

PRESCRIBING

PrEP

Pre-Exposure Prophylaxis (PrEP) is recommended as an HIV prevention option for anyone with risks of acquiring HIV infection through sex or drug use.



PrEP INDICATIONS

Discuss PrEP with all sexually active adults and adolescents. Prescribe if requested, even if person denies HIV risk factors (unless contraindicated).

PrEP is recommended for anyone with:

- Condomless vaginal or anal sex with a partner of unknown HIV status
- HIV-positive sex partner (especially if partner's HIV viral load is detectable or unknown)
- A recent bacterial sexually transmitted infection (STI) (gonorrhea/chlamydia/syphilis)

- Injection drug use with sharing of needles/equipment
- Any survival/transactional sex
- Desire to conceive with a partner who is HIV-positive

CONTRAINDICATIONS

- HIV infection
- Weight < 77 lbs
- Estimated creatinine clearance (eCrCl) < 60 mL/min for TDF/FTC or < 30 mL/min for TAF/FTC
- Possible HIV exposure within the past 72 hours: instead offer nPrEP, then consider PrEP. (*PEPline: 888-448-4911*)

WHAT TO PRESCRIBE

Daily Oral PrEP

- Tenofovir disoproxil fumarate/emtricitabine (TDF/FTC, Truvada, or generic equivalent)
 - 300 mg/200 mg, 1 tab orally (PO) daily, #30, 2 refills for a total supply of not more than 90 days
- OR**
- Tenofovir alafenamide/emtricitabine (TAF/FTC, Descovy)
 - 25 mg/200 mg, 1 tab PO daily, #30, 2 refills for a total supply of not more than 90 days
 - Not recommended as PrEP by those at risk from receptive vaginal sex

On-Demand or 2-1-1 Oral PrEP: Alternative for men who have sex with men (MSM) who have sex infrequently

TDF/FTC (Truvada or generic equivalent)

- 300 mg/200 mg, #30 with 0 refills (test for HIV before refill)
- 2-1-1 PrEP dosing:
 - 2 tabs PO taken 2-24 hours prior to having sex, then
 - 1 tab PO 24 hours after first 2 tabs taken, then
 - 1 tab PO 48 hours after first 2 tabs taken

- Continue 1 tab PO daily until 48 hours after last sexual encounter

Injection PrEP

- Cabotegravir (CAB, Apretude) 600 mg IM (gluteal muscle)
 - (optional: CAB 30 mg PO daily x 30 days as oral lead-in before 1st injection)
 - initial dose, 2nd dose 1 month after 1st dose, then every 2 months

POSSIBLE SIDE EFFECTS

Oral PrEP (TDF/FTC, TAF/FTC)

- Nausea, diarrhea, or headache; usually mild and resolves within 1 month
- Renal dysfunction; typically reversible if PrEP is stopped (risk greater with TDF)
- Slight (1%) loss of bone mineral density over 1 year; no increased risk of fractures (risk greater with TDF)
- TAF: possible weight gain

Injection PrEP (CAB)

- Injection site reactions

CAUTIONS

- Symptoms of possible acute HIV (e.g., flu-like illness); defer PrEP and evaluate immediately for acute HIV, including HIV RNA testing
- Be aware of local policies related to minors and HIV prevention/treatment
- Drug interactions: See product Prescribing Information

Oral PrEP (TDF/FTC, TAF/FTC)

- Hepatitis B (HBV) infection can flare after stopping PrEP medications; check for HBV infection before starting PrEP
- Chronic kidney disease (CKD) or significant risk of CKD
- Osteoporosis

Injection PrEP (CAB)

- Not studied for persons age < 18, not recommended
- Pregnancy/breastfeeding: discuss benefits/possible risks

LAB SCREENING AND VISITS

Assessment and counseling: At each follow up visit: assess for signs/symptoms of acute HIV; assess and support adherence and HIV risk and risk-reduction behaviors; assess and manage adverse effects; conduct contraception/conception counseling as appropriate.

Baseline labs

- **All:** HIV test within 1 week before starting PrEP (ideally HIV Ag/Ab)
- HIV RNA (if possibly infected within the past 2-4 weeks)
- STI testing: gonorrhea/chlamydia (throat, rectum, and genital/urine screening according to sites of exposure), syphilis, hepatitis C (HCV) Ab, consider hepatitis A IgG.
- **Oral PrEP:** creatinine (for estimated CrCl), hepatitis B (HBV) sAb/cAb/Ag. For TAF/FTC: cholesterol and triglycerides.

Laboratory tests: Oral PrEP

- 1 month (appropriate in some cases to ensure patient is still HIV uninfected), then at least every 3 months: HIV Ag/Ab, HIV RNA, screen for STIs (see Baseline list), pregnancy test
- Every 6 months: CrCl for persons age \geq 50 or eCrCl < 90
- Every 12 months: cholesterol and triglyceride levels. HCV Ab for MSM, transgender women, people who inject drugs.

Laboratory tests: Injection PrEP

- 1 month: HIV RNA
- Every 2 months: HIV Ag/Ab and HIV RNA. Pregnancy test as appropriate
- Every 4 months: HIV RNA, STI testing (see Baseline list)

Follow up visits: Oral PrEP

- 1 week: Call, check if prescription filled, assess adherence and side effects
- 1 month (optional)
- At least every 3 months

Follow up visits: Injection PrEP

- 1 month (at time of 2nd injection)
- Every 2 months (timed with subsequent injections)

COUNSELING TOPICS

- Importance of close adherence
- STI and HIV prevention, i.e., condom use/risk reduction
- Safer injection drug use practices
- Need for regular follow-up visits and lab tests
- Reproductive goals/contraception
- Symptoms of acute HIV infection
- Risks of stopping (e.g., HIV infection) and cautions for re-starting (need for HIV testing, risk of inadequate treatment if HIV infected). For oral PrEP: flare of HBV (if infected). For CAB: slow decline in CAB levels after stopping (risk of CAB resistance if infected with HIV during this time).
- CAB: see product Prescribing Information for management of planned or unplanned late injections
- Insurance/medication assistance
- Procedures for refills

KEY MESSAGES

- When used as directed and with close adherence, PrEP is highly effective for preventing HIV (> 90%).
- With daily TDF/FTC, maximum blood and rectal tissue drug levels are reached after 7 days and in vaginal tissue after 20 days. For TAF/FTC and CAB, no data on time to protective drug levels are available.
- If planning to stop daily PrEP, continue for 28 days after last potential HIV exposure.
- PrEP does not prevent infection with gonorrhea, chlamydia, syphilis, genital warts, herpes, or hepatitis A, B, C viruses.
- PrEP does not prevent pregnancy.
- If a potential high-risk HIV exposure occurs while NOT on PrEP, start nPEP (within 72 hours) for 28 days, then restart PrEP if still HIV Ag/Ab negative.

RESOURCES AND REFERENCES

- **National Clinician Consultation Center PrEPline** (855) 448-7737 or <https://nccc.ucsf.edu> Monday – Friday, 9:00 a.m.– 8:00 p.m. ET
- CDC, US Public Health Service: **Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update.** <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. December 2021.
- **AETC Program PrEP Toolkit:** <https://aidsetc.org/prep>

