**GLA HIV Pre-Exposure Prophylaxis (PrEP) Guidance**
(updated 1/19/23)

## Indications

Adult person without acute or established HIV infection **AND** in one of the following categories:

- Men who have sex with men (MSM) or heterosexual men and women who satisfy any of the following criteria:
  - History of inconsistent or no condom use
  - High number of sex partners in the past 6 months
  - Any sexually transmitted infection (STI) diagnosed or reported in past 6 months
  - Is in an ongoing sexual relationship with an HIV-positive partner not on suppressive antiretroviral therapy
  - Commercial sex work
- Injection drug users who satisfy any of the following criteria:
  - Any sharing in past 6 months of equipment or supplies used to prepare or inject drugs
  - Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
  - Risk of sexual acquisition (as above)

## Baseline laboratory tests/diagnostic procedures

- Documented negative HIV antigen/antibody test (standard HIV diagnostic test at GLA) and HIV RNA PCR (viral load) *within one week* prior to initiation
- Anion gap panel
- RPR, testing for gonorrhea and Chlamydia (including rectal and pharyngeal testing as appropriate)
- HBV surface antigen, core antibody, and surface antibody
- HCV antibody testing
- Pregnancy test (women of child-bearing age)
- Dexa scan in persons ≥ 50 years of age and risk factors for osteoporosis or history of pathologic fractures
- Lipid panel (for patients who will use TAF/FTC)
- Screen for acute HIV symptoms. If any signs/symptoms in previous month, may:
  - Retest antigen/antibody in one month and defer PrEP

  **OR**
  - Test viral load (HIV RNA PCR)
    - If detectable viral load: defer PrEP, refer to Infectious Diseases
    - If undetectable viral load **and** signs/symptoms present on day of blood draw: retest in one month, defer PrEP
    - If undetectable viral load **and** no signs/symptoms on day of blood draw: HIV-negative, may start PrEP

## Initial management

Approved medications:

TDF/FTC 300 mg/200 mg (Truvada) once daily

- Indicated for use in cis-gender and transgender women, injection drug users, and men who have sex with men

- **Not to be used in persons with estimated glomerular filtration rate (eGFR) <60 ml/min**
- **Caution in persons with osteopenia/osteoporosis**

TAF/FTC 25 mg/200 mg (Descovy) once daily

- Indicated for use at GLA in men who have sex with men **AND** have estimated creatinine clearance of estimated glomerular filtration rate (eGFR) <60 ml/min or osteopenia/osteoporosis
- TAF/FTC 25 mg/200 mg (Descovy) is **NOT** FDA approved for use to prevent HIV infection in cis-gender women whose sole risk is receptive vaginal intercourse or in persons whose only risk is injection drug use as there are no studies in these patient populations. High-risk individuals in these groups who are NOT candidates for Truvada should be referred for injectable PrEP (cabotegravir).
- Patients given TAF/FTC (Descovy) use should be counseled about weight gain and increased lipids while taking this regimen. These effects are not seen with TDF/FTC (Truvada).
- Drug interactions with TAF/FTC: rifamycins (rifampin, rifabutin), St. John's Wort

Cabotegravir (CAB) 600mg injection (Apretude) every 2 months (after initial injections at 0 and 1 month)

- Indicated for use in persons at high risk for HIV and one of the following criteria:
  - Intolerance to Truvada or Descovy
  - CrCl <30 or multiple risk factors for significant renal dysfunction
  - Patient specific factors impacting adherence to daily oral PrEP (e.g. cognitive difficulties, gastrointestinal dysfunction, unstable housing, stigma)
  - Patient at very high risk for HIV acquisition
- Not to be used in persons with noncompliance to follow-up appointments
- Drug interactions with cabotegravir: Rifamycin derivatives (rifampin, rifabutin), UTG1A1 inducers (carbamazepine, oxcarbazepine, phenobarbital, phenytoin), St. John's Wort

Prescribing:

**Eligible patients can either be referred to the Infectious Disease service via or managed by primary care providers who have completed PrEP training (TMS course #36785). Patients interested in cabotegravir injection must be managed by the Infectious Disease service.**

TDF/FTC 300 mg/200 mg (Truvada) once daily

TAF/FTC 25 mg/200 mg (Descovy) once daily

- All visits dispense 90-day supply **without** refills
- 1st visit: Order anion gap panel and repeat HIV antigen/antibody test for patient to complete 1 month after initiating PrEP
- All visits: Order labs (anion gap panel, HIV antigen/antibody test, STI screen) for patient to complete prior to regular 3 month follow-up appointment

Cabotegravir (CAB) 600mg injection (Apretude) every 2 months (after initial injections at 0 and 1 month)

- REFER to Infectious Disease service

Counseling:

- Relationship of adherence to efficacy of PrEP
- Reducing risk behaviors
- Urgent evaluation if signs/symptoms acute HIV infection or AKI

TDF/FTC 300 mg/200 mg (Truvada) once daily

- Common side effects of Truvada are nausea, rash, headache, flatulence ("start-up" syndrome)
- Among persons living with HIV prescribed TDF-containing regimens there is long-term risk of decreases in renal function (there have been documented occasional cases of acute renal failure, including Fanconi's syndrome) and decreased bone mineral density

TAF/FTC 25 mg/200 mg (Descovy) once daily

- Clinical studies have shown that TAF/FTC is associated with increases in fasting lipids and 1-2kg weight gain compared to TDF/FTC.

Cabotegravir (CAB) 600mg injection (Apretude) every 2 months (after initial injections at 0 and 1 month)

- Injection site pain

**Follow-up and monitoring (oral PrEP)**

Every 3 months

- Assess and reinforce adherence to medication, safer sexual practices, and laboratory follow-up
- Repeat HIV testing
- Assess for acute infection and other STI
- Conduct STI testing if high-risk (i.e. frequent STIs or suspected recent exposure)
- Assess side effects, adherence, risk behaviors
- Monitor renal function (anion gap panel) in patients with risk factors for renal disease (e.g., hypertension, diabetes)
- Repeat pregnancy testing for women who may become pregnant
- May prescribe 90 day supply **without** refills

Every 6 months

- Monitor renal function (anion gap panel) in patients without risk factors for renal disease
- Conduct STI testing (RPR, gonorrhea, Chlamydia)

Every 12 months

- Evaluate need to continue PrEP as component of HIV prevention
- Repeat HCV antibody test
- Repeat lipid panel if on TAF/FTC

**Criteria for change in therapy or discontinuation of PrEP**

TOXICITY:

- Truvada (TDF/FTC) should be discontinued in the following circumstances
  - eGFR is consistently (or significantly) below 60 ml/min
  - Development of osteopenia or osteoporosis

  NOTE: see the section on initial management for considerations regarding substituting Descovy for Truvada for patients who meet the above safety criteria for stopping Truvada
- Descovy (TAF/FTC) should be discontinued in the following circumstances
  - eGFR is consistently (or significantly) below 30 ml/min
  - Progression of osteopenia or osteoporosis

NONCOMPLIANCE:

- PrEP should be discontinued in patients who are non-compliant with two or more follow-up visits per year. PrEP can be resumed if compliance issues are satisfactorily addressed

HIV INFECTION:

- If HIV testing is positive, PrEP should be immediately stopped and the patient should be referred to Infectious Diseases for consideration of rapid start of anti-retroviral therapy.

NOTE: whenever PrEP is discontinued, the following should be documented

- HIV status at time of discontinuation
- Reason for PrEP discontinuation
- Recent medication adherence and reported sexual risk behavior