


**Y-E-S T-O G-O: Updated PrEP Guidelines**

Northern Illinois Society of Health-System Pharmacists : June 24<sup>th</sup>, 2026

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**Conflict of Interest Disclosure**

- The speaker has no conflicts of interest to disclose with ineligible companies



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**Pharmacist Objectives**

- Identify patients who could benefit from HIV PrEP
- Select an initial HIV PrEP therapy, appropriate counseling/monitoring points
- Summarize requirements to dispense PrEP under the Illinois standing order



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Technician Objectives

- Recall FDA approved medications available for HIV PrEP
- Outline where individuals can receive HIV PrEP services
- Discuss necessary labs for PrEP



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Abbreviations

- CAB – cabotegravir
- CrCl – Creatinine clearance
- FTC – emtricitabine
- LEN - lenacapavir
- MSM – men who have sex with men
- nPEP – non occupational post exposure prophylaxis
- TAF – tenofovir alafenamide
- TDF – tenofovir disoproxil fumarate
- TGW – transgender woman



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Clinical Background and Updates



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### HIV PrEP Background<sup>1-4</sup>

- FTC/TDF originally FDA approved for PrEP in 2012
- Estimated 1.2 million patients eligible, 505,730 patients who have received PrEP (42%)
  - Under prescribed, particularly among eligible Black and Latino patients
  - Men (91%) make up majority of individuals receiving PrEP
  - 6.8% of PrEP eligible Black women were prescribed PrEP
  - HIV impacts Black and Latino patients disproportionately compared to white
- States with expanded PrEP services have shown decreases in new HIV cases



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### HIV PrEP Prescribing Barriers<sup>4</sup>

- Provider related
  - Awareness
  - Education
  - Familiarity
  - Stigma
- Patient
  - Adverse effects
  - Awareness
  - Cost/insurance
  - HIV acquisition perception risk
  - Systemic
- EDUCATION and AWARENESS is important, for **EVERYONE!**



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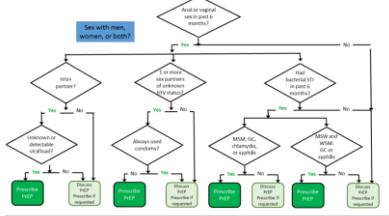
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### PrEP Initiation Sexually Active Persons<sup>1</sup>

Figure 2 Assessing Indications for PrEP in Sexually Active Persons



Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline



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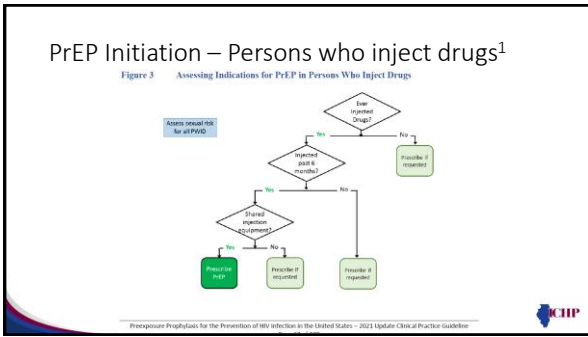
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- ### Laboratory Monitoring<sup>1</sup>
- Review for signs/symptoms of acute HIV infection
    - Fever, fatigue, muscle pain, swollen lymph nodes
  - HIV test (antibody/antigen or RNA assay)
  - Renal function (PO only)
  - Hepatitis b serology (PO only)
  - Sexually transmitted infection screening
  - **For same day PrEP**
    - Point of care testing
    - Serum creatinine
    - Ensure follow up, prescription coverage

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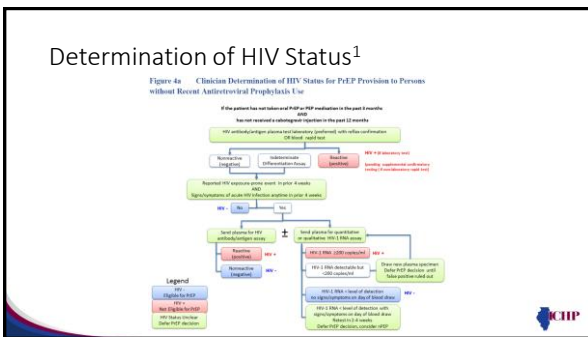
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### Truvada® (FTC/TDF 300/200 mg)<sup>1</sup>

- One tablet once a day
- CrCl > 60 mL/min
- On demand 2-1-1 (not FDA approved) – **MSM ONLY**
  - 2 pills 2-24 hours before sex (closer to 24 preferred)
  - 1 pill 24 hours after two-pill dose
  - 1 pill 48 hours after two-pill dose
  - If sex occurs day after completing, take 1 pill daily until 48 hours after sexual event
  - If < 7 days between last pill and next sexual event, resume 1 pill daily
- Common side effects
  - Headache
  - Abdominal pain
  - Weight loss



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### Descovy® (FTC/TAF 200/25 mg)<sup>1</sup>

- One tablet once a day
- **Only recommended for men and transgender women**
- CrCl > 30 mL/min
- Drug interactions
  - TAF: Metabolized via P-gp (major with inducers, minor with inhibitors)
- Common side effects
  - Diarrhea
- Lipid panel
- Insurance coverage for PrEP varies
  - May need documentation of CrCl < 60 mL/min, increased risk of bone related adverse events



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### Counseling<sup>1</sup>

Figure 5: Adherence and F/TDF PrEP Efficacy in MSM

Weekly Medication Adherence Estimated by Drug Concentration	HIV incidence per 100 persons/years
None	4.2
≤2 pills/week	2.3
2-3 pills/week	0.6
≥4 pills/week	0.0

- Adherence
  - Provide recommendations
  - Normalize occasional missed doses while emphasizing adherence
  - Identify barriers
- Side effect management
- Signs/symptoms of acute HIV infection
- Maximum concentration in rectal tissue ~ 7 days, cervicovaginal tissue ~ 20 days
- Does not protect against other sexually transmitted infections
- Importance of follow up care, HIV screening



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### Oral Agent - Monitoring<sup>1</sup>

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCl <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM, TGW	X		MSM, TGW
Gonorrhea	X	MSM, TGW	X		MSM, TGW
Chlamydia	X	MSM, TGW	X		MSM, TGW
Lipid panel (F, T, AF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM, TGW, and PWID only	

\* Assess for acute HIV infection (see Figure 4)



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### Apretude® (cabotegravir)<sup>1</sup>

- 600 mg intramuscular (gluteal injection) monthly x 2 doses, followed by every 2 months
  - Oral lead in not mandatory
- Consider for patients with severe kidney disease, concern with daily adherence, PO agent side effects
- Side effects
  - Injection site related
- Drug interactions
  - Metabolized by UGT1A1
  - Rifampin/carbamazepine/oxcarbazepine/phenobarbital/phenytoin
- Monitor with HIV RNA assay (rule out acute infection)
- ISMP alert



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### Injectable Monitoring<sup>1</sup>

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM/TGW only	Heterosexually active women and men only	X	MSM, TGW only
Gonorrhea	X			MSM, TGW only	Heterosexually active women and men only	X	MSM, TGW only
Chlamydia	X			MSM, TGW only	MSM, TGW only	Heterosexually active women and men only	MSM, TGW only

\* HIV-1 RNA assay  
 X: all PrEP patients  
 \* men who have sex with men  
 \* persons assigned male sex at birth whose gender identification is female



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**Yeztugo® (lenacapavir)<sup>5</sup>**

- Day 1: 600 mg PO (2 x 300 mg tablets), 927 mg subcutaneously (2 injections total)
  - 927 mg subcutaneously every 26 weeks (6 months +/- 2 weeks)
- Side effects
  - Injection site (nodules), headache, nausea
- Can be used as PrEP during pregnancy
- Drug interactions
  - Moderate CYP3A inhibitor
  - Metabolized through CYP3A, P-GP, UGT1A1
  - Strong CYP3A inducers: Initiate at least 2 days after LEN
  - Tadalafil, sildenafil



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**Yeztugo® (lenacapavir)<sup>5,6</sup>**

- Monitoring
  - HIV ag/ab at baseline with HIV RNA assay (RNA doesn't have to be resultud, just obtained)
  - HIV ag/ab and RNA assay at each injection (q 6 months) going forward
  - STI monitoring: based on risk (may be more frequent than 6 months)
- Missed doses
  - > 2 weeks from planned injection, provide oral dose again



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**Injectable Considerations**

- Access to medication (i.e. prior authorizations)
- Cold storage
- Scheduling
- Administering
- Monitoring
- Missed doses
- Discontinuation
  - "Tail period", discuss ongoing risk of HIV transmission, consider PO PrEP
  - Time until CAB undetectable levels: 44 weeks (men) to 67 weeks (women)



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### PrEP Failure<sup>1</sup>

- Initiate anti-retroviral therapy immediately
- Obtain viral load (if not already done), genotype
- For Cabotegravir: Symtuza® (darunavir/cobicistat/TAF/FTC)

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### Question 1 – Pharmacy Technicians

Which of the following is a medication available for PrEP?

- Bictegravir/emtricitabine/tenofovir alafenamide
- Cabotegravir
- Cabotegravir/rilpivirine
- Tenofovir alafenamide

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### Question 2 - Pharmacists

Which of the following patients would be an ideal candidate to initiate PrEP? An individual who...

- Has 2 sexual partners, uses condoms, and last tested positive for an STI 2 years ago
- Injects IV drugs and obtains needles from a needle exchange program
- Is in the emergency department being treated for chlamydia
- Has 1 sexual partner who is living with HIV (HIV viral load undetectable x 2 years)

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## PrEP Agents Insurance Coverage



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### Oral Agents

- FTC/TDF typically goes through insurance (generic available) for no copay
  - 90 day supply covered by Illinois Medicaid
  - Generic is GoodRx available (~\$15 depending on pharmacy)
- FTC/TAF may require PA for individuals ineligible for FTC/TDF (bone/renal concerns)
  - Copay card available



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### Injectable Agents

- May be covered by medical or pharmacy benefits
- Unable to be administered by pharmacist in Illinois
- CAB
  - Covered under PrEP4Illinois
  - Copay card available for pharmacy benefits
- LEN
  - Need coverage for PO and injectable
  - Tabs covered my most pharmacy plans without prior authorization
  - Copay card available for pharmacy benefits



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**Persons Who Lack Insurance Benefits**

- FTC/TDF
  - Gilead no longer offers patient assistance
  - GoodRx
- FTC/TAF
  - <https://www.gileadadvancingaccess.com/>
- **PrEP 4 Illinois** – Covers FTC/TDF (brand and generic), FTC/TAF, and CAB
  - [PrEP for Illinois Pharmacies](#)
  - Only covers medication (not associated lab fees)
  - May still have administration fee with CAB
  - Not available to bill at all pharmacies
  - LEN not on list yet



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**Medicare Part B**

- Covers the following:
  - FDA approved oral or injectable PrEP (includes LEN)
  - Up to 8 individual counseling sessions every 12 months
  - Up to 8 HIV screenings every 12 months
  - Hepatitis B screening
- Pharmacy needs to be able to bill Medicare Part B
- If patient has Medicare Advantage Plan, bill pharmacy benefits



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**Illinois Legislative Updates**



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### Why Expand to Pharmacist PrEP Dispensing<sup>4</sup>

- Lack of PrEP uptake for eligible patients
- Pharmacists and pharmacies are:
  - Highly accessible
  - Knowledgeable in public health activities
  - Medication experts
- Pharmacists have been identified as a key contributor to ending the HIV epidemic
- Increases awareness, availability



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### Pharmacist PrEP Legislation<sup>7</sup>

- As of June 2023, there were 12 states with legislation to support pharmacist provided PrEP
- Legislation differs from state to state
  - Training requirements
  - Reimbursement
  - Laboratory ordering
  - Protocols
  - Amount to dispense
- Highlights
  - California – First bill passed (2019), allows reimbursement at 85% of physician fee
  - Nevada, Oregon – Requires reimbursement for pharmacist consultation
  - New Mexico – Allows technicians and interns to perform testing



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### Illinois Legislation<sup>8</sup>

- Illinois Pharmacy Act updated January 2023 to allow registered pharmacies to dispense PrEP and nPEP
  - “[i]n accordance with a standing order by a physician licensed to practice medicine in all its branches or the medical director of a county or local health department or a standing order by the Department of Public Health, a pharmacist may provide patients with prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis.”
- Actual process for obtaining the standing order wasn't released until April 2025



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### Illinois Pharmacy PrEP and nPEP Requirements

- Pharmacist must enroll and complete ACPE approved training
  - 3 hours, \$90, [Oregon State University](#)
- Pharmacist must:
  - Have patient complete PrEP Patient Intake Form
  - Complete PrEP Assessment and Treatment Care Pathway
  - Order necessary laboratory tests (under pharmacist's NPI)
  - Report positive HIV tests to department of public health
  - Document interactions
  - [Submit quarterly reports to IDPH](#)
- Pharmacists unable to administer injectable PrEP in Illinois



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### Non-Occupational Post Exposure Prophylaxis<sup>9</sup>

- Patient presents within 72 hours of isolated sexual or injection related HIV exposure with substantial risk
- 28 day course of bicitegravir/FTC/TAF (Biktarvy<sup>®</sup>) or [dolutegravir with TAF or TDF and lamivudine or FTC]
- If repeated courses of nPEP have been administered, PrEP should be offered if HIV acquisition risks remain present



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### Pharmacy PrEP: Benefits and Barriers<sup>10</sup>

**Benefits**

- Increased awareness
- Increased patient trust
- New revenue stream
- Reduce stigma
- Reduce HIV transmissions

**Barriers**

- "Difficult" conversations
- Education/training need
- Misconceptions
- Perceived workload
- Reimbursement for services
- Stigma



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**Available PrEP services**

- Patients may need financial assistance for medication AND lab/provider services
- <https://preplocator.org/>
  - Includes options for uninsured individuals
- **Illinois PrEP sites** that offer financial assistance for HIV/STI lab and provider visits

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**Question 3 – Pharmacy Technicians**

A patient is eligible to receive FTC/TDF for HIV PrEP, but currently does not have any pharmacy insurance. Which of the following would you recommend for assisting with copays?

- Good Rx
- Medicare Part B
- PrEP 4 Illinois
- Truvada® copay card



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**Question 4 - Pharmacists**

A patient has been maintained on HIV PrEP (FTC/TDF), but has been unable to attend lab appointments for HIV monitoring due to travel schedule. There has been instances where they forgot to bring the FTC/TDF with as well. Which of the following would you recommend? May select more than one answer.

- FTC/TAF
- FTC/TDF
- Cabotegravir
- Lenacapavir



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### PrEP Pharmacy Step 1: Patient Intake Form

- Patient demographics
- Section 1: Reason for HIV PrEP and eligibility
- Section 2: HIV testing, PrEP, and HIV PEP histories; acute HIV symptom review
  - HIV ag/ab within previous 7 days, no signs/symptoms of acute HIV
- Section 3: Brief medical history to determine which PrEP medication may be best for you
- Section 4: What to expect on oral PrEP



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### PrEP Pharmacy Step 2: Assessment and Treatment Care Pathway, Provider Referral

- Provides recommendations based on patients responses on intake form
  - HIV test results
  - Medical history (renal disease, bone mineral density, hepatitis B status, pregnancy, other medications)
  - PrEP duration (30 vs. 90 days)
  - Recommended regimens (PO only)
  - STI results and monitoring
- If patient has primary care provider, can provide information to provider



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### PrEP Prescription

1. I can't find Tables 2 and 3, I assume they mean "Required Baseline Labs" table within Appendix B
2. Per CDC, for same day starts you need to have obtained SCR and HIV ag/ab

**Table 2: Laboratory Test Results for Appendix B for Detailed Information on Lab Requirements**

Ag/Ab	Required	Required, as for pretest - result, needs follow-up	Not required
Hepatitis B serology (HBsAg, anti-HBc, anti-HBs)	Required, as for pretest - result, needs follow-up	Required, as for pretest - result, needs follow-up	Not required
Renal function (creatinine)	Required, as for pretest - result, needs follow-up	Required, as for pretest - result, needs follow-up	Not required
Other	Not required	Not required	Not required


**Appendix B: Recommended Regimens**

Note: There are other FDA-Approved medications available and may be other dosing strategies for PrEP. Daily dosing of emtricitabine/tenofovir DF (Truvada®) and emtricitabine/tenofovir alafenamide (Descovy®) are the only regimens permitted for pharmacist prescribing at this time.

<b>Emtricitabine/Tenofovir DF (Truvada®)</b>	<b>Emtricitabine/Tenofovir alafenamide (Descovy®)</b>
Dose: 200/300 mg once daily	Dose: 200/25 mg once daily
<b>FDA-Approved for:</b> all HIV exposure risk indications	<b>FDA-Approved for:</b> use by oral males and transgender women only. <b>Not recommended</b> for oral females with HIV risk via vaginal sex or any persons, regardless of gender, if injection substance use is the only HIV risk.

**Some-day PrEP initiation is not appropriate for:**

- Patients who express ambivalence about starting PrEP (e.g., need more time to think)
- Patients for whom blood cannot be drawn for laboratory testing
- Patients with signs/symptoms and sexual history indicating possible acute HIV infection
- Patients with history of renal disease or associated conditions (e.g., hypertension, diabetes)
- Patients without insurance or a means to pay when picking up the prescribed medication that day
- Patients who do not have a confirmed means of contact should laboratory test indicate a need to commence PrEP (e.g., HIV infection, unanticipated sexual activities)



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### Questions

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