

Pre-Exposure Prophylaxis for HIV Infection 2024 Update

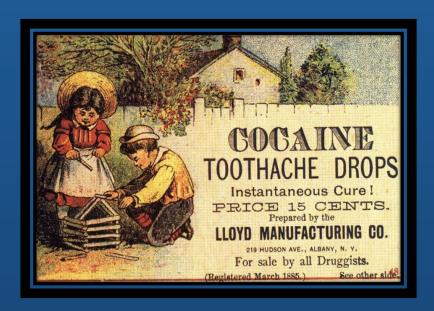
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Last Updated: 6/3/2024

Disclosures

This talk will include discussion of commercial products as well as offlabel and investigational use of products.

I have no conflicts of interests or relationships to disclose.





Data Considerations

Data in this presentation offer a limited perspective of how systemic, social, and economic factors impact health. We recognize that racism, not race, creates and perpetuates health disparities.



To Learn More:

https://www.cdc.gov/minorityhealth/racism-disparities



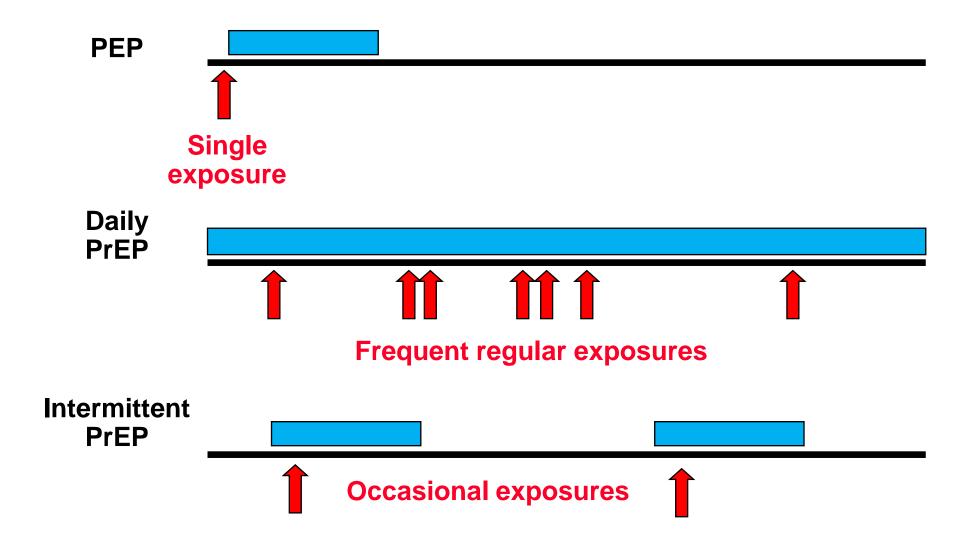
Outline

- What is PrEP?
- PrEP efficacy and effectiveness
- Side effects, STIs, HIV-1 drug resistance, and other concerns
- Nuts and bolts about prescribing and montoring PrEP

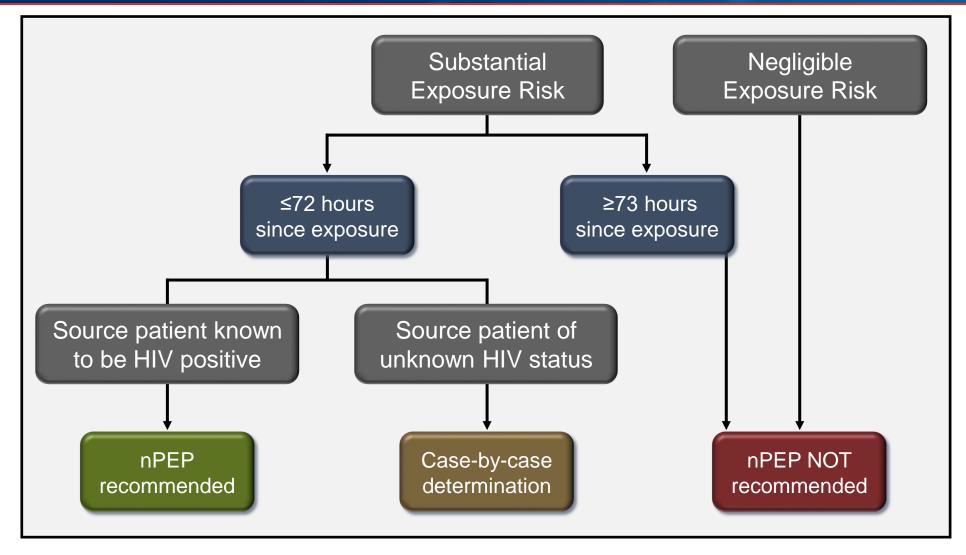


PEP=POST exposure

PrEP=PRE exposure



2016 Nonoccupational PEP Guidelines Evaluation for nPEP





When and how to refer for PEP

For

- Someone not on PrEP or not adherent to PrEP.
- Condomless insertive or receptive anal or vaginal sex in last 3 days

Key Messages

- PEP is 3 HIV medicines taken for 28 days <u>after</u> exposure.
- Two of the 3 medicines are the PrEP meds.
- PEP will be covered by insurance or assistance programs.
- If you are going to go on PEP, it is better to do it sooner.
- You can go on PrEP right after completing the 28 day course.

Very few times where I'd say "you have to go on PEP." It's often a decision made based on how well they know the partner.

What is PrEP?

PrEP (<u>Pre-Exposure Prophylaxis</u>) = HIV-negative persons taking HIV medicine to prevent them from getting HIV infection.

FDA-approved PrEP (June 2024)

Daily emtricitabine/tenofovir disoproxil fumarate (FTC/TDF: Truvada)

Requires CrCl > 60 mL/min

Daily emtricitabine/tenofovir alafenamide (FTC/TAF: Descovy)

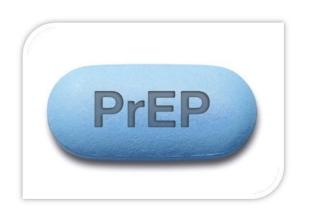
For cisgender men and transgender women (sexual exposure)

Requires CrCl > 30 mL/min

Injectable cabotegravir (Apretude)

All populations (sexual exposure)

Dapivirine vaginal ring has been withdrawn.



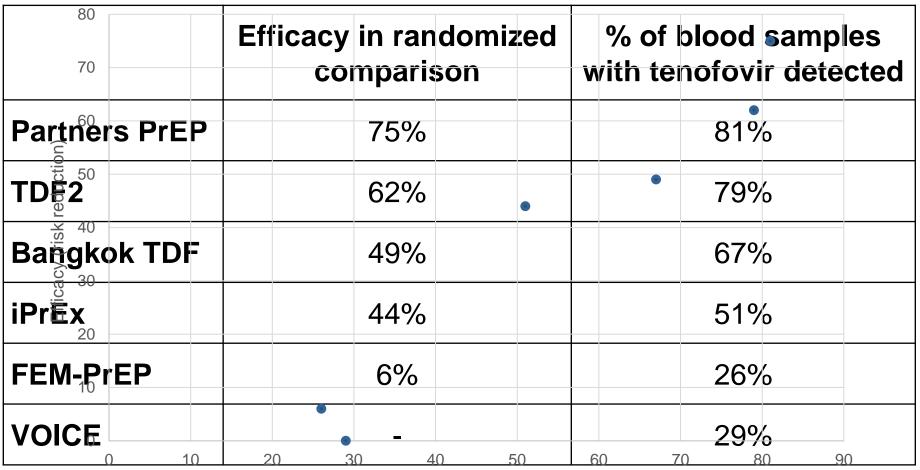


Key HIV PrEP Trials Using Oral TDF, FTC/TDF, or FTC/TAF

Study	Study Population	Study Randomization	HIV Incidence Impact
IPrEx (Brazil, Ecuador, South Africa, Thailand, US)	2499 MSM and transgender women	Daily oral TDF-FTC or placebo	TDF-FTC: 44% Ψ
Partners PrEP Study (Kenya, Uganda)	4147 heterosexual HIV discordant couples	Daily oral TDF, TDF-FTC, or placebo	TDF: 67% ↓ TDF-FTC: 75% ↓
TDF2 Study (Botswana)	1219 heterosexual men and women	Daily oral TDF-FTC or placebo	TDF-FTC: 63% Ψ
FEM-PrEP (Kenya, South Africa, Tanzania)	2120 women	Daily oral TDF-FTC or placebo	TDF-FTC: no protection
VOICE (South Africa, Uganda, Zimbabwe)	5029 women	Randomized to daily oral TDF, TDF-FTC, oral placebo, TDF vaginal gel, or gel placebo	TDF: no protection TDF-FTC: no protection TDF gel: no protection
Bangkok TDF Study (Thailand)	2413 injection drug users	Randomized to daily oral TDF or placebo	TDF: 49% ↓
IPERGAY (France, Quebec)	400 MSM	Randomized to "on-demand" TDF-FTC or placebo	TDF-FTC: 86% Ψ
PROUD (United Kingdon)	545 MSM and transgender women	Randomized to daily oral TDF- FTC immediately or delayed	Immediate TDF-FTC: 86% ↓
DISCOVER (Canada, Europe, US)	5387 MSM and transgender women	Daily oral FTC/TDF or FTC/TAF	F/TDF incidence: 0.3% F/TAF incidence: 0.16%



How well does PrEP work? Adherence & efficacy



% blood specimens with TDF detected







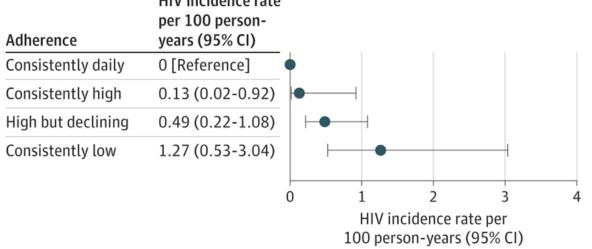
How well does PrEP work? Real life effectiveness

Estimated adherence (TDF in DBS)	Incidence	Protection
Not detected	4.7/100 person-years	
<2 tab/week	2.3/100 person-years	51%
2-3 tab/week	0.6/100 person-years	87%
4-7 tab/week	0/100 person-years	100%

Source: Grant et al (iPrEx OLE), Lancet. 2014: 14; 819-829.

Figure 4. HIV Incidence Rates Among Cisgender Women by Adherence Trajectory (n = 2954)

HIV incidence rate





How well does PrEP work? Real life effectiveness

There have been <10 well-documented cases of persons who became HIV-positive despite excellent adherence to PrEP. But there are probably others.

Oral PrEP: Knox et al NEJM 2017; 376: 501-502

Markowitz et al JAIDS 2017; 76(4): e104-106

Hoornenborg et al, Lancet HIV 2017; 4: e522-28

Injectable: Hazra et al. AIDS 2023; 37(11): 1711-1714.



What are the short-term side effects of oral PrEP?

Short-term side effects in the DISCOVER TRIAL

	FTC/TAF N=2694	FTC/TDF N=2693
Diarrhea	5%	6%
Nausea	4%	5%
Headache	2%	2%
Fatigue	2%	3%
Abdominal pain	2%	3%

Neither needs to be taken with food



What are the long-term side effects of oral PrEP?

	FTC/TAF	FTC/TDF
Drug-related AE's		
Mean change (%), spine BMD	1.0	-1.4
Mean change (%), hip BMD	0.6	-1.0
Mean change (mL/min), eGFR	-0.6	-4.1
Weight and lipids		
Mean change (kg)	1.7	0.5
Mean change total cholesterol (mg/dL)	-3	-14
Mean change LDL (mg/dL)	-2	-7



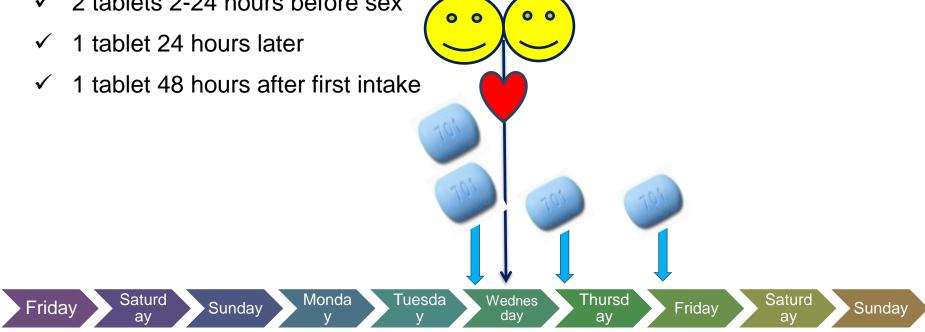
Source: Mayer et al Lancet 2020 Jul 25; 396: 239-254.

ipergay



Intermittent dosing strategy

2 tablets 2-24 hours before sex



Molina, N Engl J Med 2015;373:2237-46.



ipergay Time to HIV Infection (mITT)



Median follow-up 9.3 months.

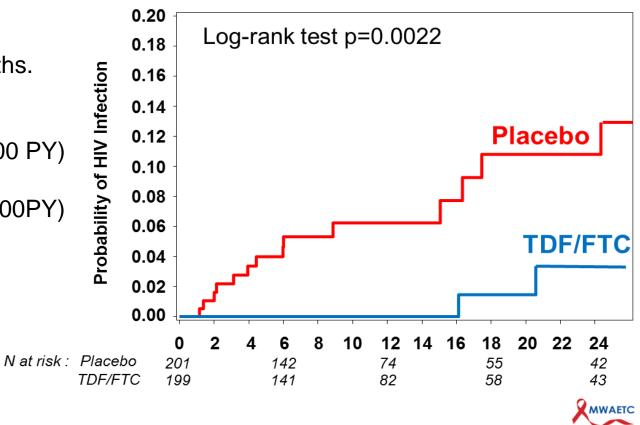
14 in placebo arm

(incidence: 6.6/100 PY)

2 in TDF/FTC arm

(incidence 0.91/100PY)

86% relative reduction (95% CI: 40-98, p=0.002)



ipergay OLE HIV Incidence – RCT v OLE



Treatment	Follow-Up Pts-years	HIV Incidence per 100 Pts-years (95% CI)
Placebo (double-blind)	212	6.60 (3.60-11.1)
TDF/FTC (double-blind)	219	0.91 (0.11-3.30)
TDF/FTC (open-label)	515	0.19 (0.01-1.08)

Median Follow-up in Open-Label Phase 18.4 months (IQR:17.5-19.1)

97% relative reduction vs. placebo



Injectable cabotegravir (CAB)

Superior to oral FTC/TDF

HPTN 083 (4570 cisgender men and transgender women)

13 infections in the CAB arm (incidence rate 0.41%)

39 infections in the FTC/TDF arm (incidence rate 1.22%).

Hazard ratio for CAB versus FTC/TDF was 0.34 (95% CI 0.18-0.62)

HPTN 084 (3223 cisgender women).

4 infections in the CAB arm (incidence rate 0.21%)

34 infections in the FTC/TDF arm (incidence rate 1.79%)

Hazard ratio for CAB versus FTC/TDF was 0.11 (95% CI 0.04-0.32)



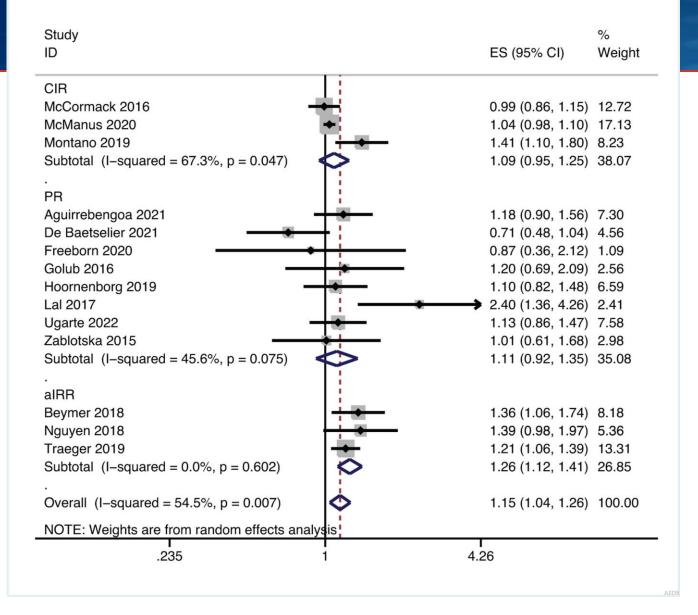


Additional benefits of PrEP

- Decreased anxiety
- Increased communication and disclosure
- Increased self-efficacy
- Increased sexual pleasure and intimacy
- Reframing of sexual health in a positive framework



Risks of PrEP: STIs





Risks of PrEP: HIV drug resistance

IAS: Grant, oral abstract TUAC0104

	Acute HIV at enrollment		HIV infection post-enrollment	
	PrEP	Placebo	PrEP	Placebo
BTS	0/0	0/2	0/17	0/33
FEM-PrEP	0/1	0/1	4/33	1/35
iPrEx	2/2	1/8	0/48	0/83
Partners	2/8	0/6	0/27	0/51
TDF2	1/1	0/2	0/9	0/24
VOICE	2/14	0/1	1/113	0/60
Total	7/26 (27%)	1/20 (5%)	5/247 (2%)	1/286 (0.3%)

Excluding acute infections when PrEP was started: 10 (39/4) infections averted per drug resistant infection.

Fonner et al, JAIDS 2016; 30(12): 1973-1983, supplement



PrEP and transgender patients

- Previously well-established that PrEP has no impact on hormone levels.
- Evidence gathering to suggest no impact of gender affirming hormone on PrEP medication levels.
- Still unclear how relates to efficacy or potential for 2-1-1 dosing.
- Barriers to uptake and persistence remain among transgender persons
 - Concern about side effects
 - Stigma and mistrust of medical providers
 - Co-location of PrEP and gender affirming care services may ↑ PrEP uptake



How to prescribe PrEP

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE





JAMA | Special Communication

Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults

2022 Recommendations of the International Antiviral Society-USA Panel

Rajesh T. Gandhi, MD; Roger Bedimo, MD; Jennifer F. Hoy, MBBS; Raphael J. Landovitz, MD; Davey M. Smith, MD; Ellen F. Eaton, MD; Clara Lehmann, MD; Sandra A. Springer, MD; Paul E. Sax, MD; Melanie A. Thompson, MD; Constance A. Benson, MD; Susan P. Buchbinder, MD; Carlos del Rio, MD; Joseph J. Eron Jr, MD; Huldrych F. Günthard, MD; Jean-Michel Molina, MD; Donna M. Jacobsen, BS; Michael S. Saag, MD

IMPORTANCE Recent advances in treatment and prevention of HIV warrant updated recommendations to guide optimal practice.

OBJECTIVE Based on a critical evaluation of new data, to provide clinicians with recommendations on use of antiretroviral drugs for the treatment and prevention of HIV, laboratory monitoring, care of people aging with HIV, substance use disorder and HIV, and new challenges in people with HIV, including COVID-19 and monkeypox virus infection.

EVIDENCE REVIEW A panel of volunteer expert physician scientists were appointed to update the 2020 consensus recommendations. Relevant evidence in the literature (PubMed and Embase searches, which initially yielded 7891 unique citations, of which 834 were considered relevant) and studies presented at peer-reviewed scientific conferences between January 2020 and October 2022 were considered.

FINDINGS Initiation of antiretroviral therapy (ART) is recommended as soon as possible after diagnosis of HIV. Barriers to care should be addressed, including ensuring access to ART and adherence support. Integrase strand transfer inhibitor-containing regimens remain the mainstay of initial therapy. For people who have achieved viral suppression with a daily oral regimen, long-acting injectable therapy with cabotegravir plus rilpivirine given as infrequently as every 2 months is now an option. Weight gain and metabolic complications have been linked to certain antiretroviral medications; novel strategies to ameliorate these complications are needed. Management of comorbidities throughout the life span is increasingly important, because people with HIV are living longer and confronting the health challenges of aging. In addition, management of substance use disorder in people with HIV requires an evidence-based, integrated approach. Options for preexposure prophylaxis include oral medications (tenofovir disoproxil fumarate or tenofovir alafenamide plus emtricitabine) and, for the first time, a long-acting injectable agent, cabotegravir. Recent global health emergencies, like the SARS-CoV-2 pandemic and monkeypox virus outbreak, continue to have a major effect on people with HIV and the delivery of services. To address these and other challenges, an equity-based approach is essential.

CONCLUSIONS AND RELEVANCE Advances in treatment and prevention of HIV continue to improve outcomes, but challenges and opportunities remain.





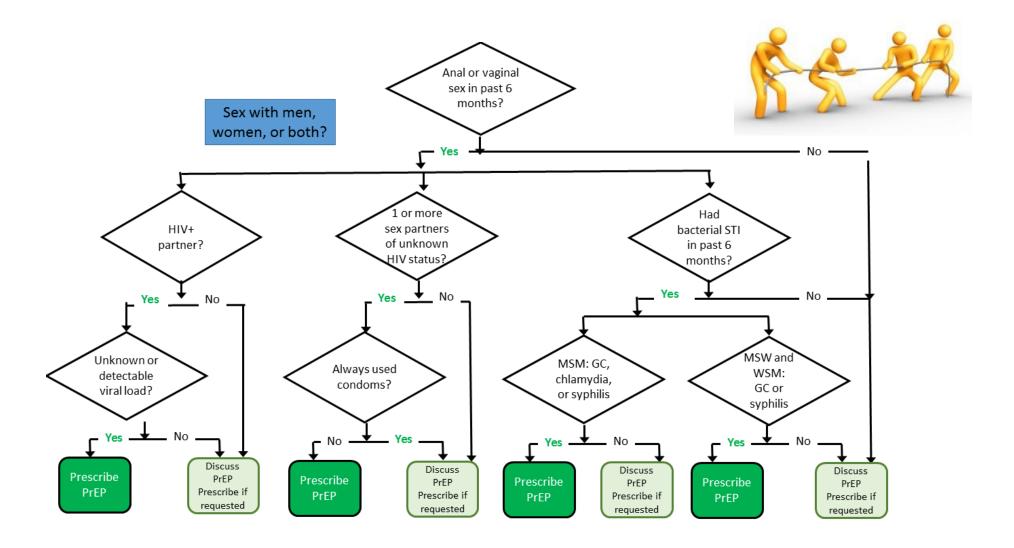


Who should be prescribed PrEP?

- All sexually active adults and adolescents should receive information about PrEP (IIIB)
- For both men and women, PrEP with daily FTC/TDF is recommended for sexually-active adults and adolescents (>35 kg) who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition (IA)
- For both men and women, PrEP with daily FTC/TDF is recommended for persons who
 inject drugs (PWID) and report injection practices that place them at substantial ongoing
 risk of HIV exposure and acquisition (IA)
- PrEP should be prescribed in discordant couples
 - If the sex partner with HIV has been inconsistently virally suppressed
 - If their VL is unknown
 - If the HIV-negative partner has other sex partners
 - If the HIV-negative partner wants the additional reassurance of protection

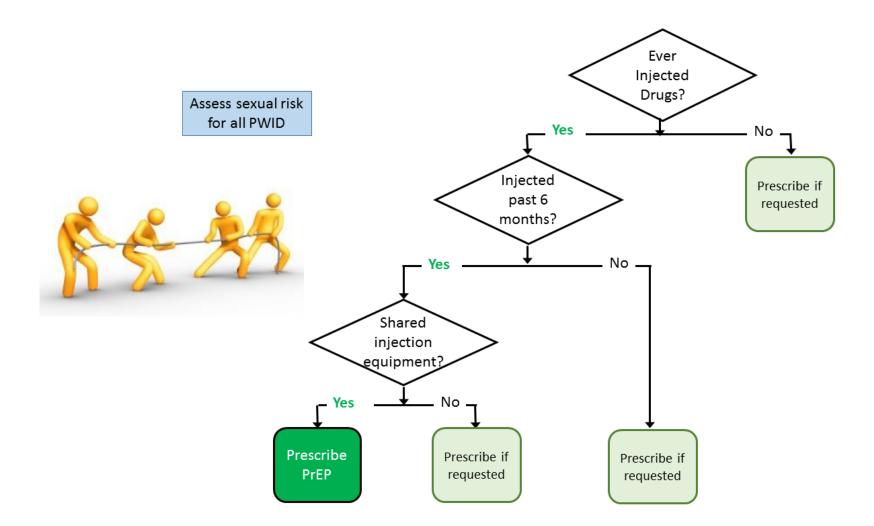


Assessing Indications for PrEP in Sexually Active Persons





Assessing Indications for PrEP in Persons Who Inject Drugs





What to prescribe as PrEP

	IAS-USA (2022)	HHS/CDC (2021)
FTC/TDF	All persons at risk from sexual or injection exposures.	All persons at risk from sexual or injection exposures.
FTC/TAF	 Preferred if eCrCl 30-60 mL/min or known osteoporosis Limited to anyone whose risks do not include receptive vaginal or neovaginal sex or exclusive IDU 	 Preferred if eCrCl 30-60 mL/min or known osteoporosis Recommended for men and TGW who have sex with men.
CAB	All persons at risk from sexual exposures and PWID with sexual risk.	All persons at risk from sexual exposures.

IAS-USA: The optimal PrEP regimen for a given person is the one most acceptable to that person and congruent with their sexual behavior, ability to take medications reliably, likelihood of anticipating sexual activity, and adverse effect profile.



What to prescribe as PrEP?

- FTC/TAF is a recommended option for men. FTC/TAF has not yet been studied in persons at risk through receptive vaginal sex. (IA)
- For transgender women who have sex with men, FTC/TAF is a recommended option. (IIB)
- For most patients, there is no need to switch from FTC/TDF to FTC/TAF.
- FTC/TAF is indicated for patients with eCrCl 30-60.
- Clinicians may prefer FTC/TAF for patients with previously documented osteoporosis or related bone disease.
- Other daily oral antiretroviral medications for PrEP have not been studied extensively and are not recommended. (IIIA)
- Conditioned on a PrEP indication approved by FDA, PrEP with intramuscular cabotegravir (CAB) injections is recommended for HIV prevention in adults and adolescents who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. (IA).



Baseline testing

	IAS-USA (2022)	HHS/CDC (2021)
HIV Ag/Ab testing	Lab based test should be performed even if PrEP started based on POC.	Lab based test should be performed even if PrEP started based on POC. Oral fluid tests should not be used.
HIV RNA testing	Recommended if: - high risk exposure in last 4 wks - Signs/sx acute HIV infection - CAB	Recommended for CAB
Serum creatinine	For oral PrEP only	For oral PrEP only
Lipid panel	Not mentioned	For persons receiving FTC/TAF
Hepatitis serologies	HAV Ab for MSM/PWID if not immune HBV sAg and sAb HCV Ab	Oral PrEP: HBV testing Others: not indicated* (but follow primary care guidelines)
STI screening	Genital/non-genital GC/CT, syphilis	Genital/non-genital GC/CT, syphilis
Pregnancy testing	If relevant	If relevant



Monitoring

	IAS-USA (2022)	HHS/CDC (2021)
HIV Ag/Ab testing	Month 1 for everyone Q3 mo for oral PrEP, Q4 mo for CAB	Oral PrEP: Q3mo CAB: Q2mo
HIV RNA testing	For CAB only: Month 1, then Q4 mo	Oral PrEP: Q3mo CAB: Q2mo
Serum creatinine	Month 3 for oral PrEP Q 3-6 mo for >50 or eCrCl<90 baseline Or Annually	Month 3 for everyone Q 3-6 mo for >50 or eCrCl<90 baseline Or Annually
Lipid panel	Not mentioned	Annual
Hepatitis serologies	HCV Ab annually, Q3-6 months for MSM, people who use drugs, or abnl LFT	
STI screening	Q3-4 months	Oral PrEP: every 3 months for MSM CAB: every 4 months for MSM/TGW, Q6mo hetero
Pregnancy testing	Q3-4 months	



How to prescribe oral PrEP Same day dosing

Same-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 discontinue PrEP (e.g., HIV infection, unanticipated renal dysfunction)

Same-day PrEP initiation may not be appropriate for:

- Patients with a very recent possible HIV exposure but no signs and symptoms of acute infection (should be evaluated for nPEP before PrEP)
- Patients who may not be easily contacted for return appointments
- Patients with mental health conditions that are severe enough to interfere with understanding of PrEP requirements (adherence, follow-up visits)



How to prescribe oral PrEP 2-1-1 dosing

	IAS-USA (2022)	HHS/CDC (2021)
Cisgender men	Recommended regardless of sexual orientation	For adult MSM who have sex less than 1x/week and can anticipate sex
Transgender women	Use with caution in TGW receiving hormone therapy	
Cisgender women, transgender men, PWID	Insufficient data	

Contraindicated in hepatitis B virus infection



Drug Interactions Oral PrEP (Table 4, p39)

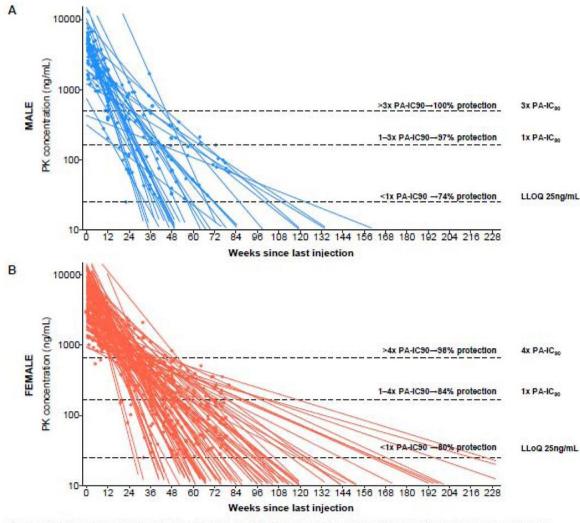
	TDF	TAF
Feminizing hormones	Lower TDF levels (unclear impact on effectiveness). No impact on hormone levels.	No data
ACV, ValACV NSAIDs (drugs that decrease kidney function)	Serum concentrations may be increased. Monitor for renal toxicity.	No data
Adefovir	Do not co-administer.	No data
Hepatitis C treatments	TDF may be increased. Monitor for toxicity.	No significant effect
St John's Wort	No significant effect.	Possible decreased TAF. Do not co-administer.
Rifampin	No significant effect	Do not co-administer unless benefits > risks.
Rifabutin, Rifapentine	No significant effect.	Do not co-administer.



How to prescribe injectable PrEP The cabotegravir tail

Median time to...

- Men:
 - CAB below LLOQ: 43.7 wks
- Women:
 - CAB below LLOQ: 67.3 wks



Curves are fitted for each individual extrapolated to the intersection with LLoQ and often extend beyond the observed concentrations. Dots represent individual participant values based on days elapsed since the last injection. The horizontal dashed lines are estimates of protection based on the SHIV challenge model indicating the proportion of rectal or vaginal challenges protected for males and females, respectively.



Adherence support

Box B: Key Components of Oral Medication Adherence Counseling

Establish trust and bidirectional communication Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

Support adherence

A Brief Medication Adherence Question

Monito

"Many people find it difficult to take a medicine every day.

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Thinking about the last week – on how many days have you <u>not</u> taken your medicine?"



Structural interventions for increased PrEP persistence

- Low-barrier care models
 - Telehealth
 - Mail-order medications
 - Mobile clinics
 - Pharmacy-based PrEP
- For transgender and nonbinary people
 - Integrate PrEP with gender-affirming care
- For people who use alcohol or other substances:
 - Integrate PrEP delivery with syringe exchange and harm reduction



Options in cases of suspected PrEP failure

Open Forum Infectious Diseases

MAJOR ARTICLE







A Strategy for PrEP Clinicians to Manage Ambiguous HIV Test Results During Follow-up Visits

Dawn K. Smith^o, William M. Switzer, Philip Peters, Kevin P. Delaney, Timothy C. Granade, Silvina Masciotra, Luke Shouse, and John T. Brooks
Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

- 1) Continue PrEP while conducting additional tests
- 2) Initiate ART while conducting additional tests
- 3) Discontinue PrEP to reassess status/conduct additional tests after a brief medication-free interval

PrEPline consultation: 855-448-7737 (11a-6p EST)



Paying for PrEP U.S. Preventative Services Task Force (Update 2023)

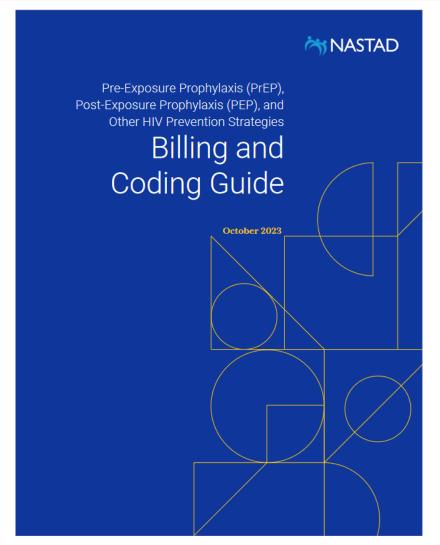
Recommendation Summary

Population	Recommendation	Grade
Adolescents and adults at increased risk of HIV	The USPSTF recommends that clinicians prescribe preexposure prophylaxis using effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV.	A
	See the Practice Considerations section for more information about identification of persons at increased risk and about effective antiretroviral therapy.	

- Most private health plans must cover PrEP without cost-sharing (such as a copay or coinsurance).
- However, prior authorizations may be allowed, or placing generics on zero cost-sharing tiers with cost sharing for brand equivalents.
- Sept 2022: Braidwood Management Inc v Becerra struck down this requirement in TX. Ruling on 5th Circuit appeal expected mid-2024.

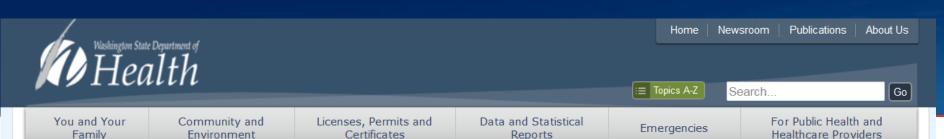


ICD-10 codes to consider for PrEP prescribing NEW CODE: Z29.81 = encounter for PrEP



ICD-10 Code	Description	Use For
Z29.81	Encounter for HIV pre-exposure prophylaxis	Primary for all PrEP services
Z01.812	Encounter for preprocedural laboratory examination	Use for urine and blood test before initiation
Z01.812	Encounter for preprocedural laboratory examination	Use for blood or urine tests before treatment.
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission	STI screening
Z11.4	Encounter for screening for human immunodeficiency virus [HIV]	HIV screening
Z11.59	Encounter for screening for other viral diseases	
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	HIV, STI screening
Z20.5	Contact with and (suspected) exposure to viral hepatitis	
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV	HIV screening
Z51.81	Encounter for therapeutic drug level monitoring	PrEP monitoring
Z79.899	Other long term (current) drug therapy	PrEP monitoring
Z86.59	Personal history of other mental and behavioral disorders	History of drug use. For opioid dependence in remission, use code from F11 series indicated below.
Z87.898	Personal history of other specified conditions	Use for a history of drug use, non-dependent, in remission.





Home ▶ You and Your Family ▶ Illness and Disease ▶ HIV/AIDS ▶ HIV Care - Client Services ▶ PrEP DAP





Flu

Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)

What is PrEP?

Pre-Exposure Prophylaxis (PrEP) is an HIV prevention method in which HIV-negative people take a daily pill to reduce their risk of becoming infected.

When used consistently, PrEP has been shown to reduce the risk of HIV-1 infection among adult men and women at very high risk for HIV infection through sex or injection drug use. TRUVADA® has been approved by the Federal Drug Administration for use in PrEP.

If you are interested, your prescribing medical provider can answer your questions.

Where can I find additional information on PrEP?

- What is PrEP?
- PrEP Facts

What is PrEP DAP?

PrEP DAP is a drug assistance program for HIV-negative people who have risk factors that expose them to HIV. PrEP DAP will pay for TRUVADA® for people who want to be on PrEP.

Learn about PrEP DAP in our brochure - English (PDF)

PrEP DAP brochure - Spanish version (PDF)



Questions without answers

- How long does it take to achieve protection on PrEP?
- When discontinuing PrEP, how long does someone need to continue PrEP after their exposure?
- How will injectable PrEP be implemented?
- Will healthcare insurance cover injectable PrEP?



Years Ahead in HIV Prevention Research Time to Market **Prevention Product** 2022 2023 2024 2026 2027 2028 2025 Demonstrated modest efficacy Unclear demand & limited initial supply Initial price ~\$180 per year Multiple regulatory Multiple implementation science projects • Oct 2023: A memorandum of understanding has been Vaginal **Dapivirine** reached on a product license with Kiara monthly • 3-monthly ring is currently in development and could be submitted to regulators in 2025 Selected Global Fund procurement and programs Opportunity to build market and platforms for vaginal rings · Demonstrated high efficacy Unclear demand & limited initial supply Initial LMIC price ~\$240/yr; in 2024 ~\$170/yr March 2023: MPP & ViiV licensed to 3 generics with likely Cabotegravir submission to regulators by 2027 One intramuscular injection 4-monthly formulation is currently in development, but the (3ml) every 2 months regulatory timeline is unclear **Long-Acting** Opportunity to build market and platforms for injectables **Injectables** Possible product introduction Lenacapavir F/TAF Phase 3: part of PURPOSE 1 daily MK-8527 Phase 2a: MK-8527-07 Possible Go/No-Go Decision for Phase 3 in Q1 2025 monthly Co-formulated Pilot bioequivalence (BE) study Pivotal BE Possible product introduction TDF/FTC and Dual ethinyl estradiol/ **Prevention** levonorgestrel oral Acceptability Study: HPTN 104 contraceptive pill AVAC May 2024



What is doxyPEP?

- 200mg doxycycline <72 hours after sex to prevent bacterial STIs.
- Recommended for MSM/TGW with an STI in the last 12 months.
- Only study in cisgender women showed no efficacy.
- "Providers should use their clinical judgement and shared decision-making to inform use of doxy PEP with populations that are not part of CDC recommendations."



Resources

National HIV PrEP Curriculum

https://www.hivprep.uw.edu/

CDC/HHS

www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf

IAS-USA

www.iasusa.org/resources/guidelines/

Consultation PrEPLine (855-448-7737)
For urgent questions or ambiguous test results



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