

PRESCRIBING PrEP



Pre-Exposure Prophylaxis (PrEP) is recommended as a HIV prevention option for anyone with reasons for acquiring HIV through sex or drug use.

PrEP INDICATIONS

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

PrEP is recommended for anyone:

- Having condom-less vaginal or anal sex with a partner who has an unknown HIV status,
- With a HIV-positive sex partner (especially if partner's HIV viral load is detectable or unknown),
- With a recent bacterial sexually transmitted infection (STI),
- Using injection drugs and sharing needles and/or equipment,
- Having survival and/or transactional sex, and/or
- Seeking to get pregnant with sex partner who is HIV-positive.

CONTRAINDICATION

- Living with HIV/AIDS
- Weight < 77 lbs.
- Estimated creatinine clearance (eCrCl) < 60mL/min for TDF/FTC or < 30 mL/min for TAF/FTC
- Possible HIV exposure within the past 72 hours: **instead** offer nPEP, then consider PrEP following the completion of the nPEP regimen.

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 for those whose reason is having 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) can flare after stopping PrEP medications; test for HBV 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, evaluate for signs/symptoms of acute HIV;
 - Assess and support adherence, HIV risk and risk-reduction behaviors; assess and manage adverse effects; conduct contraception and/or conception counseling, as appropriate.

Baseline Lab Work

- ALL: HIV test within 1 week before starting PrEP (ideally HIV Ag/Ab test)
 - HIV RNA (if possibly contracted HIV within the past 2-4 weeks)
 - STI tests: gonorrhea and chlamydia (throat, rectum, genital and/or urine screening, based on sites of exposure), syphilis, hepatitis C (HCV) Ab and consider hepatitis A IgG.
- Oral PrEP: creatinine (for estimated CrCl), hepatitis B (HBV) sAb/cAb/Ag. For TAF/FTC: cholesterol and triglycerides.
- Labs - Oral PrEP:
 - 1 month (appropriate in some cases to ensure patient is HIV-negative), then at least every 3 months: HIV Ag/Ab, HIV RNA, screen for STIs (see Baseline list) and pregnancy test
 - Every 6 months: CrCl for persons age ≥ 50 or eCrCl < 90
 - Every 12 months: cholesterol and triglyceride levels. HCV Ab for MSM, transgender women and people who inject drugs.
- Labs - 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, e.g., condom use, reduce risk - safer injection drug use practices
- Need for regular follow-up visits and lab tests
- Reproductive goals and/or contraception
- Symptoms of acute HIV infection
- Risks of stopping PrEP (e.g., HIV infection) and cautions for restarting (need for HIV testing, potential for inadequate treatment, if HIV-positive). For oral PrEP: flare of HBV (if positive). For CAB: slow decline in CAB levels after stopping (risk of CAB resistance if living 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: **Pre-Exposure 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>

For more information:
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