trchealthcare

HIV Pre-Exposure Prophylaxis (PrEP)

Updated May 2025

Use this checklist to identify high-risk patients and safely prescribe and monitor HIV PrEP therapy.

1 Identify potential candidates.

- Talk about HIV PrEP with ALL sexually active adults and adolescents.[3] About 14% of people with HIV in the US and Canada are unaware that they are infected.[2,11]
- Be aware of high-risk activities (realizing that not all patients will openly share this information), including:[2,14,23]
  - having condomless sexual activity with multiple partners, especially men who have sex with men.
  - having condomless sexual activity with an HIV positive person (or whose HIV status is unknown) who is not on treatment or has a high viral load.
  - recent (within the previous six months) IV drug use, especially if sharing needles.
  - recent (within the previous six months) STIs (e.g., chlamydia, syphilis, gonorrhea).
  - having medical procedures in regions where HIV is endemic.

2 Screen potential candidates.

- Look for signs and symptoms of acute HIV infection (e.g., fever, night sweats).[1,14]
- Document a negative laboratory (preferred) antibody/antigen plasma HIV test and/or HIV-1 RNA assay.[1,14,15]
  - If suspicion is high for an acute HIV infection, repeat the HIV test in about a month to confirm a negative result before prescribing PrEP.[1]
  - All formulations used for PrEP carry boxed warnings for the development of drug-resistant HIV when used in HIV-positive patients.[1,8,9,20,27]
  - Note that testing recommendations differ if patients have recently been on PrEP or post-exposure prophylaxis (PEP) (three months for oral PrEP or PEP and twelve months for injectable cabotegravir).[15]
- Determine pregnancy and breastfeeding status and discuss risks and benefits.
- Screen for STIs, hepatitis B in all patients, and hepatitis C in high-risk patients.[1] (Note: data unavailable for PrEP with cabotegravir if coinfected with hepatitis B or C.[20,27])
- Complete other appropriate baseline monitoring (e.g., serum creatinine, lipids)

3 Be familiar with possible HIV **PrEP regimens**.

- Approved PrEP options for adults and adolescents ≥35 kg include:
  - **Truvada**, generics (emtricitabine [FTC] 200 mg/tenofovir disoproxil fumarate [TDF] 300 mg) orally once daily.[3,5,8,9] (In Canada, Truvada is only approved for use as PrEP in adults.[9])
  - **Descovy** (emtricitabine 200 mg/tenofovir alafenamide [TAF] 25 mg) orally once daily (select patient groups, see row "Consider high-risk behaviors").[3,19]
  - **cabotegravir** (Apretude) 600 mg IM (first two doses separated by four weeks, then continued every eight weeks; injected by a healthcare professional).[3](Note there is an optional four-week oral lead-in).[15,20,a]
- Usually consider an oral option as first-line PrEP (See considerations in the rows below).[15]
- Think of long-acting IM cabotegravir PrEP for patients who:[15]
  - have difficulty taking oral PrEP options.
  - prefer getting a shot every two months over taking daily oral PrEP.
  - have severe kidney impairment (CrCl <30 mL/min) (see row "Consider kidney function").

4 Consider **high-risk behaviors** when choosing a PrEP regimen.

- Truvada is a recommended PrEP option regardless of high-risk behaviors due to extensive experience, proven efficacy, and tolerability.[21]
- **Males or transgender females who have sex with males**:
  - IM cabotegravir has been shown to be more effective than Truvada in males, females, and transgender females who have sex with males.[4,26] Note that this difference in efficacy may be due to lack of adherence with oral regimens.[21]
- **Receptive vaginal sex**: Descovy is NOT approved for PrEP in this group due to lack of data.[17,18]
- **IV drug use**: Truvada is the preferred PrEP regimen, due to lack of data with Descovy and IM cabotegravier.[21]

5 Consider **kidney function** when choosing regimen.

- Ensure CrCl is:[5,8,9,15,17,18]
  - ≥60 mL/min (Truvada, when used for PrEP) OR ≥30 mL/min (Descovy)
- Consider IM cabotegravir in non-dialysis patients with severely impaired kidney function (CrCl ≥15 to <30 mL/min).[15,20,27]

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6 Consider **pregnancy and breastfeeding** status.

- Experts recommend use of Truvada as PrEP in pregnant or breastfeeding patients at high risk of HIV who have receptive vaginal sex, due to known safety and efficacy.[24]
- Human data are lacking to evaluate the dosing, efficacy, and safety of Descovy or IM cabotegravir in patients who are pregnant or breastfeeding and their use is not recommended.[17,18,24]
  - If patients taking IM cabotegravir become pregnant, the limited safety data and long half-life should be discussed during shared decision making with the patient to determine options. Expert consultation should be considered. Patients should be registered with the Antiretroviral Pregnancy Registry (US).[24]

7 **Consider** drug-drug **interactions**.

- Consider using the Liverpool HIV Drug Interactions website (https://www.hiv-druginteractions.org/checker) or HIV/HCV Drug Therapy Guide website (https://hivclinic.ca/app/#drugInt) to screen for drug-drug interactions.
- There may be an increase in tenofovir levels (and therefore adverse effects) when **Truvada** is used with certain hepatitis C meds (e.g., ledipasvir/sofosbuvir [Harvoni], velpatasvir formulations [Epclusa, Vosevi]).[8,9]
- Drugs that significantly induce uridine diphosphate glucuronosyltransferase (UGT) 1A1 (e.g., carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine) are **contraindicated with cabotegravir** due to decreased levels of cabotegravir.[20,27]
- Several meds (e.g., tipranavir/ritonavir, carbamazepine, phenobarbital, rifampin, St. John's wort) can decrease **tenofovir alafenamide** levels, possibly reducing PrEP effectiveness. Coadministration with Descovy is not recommended.[17,18]
- Emtricitabine and tenofovir are both excreted by the kidneys by (in part) active tubular secretion. Interactions with other meds excreted via active tubular secretion (e.g., acyclovir, cidofovir, gentamicin, high-dose or multiple nonsteroidal anti-inflammatory drugs [NSAIDs]) have not been observed; however, there is a risk of increased adverse effects with emtricitabine, tenofovir, or the interacting med, when used together, especially if there is kidney dysfunction.[8,9,17,18,22]

8 Consider **cost**. (See step 13, "Help patients afford PrEP.")

- Without insurance, PrEP costs:[b]
  - Truvada: US ~ $1,840 (brand) or ~ $30 (generic); Canada ~ $915 (brand) or ~ $475 (generic) for one month.
  - Descovy: ~ $2,200 (US); ~ $845 (Canada) for one month.
  - Apretude: ~$4,025 (US); ~$1,850 (Canada) per dose.

9 Determine if **on-demand oral PrEP** is an option.

- Non-daily PrEP or on-demand PrEP may also be referred to as "event-driven" or "intermittent" PrEP.[15]
- On-demand Truvada (not an FDA- or Health Canada-approved indication) may be considered for men who have sex with men.[5,12,13,15] (No data for on-demand Descovy.[13])
- On-demand Truvada (200 mg/300 mg) can be complicated. Use "2-1-1" to help patients with on-demand dosing:[5,12,13,15]
  - 2: take two tablets two to 24 hours prior to sexual exposure (closer to 24 hours is preferred).
  - 1: take one tablet 24 hours after the first dose.
  - 1: take one tablet 48 hours after the first dose.
- If the interval between the last dose of a 2-1-1 regimen and the next sexual encounter is:[13]
  - <7 days: take one tablet daily (every 24 hours) until 48 hours after the last sexual encounter.
  - ≥7 days: use the 2-1-1 regimen as described above.

10 **Monitor** patients receiving **oral** PrEP.

- Patients receiving oral PrEP should be seen at least every 90 days. Recommended monitoring includes:
  - Every three months:[15]
    - check HIV status.
    - screen for bacterial STI in men and transgender women who have sex with men with certain risk factors (e.g., multiple sex partners) (screen all patients per Canadian guidelines.[5])
    - test sexually active patients with signs or symptoms of STIs.
    - assess medication adherence and drug-drug interactions (See the row above "Consider drug-drug interactions").
    - provide access to clean needles and drug treatment services (patients who inject IV drugs).
    - check pregnancy status (patients with potential to become pregnant).[24]

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10 **Monitor** patients receiving **oral** PrEP (continued).

- Every six months:[15]
  - assess kidney function for patients ≥50 years or with a CrCl <90 mL/min when PrEP was started (no specific recommendations in Canadian guidelines.[5]). Assess kidney function more often if there are additional risk factors.
  - screen for bacterial STI in all sexually active patients (every three months per Canadian guidelines.[5]).
- Every 12 months:[15]
  - assess kidney function for all patients (no specific recommendations in Canadian guidelines.[5])
  - screen for chlamydia in heterosexually active patients (not specifically addressed in Canadian guidelines.[5])
  - monitor weight, triglycerides, and cholesterol for patients taking Descovy PrEP (US).
  - screen for hepatitis C in patients at high-risk (e.g., patients who inject drugs, men who have sex with men).
- Bone mineral density decreases have been associated with tenofovir; however, monitoring is not necessary for most patients taking PrEP.[8,9,17,18]
  - Bone mineral density assessment may be considered for patients on Truvada with a history of fracture or with risk factors for osteoporosis.[8,9]
- Monitor liver function tests if patients become HIV positive and are coinfected with hepatitis B.
  - Stopping Descovy or Truvada in patients coinfected with hepatitis B and HIV can lead to acute hepatitis B exacerbations.[8,9,17,18]

11 **Monitor** patients receiving **IM cabotegravir** for PrEP.

- One month after the first injection: check HIV status.[15]
- Every two months (starting with the third injection [i.e., month 3 of therapy]):[15]
  - check HIV status
  - provide access to clean needles and drug treatment services for people who inject IV drugs
- Every four months (starting with the third injection [i.e., month 3 of therapy]):[15]
  - screen for bacterial STIs in men and transgender women who have sex with men.
- Every six months (starting with the fifth injection [i.e., month 7 of therapy]):[15]
  - screen for bacterial STIs in all heterosexually active patients.
- Every 12 months (starting one year after the first injection [i.e., month 13 of therapy]):[15]
  - evaluate patient's desire to continue cabotegravir for PrEP.
  - screen for chlamydia in heterosexually active men and women.
- When stopping IM cabotegravir, continue to check HIV status every three months for 12 months AND:[15]
  - discuss HIV prevention plans.
  - educate patients about the "tail" effect (i.e., slowly declining cabotegravir levels over many months) and the risk of developing drug-resistant HIV if the patient becomes infected with HIV during this time period.
  - start oral PrEP (if ongoing risk of HIV exposure) within eight weeks after the last cabotegravir injection.

12 **Counsel** patients.

- Tell patients who are initiating or restarting (e.g., after a hospital admission) oral PrEP how long it takes for drug levels to build up for maximal protection (i.e., ~7 days [rectal tissue], ~21 days [blood and vaginal tissue]).[1,3]
- Stress adherence. Missed doses are linked to reduced effectiveness.[1]
  - Oral Descovy or Truvada significantly reduce the risk of HIV [Evidence Level A-1] when taken on schedule.[1,12] For example, one case of HIV can be prevented by treating about 50 adults for four months to four years with emtricitabine/tenofovir disoproxil fumarate [Evidence Level B-2].[10]
  - There is a 14-day window for administering IM cabotegravir (i.e., injections can be given up to seven days BEFORE or AFTER the due date).[20,27]
    - If a patient knows they will miss an IM cabotegravir dose (e.g., due to a vacation), patients can take oral cabotegravir 30 mg (Vocabria [US], Apretude [Canada]) once daily (starting two months after the last injection) for two months to replace one missed dose of IM cabotegravir (see footnote a).[20,27]
    - For recommendations on unintentional missed doses, consult the product labeling for detailed instructions based on which injection is missed and how long it has been since the last injection.[20,27]
- Tell patients about possible adverse effects including diarrhea, nausea, abdominal pain, flatulence, headache, and weight loss. Reassure patients that most adverse effects often go away within days to weeks.[1,6]
- Encourage acetaminophen if patients need something for pain. If possible, patients should avoid high dose or multiple NSAIDs, due to potential to reduce kidney function.[8,9,17,18]
- Encourage safe sex practices, including condoms. PrEP only protects against HIV, not other STIs (or pregnancy).[1,15]

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13 Help patients **afford PrEP**.

- In the US, the Affordable Care Act requires plans and insurers to completely cover PrEP for patients at high risk of acquiring HIV including screening and laboratory testing, at least one medication, necessary monitoring, adherence counseling, and associated office visits.[25]
  - For patients without insurance, see if patients qualify for assistance:
    - NASTAD PrEP and PEP Assistance Programs (https://nastad.org/prepcost-resources/prep-assistance-programs).
    - manufacturers: https://www.gileadadvancingaccess.com, https://www.viivconnect.com/.
    - Centers for Disease Control and Prevention (CDC): https://www.cdc.gov/hiv/prevention/prep.html#cdc_prevention_pre-paying-for-prep.
    - See our chart, Guide for Helping Patients Afford Their Medications, for other possible resources.
- In Canada, for specific provincial and territorial coverage see: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/summary-hiv-antiretroviral-medication-coverage/phac-drugcoveragedoc.pdf.

Footnotes:
a. Oral cabotegravir (Vocabria [US], Apretude [Canada]) is approved for short-term PrEP as optional lead-in therapy prior to the first cabotegravir injection (to help assess tolerability) or as temporary coverage (up to two months) for patients receiving IM cabotegravir if an injection is to be intentionally missed.[16,20,27]
b. Pricing based on wholesale acquisition cost (WAC).US medication pricing by Elsevier, accessed April 2025.

Abbreviations:
BMD = bone mineral density; CrCl = creatinine clearance; FTC = emtricitabine; HIV = human immunodeficiency virus; IM = intramuscular; IV = intravenous; PrEP = pre-exposure prophylaxis; STI = sexually transmitted infection; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate.

Levels of Evidence:
In accordance with our goal of providing Evidence-Based information, we are citing the **LEVEL OF EVIDENCE** for the clinical recommendations we publish.

Level	Definition	Study Quality
A	Good-quality patient-oriented evidence.*	1. High-quality randomized controlled trial (RCT) 2. Systematic review (SR)/Meta-analysis of RCTs with consistent findings 3. All-or-none study
B	Inconsistent or limited-quality patient-oriented evidence.*	1. Lower-quality RCT 2. SR/Meta-analysis with low-quality clinical trials or of studies with inconsistent findings 3. Cohort study 4. Case control study
C	Consensus; usual practice; expert opinion; disease-oriented evidence (e.g., physiologic or surrogate endpoints); case series for studies of diagnosis, treatment, prevention, or screening.	

***Outcomes that matter to patients** (e.g., morbidity, mortality, symptom improvement, quality of life).
[Adapted from Ebell MH, Siwek J, Weiss BD, et al.Strength of Recommendation Taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. Am Fam Physician 2004;69:548-56. https://www.aafp.org/pubs/afp/issues/2004/0201/p548.html.]

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