

# Speaker Disclosures

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AIDS Foundation (& Magnet Medical Director)  
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*[does not speak for, invest in, or otherwise directly receive support from pharma]*

# What *is* HIV Pre-Exposure Prophylaxis?

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Antiretroviral (ARV) medication taken to reduce the risk of sexually-acquired HIV infection in adults and adolescents. Importantly, PrEP is:

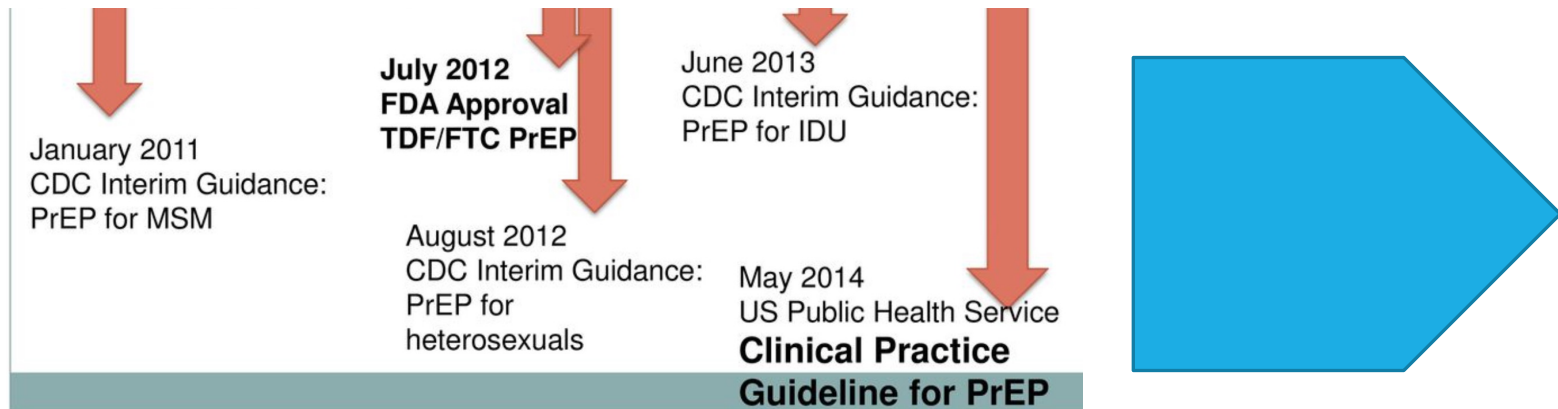
- Not just a *medication*, but also:
- **Wrap-around services**, incl *logistical & financial* navigation

Currently available PrEP medication forms usually taken **daily**, regardless of plans for sex

*Part of* a comprehensive, personal HIV prevention plan

*Includes* regular monitoring for acute HIV infection, intercurrent bacterial STIs, drug safety, and adherence

# PREP Guidelines & Recommendations



Released  
12/8/2021

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

A Clinical Practice Guideline



# How to PrEP?

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All sexually active adult and adolescent patients (*and those planning to become sexually active*) should receive information about PrEP.

Daily oral PrEP (**two** currently available formulations):

**TDF-FTC\*** for men and women at risk for acquiring HIV sexually  
or **TAF-FTC** for cisgender men and transgender women at risk for acquiring HIV sexually

**TDF-FTC** for men and women who are injection drug users and have injection practices that put them at risk for acquiring HIV

*At this time Descovy is not recommended for women or other persons at risk through receptive vaginal sex (though further research in progress).*

*\* Multiple generics available as of April 1, 2021*

# TDF-FTC vs TAF-FTC

DESCOVY



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TRUVADA



19mm x 8.5mm

Truvada (TDF-FTC or F/TDF)	Descovy (TAF-FTC or F/TAF)
>99% effective	>99% effective
Daily and 2-1-1	Daily
Effective for everyone	Gay, bisexual men, transwomen
Avoid if osteoporosis	Safer with osteoporosis
Avoid if kidney disease	Safer with kidney disease
May cause small weight loss	May cause small weight gain
Small decrease in cholesterol	Small increase cholesterol and triglycerides

# Health Care Policy and PrEP

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Policy, date	Requirements
<u>Federal</u> USPSTF – June 2019	<b>Grade A recommendation:</b> The USPSTF concludes with high certainty that the net benefit of the use of PrEP to reduce the risk of acquisition of HIV infection in persons at high risk of HIV infection is substantial. “Most US public and private insurers use the USPSTF grading scheme to guide their decisions about which preventive services to cover.” – Rochelle Walensky, in JAMA (2019).
<u>Federal</u> ACA – July 2021	On July 19, 2021, the Departments of Health and Human Services, Labor, and the Treasury issued new guidance to clarify the coverage of pre-exposure prophylaxis (PrEP) as a <b>preventive service</b> under the Affordable Care Act (ACA) [except “grandfathered” plans]
<u>California</u> CA SB-159 – October 2019	Insurance companies <b>may not requiring “step therapy” or prior authorization</b> for antiretroviral drugs, including PrEP and PEP.



# Influence of Guidelines on Oral PrEP Prescribing

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## CDC – 2021 (revised)

"F/TDF continues to be most commonly prescribed for PrEP (including PWID) who meet criteria for PrEP use. F/TDF is available as a generic medication that is equivalent to the brand name medication (Truvada)...F/TAF has recently been approved for daily PrEP use by men and transgender women at sexual risk....F/TAF and F/TDF have equivalent high efficacy and safety as PrEP for men at sexual risk. Generic F/TAF is not available....For most patients, there is no need to switch from F/TDF to F/TAF. While incremental differences in laboratory markers of bone metabolism and renal function have been seen in some studies, no differences in clinically meaningful adverse events have been seen...F/TAF is indicated for patients with eCrCl <60 ml/min but ≥30 ml/min. Either F/TDF or F/TAF can be used when eCrCl ≥60 ml/min...Clinicians may prefer F/TAF for persons with previously documented osteoporosis or related bone disease but routine screening for bone density is not recommended for PrEP patients."

## Ex: NYS 2021 (revised)

"TDF/FTC is the preferred PrEP regimen because of its proven efficacy and safety in trials as well as its suitability for use as PrEP across all populations. TAF/FTC is an alternative option for men who have sex with men (MSM) and transgender women and is preferred in cisgender MSM and in transgender women with preexisting renal disease or osteoporosis, and may also be preferable in individuals with multiple risk factors for the development of either renal disease or osteoporosis."

## Provider Prescribing Practices

## Patient Shared Decision-Making

## UpToDate 2020

"For most adults and adolescents, we suggest TDF-FTC rather than TAF-FTC. We give TDF-FTC once daily for as long as the risk of infection persists...We generally prefer TDF-FTC rather than TAF-FTC for PrEP initiation because of the extensive experience with the use of this agent...In addition, TAF-FTC has been associated with mild but greater weight gain and slight changes in lipid parameters that are less favorable compared with TDF-FTC...However, in certain MSM and transgender women with bone and renal issues who are not eligible for TDF-FTC, TAF-FTC is preferred."



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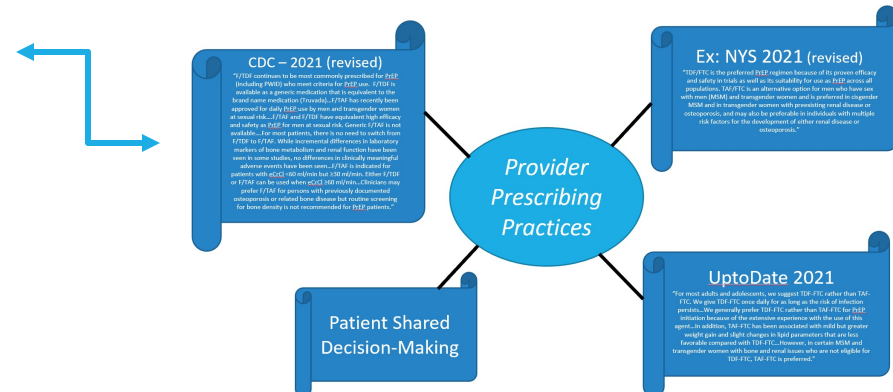
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## 2021 CDC PrEP Guidelines *revised*





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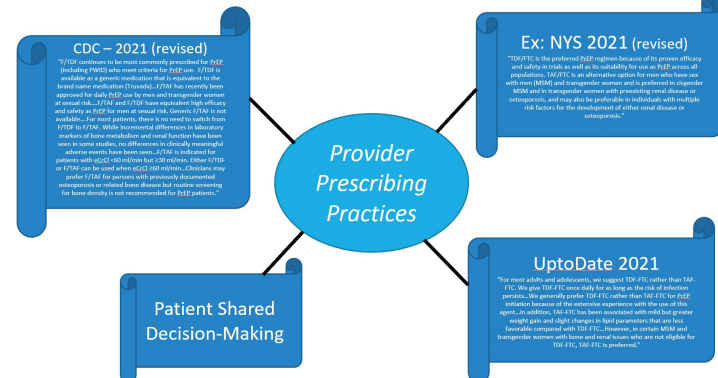
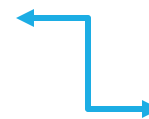
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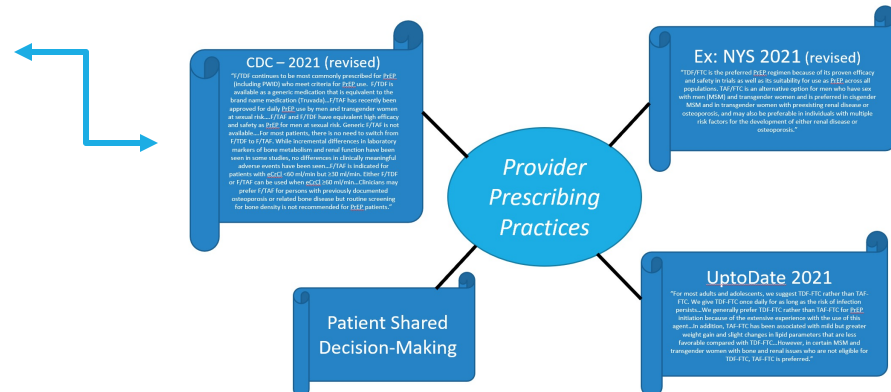
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## UpToDate, 2020

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# Influence of Practice Setting on Oral PrEP Choice

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PRACTICE SETTING	↑ Truvada (TDF-FTC or F/TDF)	↑ Descovy (TAF-FTC or F/TAF)
<b>Public health clinic</b> <i>Can access F/TDF at 340b or generic price for distribution</i>	May favor F/TDF prescribing because medication + wrap-around services can be provided feasibly at low-cost	<ul style="list-style-type: none"> <li>Fewer insured patients</li> <li>Clinic may not accept/utilize patient insurance</li> </ul>
<b>340b-powered clinic</b> <i>Marginal revenues from mostly brand prescribing are redeployed to program support/expansion or reaching new patients</i>		May favor F/TAF prescribing because marginal revenues support clinic (which invites critiques of medical necessity)
<b>Private providers</b>	Providers may be more accustomed to prescribing TDF, as FDA approved for PrEP since 2012	<ul style="list-style-type: none"> <li>Private providers habituated to prescribing “latest advances in therapy”</li> <li>Patients more likely to be commercially insured</li> </ul>
<b>Patient shared decision making focus</b>	<i>Advantages and disadvantages of each option discussed with patient; patient’s preferences taken into account, arriving at shared decision of medication choice</i>	

**These are observations, not opinions or recommendations**

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# Truvada vs. Descovy

## Key infographic tool

(Julia Marcus, PhD, MPH)

### Which medication should I prescribe for daily PrEP?

#### TDF/FTC (Truvada)

FDA approval: 2012



19 mm



#### EFFECTIVENESS

- ✓ for multiple populations

#### SAFETY

- Small ↓ in eGFR and BMD

#### COST

- \$1,845/month in 2019
- Generic in 2020



#### EFFECTIVENESS\*

MSM & TRANS WOMEN  
HETEROSEXUALS  
PWID

#### SAFETY / 48 WKS

eGFR (mL/min)  
HIP BMD  
LDL (mg/dL)  
BODY WEIGHT (kg)



12.5 mm

#### TAF/FTC (Descovy)

FDA approval: 2019



#### EFFECTIVENESS

- ✓ for MSM and transwomen
- ? for other populations

#### SAFETY

- Small ↑ in LDL and weight

#### COST

- \$1,845/month in 2019



\*No data available for trans men. Sources: [fda.gov/media/129607/download](https://www.fda.gov/media/129607/download); [fda.gov/media/129609/download](https://www.fda.gov/media/129609/download); [cdc.gov/hiv/risk/estimates/preventionstrategies.html](https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html) Created by: @JuliaLMarcus

# PrEP Basics

## *Key Messages for Your Patient*

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PrEP is safe and can reduce your risk of HIV by more than 90%



It takes at least 1 week on Truvada before you'll be protected for anal sex. 3 weeks for vaginal sex



Take 1 pill once a day. Finding a routine is essential



Get tested for HIV, STDs and have your kidneys checked every 3-6 months



Tell your provider if you plan to stop (or restart) PrEP

# Summary of Safety & Tolerability Issues

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## Safety\*

- Small but clinically significant decrease in creatinine clearance; resolved after interruption, usually w/o recurrence
- Small but sig. decrease in bone mineral density (BMD), without difference in fractures

## Tolerability\*

- Adverse effects occurred in minority of subjects
- GI adverse effects (eg, nausea and weight loss) more common in those receiving PrEP than placebo
  - Occurred in < 10% and primarily during the first month only (PrEP “start up” symptoms)

## Resistance

- Rare except in those with acute HIV at enrollment



# Follow-up Care on PrEP

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## **Every 3 months:**

- HIV test, medication adherence, and risk counseling
  - 2021 CDC GLs add HIV RNA to quarterly Ag/Ab testing
- Bacterial STI testing
- Pregnancy testing, as appropriate
- Prescription for 30 day supply with 2 refills

## **Every 6-12 months:**

- Kidney testing every 6 months
  - 2021 CDC GLs permit q12m creatinine testing for age <50 and CrCl  $\geq 90$  at PrEP initiation
- Lipids / triglycerides annually for TAF-FTC users
- HCV serology annually for MSM, TGW, and PWID

# Lab Testing Schedule for Oral PrEP Patients

**Table 5 Timing of Oral PrEP-associated Laboratory Tests**

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

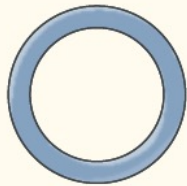
\* Assess for acute HIV infection (see Figure 4)

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# *What Types of Long-acting HIV Prevention Tools Are Under Study*

**NIAID is funding research on 4 types of long-acting HIV prevention.**

## **INTRAVAGINAL RING (IVR)**



Polymer ring inserted into the vagina releases antiretroviral drug over time.

## **IMPLANT**



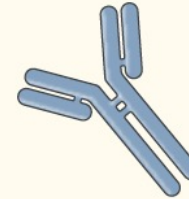
Device implanted in the body releases antiretroviral drug over time.

## **INJECTABLE**



Long-acting antiretroviral drug is injected into the body.

## **ANTIBODY**



Antibody is infused or injected into the body.

<https://www.hiv.gov/hiv-basics/hiv-prevention/potential-future-options/long-acting-prep>

# Injectable PrEP:

## *First-up: Cabotegravir-LA*

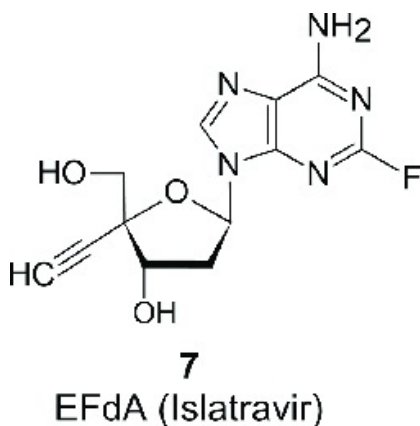
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- HPTN 083 showed non-inferiority to Truvada
- Not yet FDA approved (*watch for Q1 2022*)
- Injection (IM) in buttock every 8 weeks
- Risk from sex or injection drug use
- First dose, second dose after 4 weeks then every 8 weeks
- HIV testing at 1 month then every 2 months
- STD testing every 4 months
- Likely a “tail dose of oral PrEP for those discontinuing”

# Longer-acting Oral PrEP: *Islatravir for Monthly PrEP*

**Poz Magazine**  
January 26, 2021



SCIENCE NEWS

## Islatravir Shows Promise for Once-Monthly Oral PrEP

Monthly islatravir pills are just one of the long-acting options in the HIV prevention pipeline.



California PTC

# The PrEP Research Pipeline:

## *Future options will be varied*

The pipeline of non-vaccine HIV prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable antiretrovirals and more.

Also pictured are the range of multipurpose prevention technologies in development that aim to reduce the risk of HIV and STIs and/or provide effective contraception for women.

