PrEP: Preexposure Prophylaxis for HIV Prevention - RD 17

DEFINITION

Preexposure prophylaxis for HIV prevention (PrEP) in the United States includes a fixed-dosage, daily oral combination medication of either tenofovir disoproxil fumarate/emtricitabine (F/TDF) or tenofovir alafenamide/emtricitabine (F/TAF) to reduce the risk of acquiring HIV infection in adults (≥ 18). F/TAF is approved for use by men and transgender women and not for women at risk through receptive vaginal intercourse.
Additionally in December 2021, the FDA approved cabotegravir an IM injectable PrEP medication. Cabotegravir may be considered for those patients with significant renal disease or those who have difficulty with daily adherence of oral PrEP. When combined with other prevention strategies, PrEP provides additional protection from acquiring HIV infection. All sexually active adults and adolescents (age 15 or greater), and all individuals at risk for HIV acquisition through non-sterile injection drug use practices, should be informed about PrEP.

SUBJECTIVE

Should include:
1. Sexual history; HIV risk assessment
    a. Anal or vaginal sex in the past 6 months AND any of the following:
        i. HIV-positive sexual partner (especially if viral load is unknown or detectable)
        ii. Bacterial STI in the past 6 months
        iii. History of inconsistent or no condom use
2. Social history; alcohol use disorder, use of illicit non-injection drugs, HIV-positive injecting partner OR sharing injection equipment, non-sterile injection behaviors
3. Medical history and medication reconciliation to evaluate potential contraindicated medications
4. Willingness to RTC Q 3 months for follow up testing and medication refills
5. Reproductive life plan; pregnancy intentions

Should exclude:
1. non-specific symptoms of a viral infection indicating potential recent HIV infection during preceding month or on the day of evaluation including fever, fatigue, myalgia, skin rash, headache, pharyngitis, swollen lymph nodes, arthralgia, night sweats or diarrhea

OBJECTIVE

Should include:
1. Vital signs
2. Height/weight/BMI; Weight greater than 77#
3. Objective focused physical exam must exclude signs and symptoms of acute HIV infection; (i.e. fever, skin rash, lymphadenopathy, pharyngitis)

May include:
1. Documentation of Hep B vaccination series
2. Age-appropriate physical exam

LABORATORY

Should include:
1. HIV test within the week before starting medication and every 3 months thereafter accomplished by 1) draw blood and send specimen to a lab for an antigen/antibody test or antibody only test or 2) performing a rapid point-of-care, FDA approved, finger stick Ag/Ab blood test. Rapid oral tests should not be used. If prescribing Cabotegravir IM injection an HIV RNA assay is required within one week of initiating therapy.
2. HBsAg screening serology at initiation of therapy

3. Estimated CrCl of ≥ 30 ml/min for use of F/TAF; ≥60 ml/min for F/TDF: calculated with serum creatinine using Cockcroft-Gault formula at initiation, Q 6 months if age ≥50 or eCrCl <90 ml/min at PrEP initiation and q12 months if age <50 and eCrCl ≥90 ml/min at PrEP initiation.
4. Negative pregnancy test if female
5. HCV test for MSM (men who have sex with men), TGW (transgender women), and PWID (person who inject drugs) at initiation and Q12 months after
6. Lipid panel if prescribing F/TAF at initiation and Q12 months thereafter
7. STI testing for gonorrhea, chlamydia and syphilis

ASSESSMENT

Candidate for PrEP

PLAN

Initial visit:

1. Provide 90-day prescription tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg (brand name Truvada) 1 tablet po daily after required lab values are known, within one week of HIV testing.
   a. For men and transgender women, may consider oral, daily dosing, of F/TAF (brand name Descovy); provide 90-day prescription. F/TAF is indicated for patients who eCrCl ≤60 ml/min but ≥30 ml/min. Dosage 200mg/25mg, once per day.
   b. May consider prescription of Cabotegravir IM injection PrEP; 600 mg administered as one 3 mL IM injection in gluteal muscle at initial visit; second dose is 4 weeks after first dose; then, every 8 weeks thereafter. 30 mg daily oral cabotegravir is optional for 4-week lead-in prior to IM injections.
2. Initiate HPV, Hep B series and Hep A vaccination with patients that are identified as being susceptible infection (see addended table)
3. Counseling/education as outlined in Client Education
4. Advise client of the need to follow up for assessment, required lab work and refill of prescription.

ORAL PrEP:

(See Table 1a on page 15 of Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline)

Follow up every three months is required for continued prescription:

1. HIV testing; Ag/Ab test or HIV-1 RNA assay
2. Physical exam as indicated; bacterial STI screening for MSM and transgender women who have sex with men
3. Assessment of medication compliance/side effects
4. Required lab work as outlined in lab section
5. Review education on safer sex practices; behavioral risk reduction support

Follow up every six months:

1. Assess renal function for patients age ≥50 or who have eCrCl <90 ml/min at time of initiation
2. Bacterial STI screening for all sexually active patients
3. Syphilis screening

Follow up every twelve months:

1. Assess renal function for all patients
2. Assess weight, triglyceride and cholesterol levels for patients taking F/TAF
3. HCV serology for MSM, TGW and PWID

When stopping oral PrEP:

1. HIV test
2. eCrCL
3. Syphilis, chlamydia and gonorrhea test for MSM and TGW

INJECTION PrEP (Cabotegravir) (not currently available with ND STD/HIV program):

(See Table 1b on page 16-17 of Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline)

Follow-up visit 1-month after initial injection
1. HIV testing; Ag/Ab test and HIV-1 RNA assay

Follow-up visits every two months (beginning with third injection)
1. HIV testing; Ag/Ab test and HIV-1 RNA assay
2. bacterial STI screening for MSM and transgender women who have sex with men

Follow-up visits every six months (beginning with the fifth injection)
1. Bacterial STI screening for all heterosexually active women and men
2. Syphilis screening

Follow-up visits at least every 12 months after initial injection:
1. Assess desire to continue injections for PrEP
2. Chlamydia screening for heterosexually active women and men

Follow-up visits when discontinuing injections:
1. Provide education and "tail" of discontinuing cabotegravir and the risks during declining levels; risk of developing drug-resistant HIV if infection acquired during that time
2. Assess ongoing HIV risk; prevention plans
3. If PrEP is indicated, prescribe daily oral regimen beginning within 8 weeks after last injection
4. Continue HIV testing quarterly for 12 months

CLIENT EDUCATION

1. Inform client of the need to RTC as indicated for follow-up visits and lab analysis Medication adherence counseling
2. Potential medication side effects, per CDC clinical practice guidelines
3. Use of OTC products for GI side effects and headache, or injection site reactions
4. Safer sex education (see protocol)
5. Reproductive life plan (see protocol)
6. Harm-reduction services (clean needle exchange program)
7. Education regarding use of PrEP in pregnancy if indicted

CONSULT / REFER TO PHYSICIAN

1. Active HIV infection
2. Active Hepatitis B infection
3. Active HCV infection
4. Renal dysfunction
5. Person with a history of pathologic or fragility bone fractures or who has signs or risk factors of osteoporosis.
6. Women who become pregnant on PrEP
7. Breastfeeding Women
8. Individuals under the age of 18
9. Appropriate substance-use treatment resources, mental health services

REFERENCES

1. U.S. Centers for Disease Control and Prevention. (2024). *Preventing HIV with PrEP*. Retrieved from https://www.cdc.gov/hiv/prevention/prep.html
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3. Malcolm, N.,Marx, K.,Hart, J.,Rollison, J.,Erickson, C.,Hall, C.,Johnson, D. & Moskosky, S. (2019). *Decision-making guide for the provision of PrEP services in title X-funded family planning service sites*. Rockville, MD: U.S. Department of Health and Human Services, Office of Population Affairs. Retrieved from https://opa.hhs.gov/sites/default/files/2020-07/OPA-PrEP-Decision-Guide_0.pdf

4. U.S. Centers for Disease Control and Prevention. (2021). *Preexposure prophylaxis for the prevention of HIV infection in the united states – 2021 update: Clinical practice guideline*. Retrieved from https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf