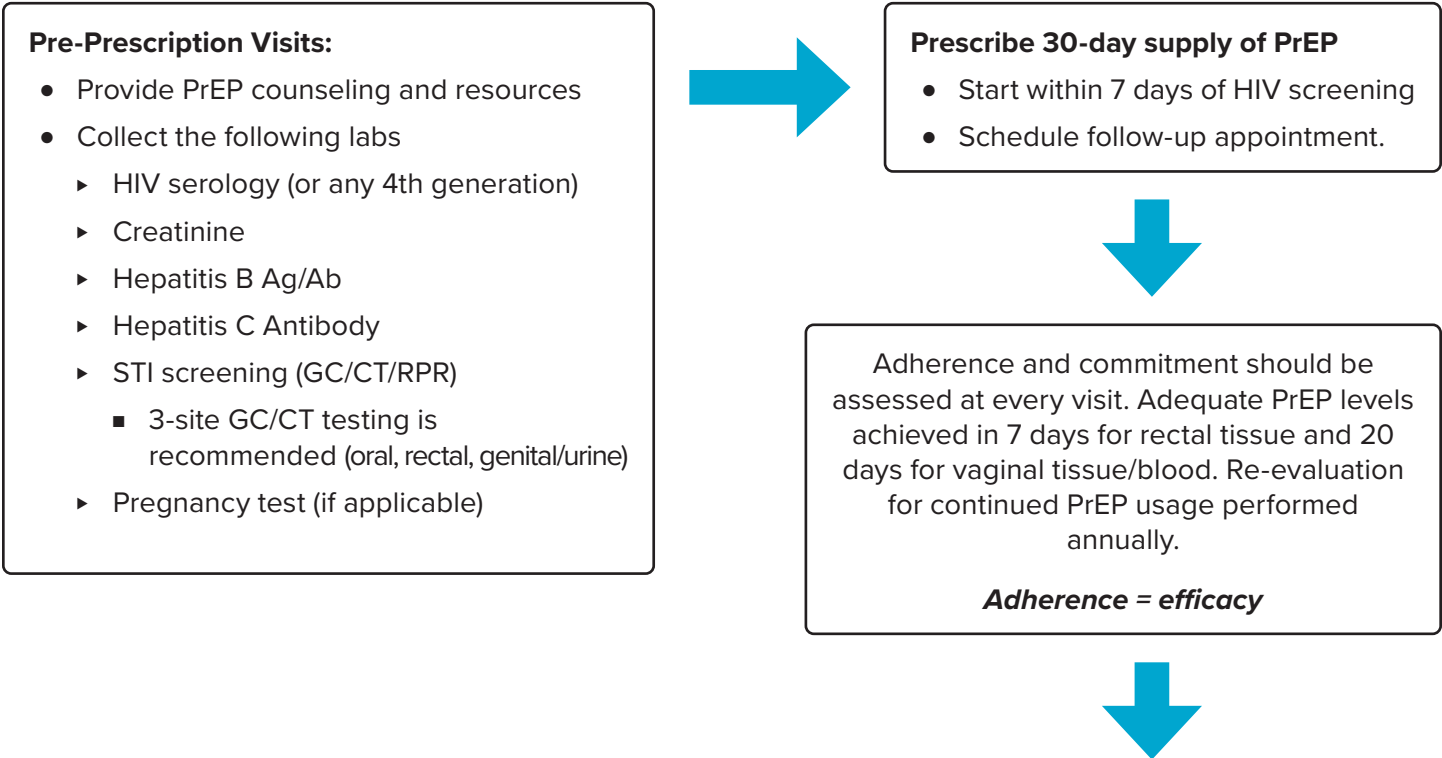
- EvaluationWeb- Prevention grantees
- PrEP QA Monitoring Tool

Non-DHEC funded agencies (providers) can utilize the PrEP QA Monitoring tool to report PrEP data. Please submit report by the 15th of each month to preventionreports@dhec.sc.gov.

IX. Clinical Support and Resources

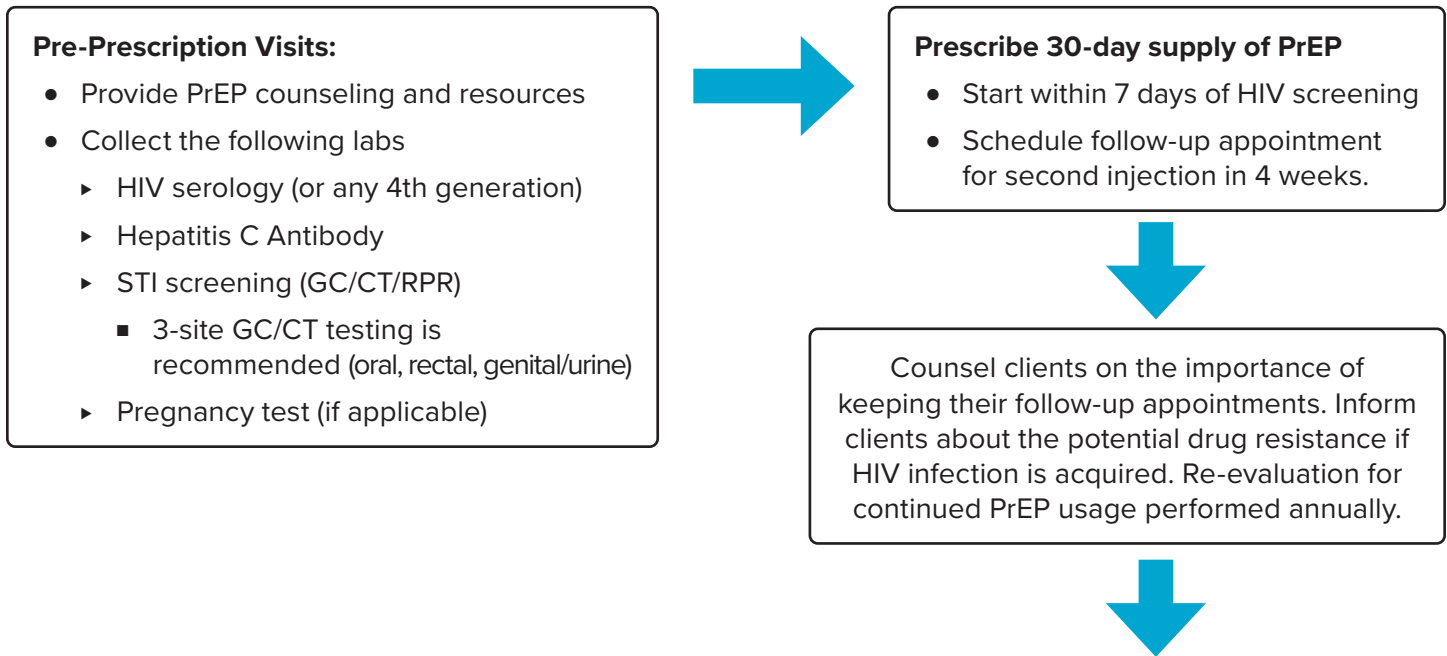
1. **DHEC STD/HIV/VH Division**
Nurse Practitioner, PrEP Program Manager
803-898-3939
PrEPMeSC@dhec.sc.gov
2. **Clinician Consultation Center PrEPLine**
1-855-448-7737
Clinicians are available Monday through Friday, 9 a.m. – 8 p.m. EST
3. **University of South Carolina Telehealth**
803-545-5402
schivtc.med.sc.edu
4. **The Southeast AIDS Education & Training Center Program**
seaetc.com

X. Quick Provider Reference for Oral HIV Pre-Exposure Prophylaxis (PrEP)



30-day Follow-up visit Rx- 60-day supply	Assess for side effects
	Serum creatinine
	Assess for signs and symptoms of acute HIV infection.
	Adherence and risk reduction counseling. Provide condoms
3-month visit Rx- 90-day supply	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	Serum creatinine (if not performed at 30-days)
	Adherence and risk reduction counseling. Provide condoms
6-month visit Rx- 90-day supply	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	Adherence and risk reduction counseling. Provide condoms.
	Serum creatinine
9-month visit Rx- 90-day supply	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	Adherence and risk reduction counseling. Provide condoms.
12-month visit Rx- 90-day supply	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	HCV serology for MSM, IDUs, and those with multiple sex partners
	Serum creatinine and Lipid panel (F/TAF)
	Adherence and risk reduction counseling. Provide condoms.
	Assess for continued PrEP usage

XI. Quick Provider Reference for Injectable HIV Pre-Exposure Prophylaxis (PrEP)



30-day Follow-up visit Rx- 8-week injection	Assess for side effects
	HIV-1 RNA test
	Assess for signs and symptoms of acute HIV infection.
	Risk reduction counseling. Provide condoms
2-month visit Rx- 8-week injection	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	HIV-1 RNA test
	Risk reduction counseling. Provide condoms
4-month visit Rx- 8-week injection	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	HIV-1 RNA test
	Risk reduction counseling. Provide condoms
6-month visit Rx- 8-week injection	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	HIV-1 RNA test
	Risk reduction counseling. Provide condoms
8-month visit Rx- 8-week injection	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	HIV-1 RNA test
	Risk reduction counseling. Provide condoms
12-month visit Rx- 8-week injection	HIV and STI (GC/CT/RPR) testing (3-site for GC/CT testing recommended)
	HIV-1 RNA test
	Risk reduction counseling. Provide condoms
	Assess for continued PrEP usage.

XII. References

1. Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published 2021.
2. Truvada (emtricitabine and tenofovir disoproxil fumarate) [package insert] Foster City, CA: Gilead Sciences, Inc.; 2018. https://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdf
3. Descovy (emtricitabine and tenofovir alafenamide tablets) [package insert] Foster City, CA: Gilead Sciences, Inc.; revised 2019. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf
4. Apretude (cabotegravir extended-release injectable suspension) [package insert] Research Triangle Park, NC: Viiiv Healthcare; 2021. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF.

Additional Resources can be found at:

Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33.

<https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>.

Published May 2022. Accessed [September 21, 2022].

South Carolina Department of Health and Environmental Control. [South Carolina epidemiologic profile of HIV, AIDS, and sexually transmitted infections 2020](#). South Carolina Epidemiologic Profile of HIV, AIDS, and Sexually Transmitted Infections 2020. Accessed [September 21, 2022].

