Monitoring Patients on PrEP

Monitoring patients on daily oral PrEP

- Follow-up visits at least every 3 months:
  - HIV Ag/Ab test and HIV-1 RNA assay*, medication adherence and behavioral risk reduction support
  - Bacterial STI screening for MSM and transgender women who have sex with men – oral, rectal, urine, blood
  - Access to clean needles/syringes and drug treatment services for PWID

- Follow-up visits every 6 months:
  - Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation
  - Bacterial STI screening for all sexually-active patients – vaginal, oral, rectal, blood, as indicated

- Follow-up visits every 12 months:
  - Assess renal function for all patients
  - Chlamydia screening for heterosexually active women and men – vaginal, urine
  - For patients on FTC/TAF, assess weight, triglyceride and cholesterol levels

Monitoring patients on injectable PrEP

- At follow-up visit 1 month after first injection:
  - HIV Ag/Ab test and HIV-1 RNA assay*

- At follow-up visits every 2 months:
  - HIV Ag/Ab test and HIV-1 RNA assay*
  - Access to clean needles/syringes and drug treatment services for PWID

- At follow-up visits every 4 months:
  - Bacterial STI screening for MSM and transgender women who have sex with men – oral, rectal, urine, blood

- At follow-up visits every 6 months:
  - Bacterial STI screening for all sexually-active patients – vaginal, oral, rectal, blood, as indicated

- At follow-up visits at least every 12 months (after the first injection) provide the following:
  - Chlamydia screening for heterosexually active women and men – vaginal, urine

- At follow-up visits when discontinuing cabotegravir:
  - Re-educate patients about the “tail” and the risks during declining CAB levels
  - Assess ongoing HIV risk and prevention plans
  - If PrEP is indicated, prescribe daily oral FTC/TDF or FTC/TAF beginning within 8 weeks after last injection
  - Continue follow-up visits with HIV testing quarterly for 12 months

*Consider only ordering HIV Ag/Ab test if HIV-1 RNA is not routinely covered by insurance in patients without HIV in your state.

Key: CAB = cabotegravir; eCrCl = estimated creatinine clearance; FTC = emtricitabine; HIV = human immunodeficiency virus; MSM = men who have sex with men; PrEP = pre-exposure prophylaxis; PWID = persons who inject drugs; STI = sexually transmitted infection; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate

Goals for treatment:

- Prevent the acquisition of HIV infection
- Provide HIV risk-reduction support and prevention services
- Provide (or refer for) effective contraception to persons with childbearing potential who do not wish to become pregnant
- Monitor patients to detect HIV infection, medication toxicities, and levels of risk behavior in order to make indicated changes in strategies to support patients’ long-term health

Indications for PrEP:

- Sexually active adults and adolescents:
  - Anal or vaginal sex in past 6 months AND any of the following:
    - HIV-positive sexual partner
    - Bacterial STI in past 6 months
    - History of inconsistent or no condom use

- Persons who inject drugs AND any of the following:
  - HIV-positive injecting partner
  - Sharing injection equipment

- Discuss PrEP with all sexually active patients and patients who use drugs and prescribe to anyone who requests it

Taking a sexual history:

A sexual history allows you to provide high-quality patient care by appropriately assessing and screening individuals for a broad range of sexual health concerns. Prior to starting dialogue, explain to patient why you are taking a sexual history, and ask if they are okay with you asking them these questions. Consider using the five “P”s to guide your dialogue with your patient about their sexual history:

- Partners
- Practices
- Protection from STIs
- Past history of STIs
- Pregnancy Intentions

For more information on how to take a sexual history and for examples of dialogue, visit the CDC website at the QR code to the right.

Candidates for PrEP

For more information on how to take a sexual history and for examples of dialogue, visit the CDC website at the QR code to the right.

This conference is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $4,067,580 with zero percentage financed with nongovernmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS or the U.S. Government.

June 2023
Baseline Laboratory Requirements

Baseline laboratory testing should include the following:

- HIV Test
- Renal panel
- Syphilis
- Chlamydia
- Gonorrhea
- Lipid panel (for those starting treatment with FTC/TAF)
- Hep B Serology
- Hep C Serology

Assess for Acute HIV Infection:

<table>
<thead>
<tr>
<th>Result</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive (positive)</td>
<td>Send plasma for HIV antibody/antigen plasma test lab (preferred) with reflex confirmation OR blood rapid test</td>
</tr>
<tr>
<td>Nonreactive (negative)</td>
<td>Indeterminate</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>HIV-1 RNA ≥ 200 copies/mL</td>
</tr>
<tr>
<td>HIV-1 RNA detectable but &lt;200 copies/mL</td>
<td>HIV-1 RNA &lt; level of detection with signs/symptoms of acute infection on day of test</td>
</tr>
<tr>
<td>HIV-1 RNA &lt; level of detection and no signs/symptoms of acute infection</td>
<td>Eligible for PrEP</td>
</tr>
<tr>
<td>HIV-1 RNA ≥ 200 copies/mL</td>
<td>Not eligible for PrEP</td>
</tr>
</tbody>
</table>

Source: Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2021 Update. CDC

**Treatment Options**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Prevention Option</th>
<th>Dosage</th>
<th>Time to Tissue Penetration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexually active males or females and persons who inject drugs</td>
<td>Emtricitabine/tenofovir disoproxil fumarate</td>
<td>Oral: 7 days Vaginal: 20 days</td>
<td></td>
</tr>
<tr>
<td>Sexually active males or transgender females</td>
<td>Emtricitabine/tenofovir alafenamide</td>
<td>unknown</td>
<td></td>
</tr>
<tr>
<td>Sexually active males or females and persons who inject drugs*</td>
<td>Long-acting cabotegravir</td>
<td>unknown</td>
<td></td>
</tr>
</tbody>
</table>

*Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated.

**Eligibility Criteria**

- HIV negative
- No signs of acute HIV infection
- eCrCl ≥ 60 ml/min

**Dosage**

- Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg PO daily
- Emtricitabine 200 mg/tenofovir alafenamide 25 mg PO daily
- Optional: cabotegravir 30 mg PO daily
- 600 mg (3 mL) IM cabotegravir administered in the gluteal muscle
  - Second dose 4 weeks after first dose
  - Every 8 weeks thereafter

**Clinically Eligible**

- HIV negative
- No signs of acute HIV infection
- eCrCl ≥ 30 ml/min

**Prevention Option**

- Emtricitabine/tenofovir disoproxil fumarate
- Emtricitabine/tenofovir alafenamide
- Long-acting cabotegravir