

# Prepping for PrEP

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# Disclosures

- I have no financial disclosures or conflicts of interest with the material in this presentation.



# Outline

INTRODUCTION

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DISCUSSING PrEP

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PRESCRIBING PrEP

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MONITORING PrEP

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SUMMARY

# Introduction

- Over 1 million new human immunodeficiency virus (HIV) infections occur annually worldwide
- More than 30,000 HIV infections occur annually in the United States
- There are no effective vaccines to prevent HIV transmission
- The use of pre-exposure prophylaxis (PrEP) with antiretroviral therapy (ART) has been proved to be an effective HIV prevention strategy

# Introduction

- Less than one-third of people who meet PrEP indications have ever been prescribed PrEP
- PrEP prescriptions have been particularly limited in the United States in certain at-risk patient populations such as Black patients, Hispanic/Latinx patients, adolescents, and transgender individuals

# PrEP (pre-exposure prophylaxis)

- Medicine that reduces the chances of acquiring HIV through sex or injection drug use
- When taken as prescribed, it is highly effective for preventing HIV
  - Reduces the risk of getting HIV from sex by about 99% and from injection drug use by at least 74%

# Who can benefit from PrEP?

- **CDC recommendation:** All sexually active patients should be informed about PrEP
- **USPSTF recommendation:** PrEP should be **prescribed** to patients who are at high risk of HIV acquisition

Population	Recommendation	Grade
Adolescents and adults at increased risk of HIV	<p>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.</p> <p>See the Practice Considerations section for more information about identification of persons at increased risk and about effective antiretroviral therapy.</p>	<b>A</b>

# USPSTF Risk Assessment

**The USPSTF recommends that the following persons be considered for HIV PrEP:**

1. Sexually active adults and adolescents weighing at least 35 kg (77 lb) who have engaged in anal or vaginal sex in the past 6 months and have any of the following:
  - A sexual partner who has HIV (especially if the partner has an unknown or detectable viral load).
  - A bacterial sexually transmitted infection (syphilis, gonorrhea, or chlamydia for men who have sex with men and transgender women; gonorrhea and syphilis for heterosexual women and men) in the past 6 months.
  - A history of inconsistent or no condom use with sex partner(s) whose HIV status is not known; assessing risk in conversation with the patient and considering factors such as number of partners, the specific sexual activities a person engages in, and whether their sex partner or partners are in a group with a higher prevalence of HIV (eg, men who have sex with men or with men and women, transgender women, persons who inject drugs, and persons who engage in transactional sex).
2. Persons who inject drugs and have a drug injecting partner who has HIV or who shares injection equipment.

# USPSTF Risk Assessment

Transgender women are at especially high risk of HIV acquisition and should be considered for PrEP based on the criteria outlined above.

Persons who engage in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers or persons trafficked for sex work, constitute a group at increased risk of HIV acquisition and should be considered for PrEP based on the criteria outlined above.

Persons who request PrEP may have undisclosed behaviors that put them at risk.

# Racial disparities

- PrEP is underutilized, particularly for Black and Hispanic/Latinx patients with indications for PrEP
- In 2021, Black Americans accounted for approximately 40% of new HIV diagnoses
- In 2021, only 11% of Black patients who were expected to benefit from PrEP received it
- In 2021, 78% of White patients who met criteria for PrEP received it

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# Discussing PrEP

# Discussing PrEP with patients

- Be present, listen
- Routinely take a sexual and injection drug use history for all patients
- Inform all adolescents and adults who are sexually active or who inject drugs that there are ways to help prevent acquisition of HIV
- Ask about interest in and readiness for PrEP
  - *What do you know about PrEP?*
  - *Do you know anyone on PrEP?*
  - *What makes you want to start PrEP?*
  - *What barriers do you foresee?*

# Types of PrEP

## TRUVADA

- Pill
- Combination of emtricitabine and tenofovir disoproxil fumarate
- For people at risk through sex or injection drug use
- Estimated GFR should be at least 60



**Truvada®**

**Tenofovir disoproxil fumarate 300 mg +  
Emtricitabine 200 mg (F/TDF)**

## DESCOVY

- Pill
- Combination of emtricitabine and tenofovir alafenamide
- For people at risk through sex
- Not approved for people assigned female at birth who are at risk for HIV through receptive vaginal sex
- Estimated GFR should be at least 30



**Descovy®**

**Tenofovir alafenamide 25 mg +  
Emtricitabine 200 mg (F/TAF)**

## APRETUDE

- Shot
- Cabotegravir
- For people at risk through sex
- Administered every month for 2 months, and then every 2 months

*All types: patient must weigh at least 77 lbs (35 kg)*

# Side effects

## Truvada

- Headache – often resolves in a few weeks
- Abdominal discomfort, nausea, diarrhea – often resolves in a few weeks
- Small decrease in eGFR – improves upon discontinuation
- Slightly decreased bone density (no increased risk of fractures; greatest during first 6 months then stabilizes)

## Descovy

- Headache – often resolves in a few weeks
- Abdominal discomfort, nausea, diarrhea – often resolves in a few weeks
- Small increase in LDL
- Slight increase in body weight

# Cabotegravir LA injection

- Has a long half-life (may be detectable in blood for more than a year)
- Can be considered for patients with conditions that are associated with an increased risk of adverse events with Truvada or Descovy (i.e. reduced kidney function or bone disease)
- An oral agent (Truvada or Descovy) is required for a period of time when discontinuing cabotegravir LA injections to reduce risk of developing resistance if HIV infection is acquired when cabotegravir levels are suboptimal
- Patient needs to be near a center that administers cabotegravir LA so doses are not missed
- Mild injection site reactions can occur (injected into gluteal muscle)
- For patients concerned about side effects of cabotegravir LA (such as headache), oral cabotegravir (30 mg once daily) can be administered for 4 weeks leading up to injection initiation

# How long does PrEP take to work?

- Receptive anal sex (rectal tissue): pills reach maximum protection from HIV at about 7 days of daily use
- Receptive vaginal sex (cervico-vaginal tissue): pills reach maximum protection at about 21 days of daily use
- Injection (blood exposures): limited data, possibly 21 daily doses
- Insertive anal sex, insertive vaginal sex: limited data available
- Cabotegravir injection: limited data available (likely 7-30 days)

# “On-Demand” PrEP 2-1-1 Dosing

- For MSM with anal exposures only
- Only for use with Truvada
- There is substantial published data supporting this dosing strategy, but it has not been reviewed by the FDA or recommended by the CDC
- The International AIDS Society of the US, European AIDS Clinical Society, WHO all endorse this dosing strategy

# “On-Demand” PrEP 2-1-1 Dosing

- 2 pills 2-24 hours before anal sex (24 hours before for optimal protection)
- 1 pill 24 hours after first dose
- 1 pill 24 hours after second dose
  
- *If there is another exposure within 7 days of the last dose, take 1 pill 2-24 hours before anal sex, then 1 pill 24 hours after first dose, then 1 pill 24 hours after second dose*
- *If there are continued daily sexual exposures, continue 1 pill daily until 48 hours has passed since last sexual encounter*

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# Prescribing PrEP

# History Taking

- Take a medical, sexual, and substance use history
- Check for HIV exposures in past 72 hours (offer post-exposure prophylaxis)
- Check for recent symptoms of flu-like/mono-like illness (fever, sore throat, rash, headache)
- Ask about any history of renal disease
- Discuss willingness and ability to take a medication on a daily schedule and to return for regular appointments and labs while taking PrEP

# Baseline testing

- **HIV test:** HIV antibody test (4<sup>th</sup> gen Ag/Ab recommended)
  - Include HIV RNA PCR viral load for patients with acute HIV symptoms and possible HIV exposure within the last month
- **Serum creatinine:** BMP or CMP
- **Hepatitis B testing**
- **Hepatitis C antibody**
- **STIs** (based on sexual exposures)
  - Syphilis
  - Urethral/Vaginal, Rectal, Pharyngeal GC/CT (consider self collected swabs)
- **Pregnancy test** when appropriate
- **Lipid Panel** if Descovy is being considered

# Hepatitis B testing

- Tenofovir and emtricitabine are also used to treat chronic HBV
- Patients can experience significant hepatitis flares if tenofovir is discontinued
- Testing for HBV infection should include hepatitis B surface antigen, hepatitis B core antibody, hepatitis B surface antibody
- Patients without evidence of immunity should be vaccinated against HBV
- For patients who have chronic HBV infection and require treatment, tenofovir-containing PrEP may be appropriate
- For patients who have chronic HBV infection and don't require treatment, cabotegravir LA may be preferred

# Prescribing PrEP

- It is recommended to prescribe oral PrEP the same day as the initial visit
- Typically, a 30-day supply is prescribed with a 1-month follow-up visit
- Testing for HIV and HBV should ideally be done prior to the visit however testing can be done the same day as the harms of short-term PrEP are likely to be minimal, even if a patient has undiagnosed renal disease, HBV, or HIV

# PrEP Smart Set

PLAN **SmartSets** Research BPAs

SmartSets

Prep

Search Results

PrEP Management (HIV prevention)

SmartSet Search

Prep

SmartSets

Search SmartSets by user

Name	User Version Name	Type
PrEP Management (HIV prevention)		SmartSet
PrEP Cabotegravir Focused		SmartSet
IR SANTA MONICA CLINIC Pre Procedure Outpatient		

PrEP Management (HIV prevention) [Manage User Versions](#)

- ▶ Goal of Protocol
- ▶ Target Population
- ▶ PrEP Counseling and Drug-Drug Interactions
- ▼ PrEP Pre-Initiation Orders (obtain before starting PrEP)
  - ▶ PrEP Pre Order [Click for more](#)
  - ▶ PrEP Medication Orders
- ▶ Referrals
- ▶ Monitoring/Orders During Treatment
  - Activate Health Maintenance for tracking of PrEP (Uncheck order if HM Monitoring is not desired)  
[Clinic Performed](#)
- ▶ Patient Follow-up
- ▶ After Visit Summary Patient Instructions
- ▶ PrEP Diagnosis Codes
- ▶ Progress Notes
- ▶ Additional SmartSet Orders

# PrEP Smart Set

## ▼ PrEP Pre-Initiation Orders (obtain before starting PrEP)

### ▼ PrEP Pre Order

Guidelines recommend baseline testing of all the following in the PrEP Pre-Orders section.

The only contraindications to starting PrEP are a positive HIV test or a eGFR of < 60.

#### LAB RESULTS

Lab Test	Last Value
HepA (IgG + IgM)	No results found for: "HEPATITISAAB"
HBsAb	No results found for: "HEPBSURFACEAB"
HBsAg	No results found for: "HEPBSURFACEAG"
HCV Ab	HCV Ab Screen (no units) Date: 10/18/2023 Value: Nonreactive
RPR	No results found for: "RPR"
HIV	HIV-1/2 Ag/Ab Screen 4th Generation Date: 10/13/2023 Value: Nonreactive Ref Range: Nonreactive Status: Final Comment: <i>This test was performed using the Elecsys HIV Duo assay on a Roche e801 analyzer.</i>
eGFR	No results found for: "NORMCREATCL", "GFRESCYSCCR"

PrEP initiation should not be withheld while waiting for HBV test results. If positive for active Hepatitis B, patients should be seen by an infectious disease consultant.

Lab Test	GC PCR	CT PCR
GC/CT NAAT (Last Year)	No results found for: "NEISSERIAGONORRHOE AEP CR"	No results found for: "CHLAMYDIATRACHOMATI SPCR"

HIV-1/2 Ag/Ab 4th Generation with Reflex Confirmation ■

Routine

Comprehensive Metabolic Panel ■

Routine

Hep A Ab, Total ■

## ▼ PrEP Medication Orders

### Truvada is first line for PrEP at UCLA

- cost-effective for patients
- slight reductions in LDL and HDL levels

Descovy is not recommend unless clinically indicated below:

- For documented  $30 \leq \text{eGFR} \leq 60$
- For known osteopenia/osteoporosis
- For intolerance to Truvada pill size

Additionally, Descovy:

- Is only approved for non-vaginal routes of HIV exposure
- May increase weight, LDL, and total cholesterol levels.

### ▼ Truvada: Recommended first line

PrEP at Start (**Month 1**): Rx lasts 30 days.

PrEP at Month **2 and 3**: Rx lasts 60 days.

PrEP at Month **4+**: Rx lasts 90 days.

For PrEP at Start (Month 1): emtricitabine-tenofovir (TRUVADA) 200-300 mg tablet  
Disp-30 tablet, R-0

For PrEP at Month 2 and 3: emtricitabine-tenofovir (TRUVADA) 200-300 mg tablet  
Disp-60 tablet, R-0

For PrEP at Month 4+: emtricitabine-tenofovir (TRUVADA) 200-300 mg tablet  
Disp-90 tablet, R-0

▶ Descovy: High Cost, only if clinically indicated

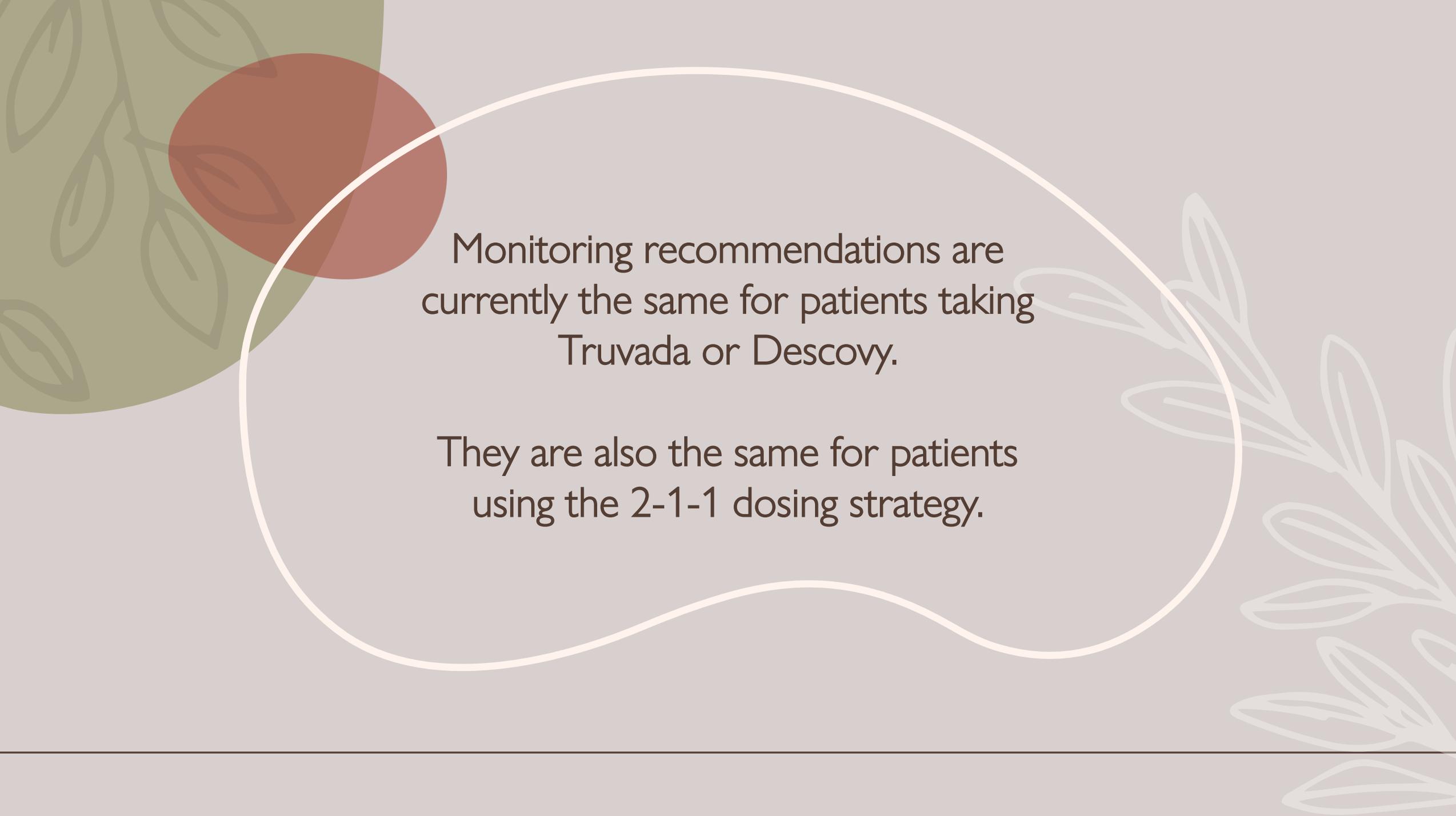
[Click for more](#)

# Post-exposure prophylaxis

- Should be given within 72 hours of an exposure
- Three drug regimen: Truvada (tenofovir disoproxil fumarate-emtricitabine) PLUS integrase strand transfer inhibitor (raltegravir twice daily or dolutegravir once daily)
- Typical duration of 28 days

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# Monitoring PrEP

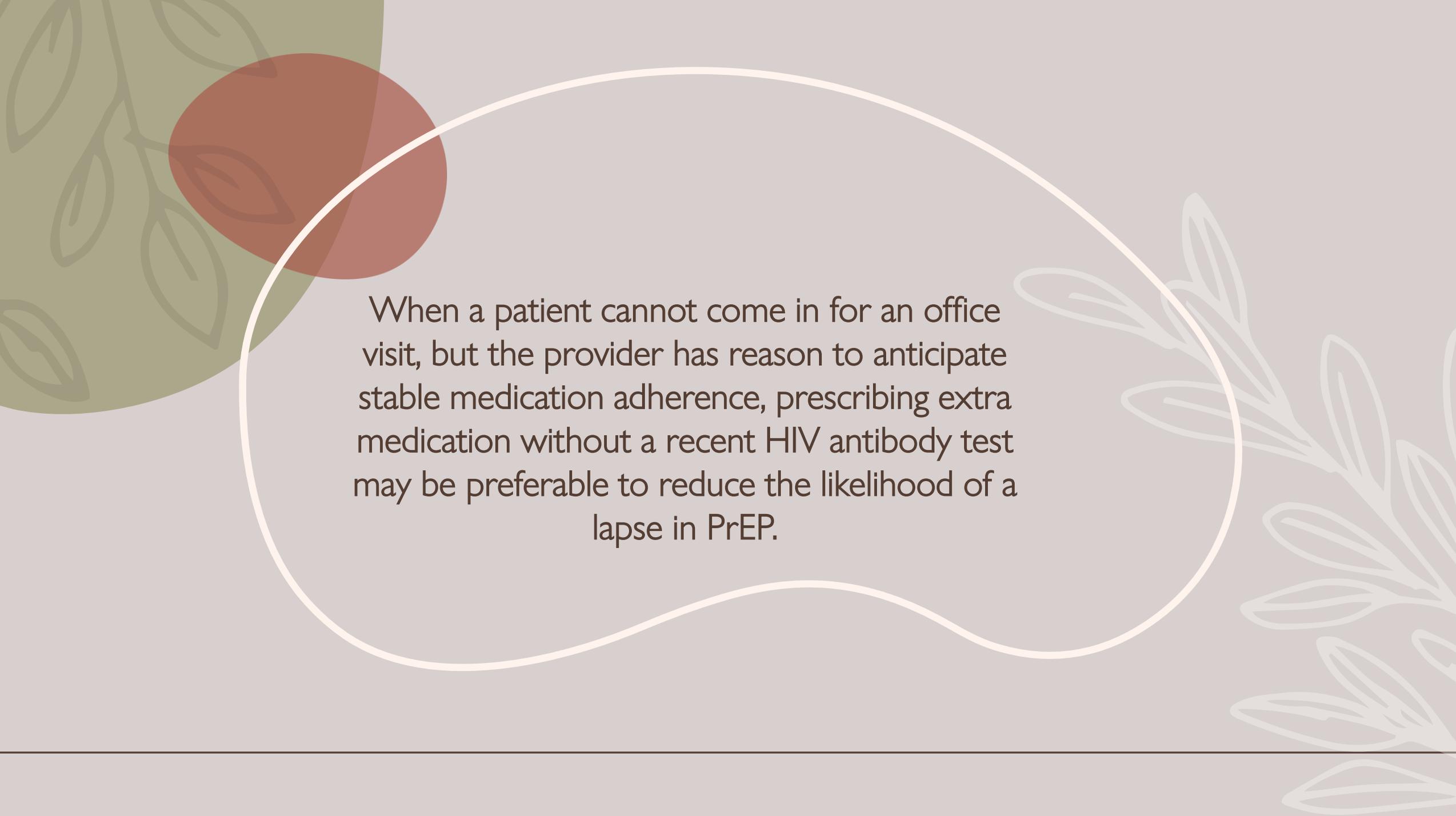


Monitoring recommendations are currently the same for patients taking Truvada or Descovy.

They are also the same for patients using the 2-1-1 dosing strategy.

# Follow-up Timeline

- **30 days after initiation**
  - Discuss side effects, patient interest in continuing, adherence, ongoing risk, signs and symptoms of acute HIV infection
  - Prescribe an additional 60-day supply
- **Every 3 months**
  - HIV test (4<sup>th</sup> gen antigen/antibody test), STI screening, pregnancy test when appropriate
  - Prescribe 90-day supply if HIV test is negative at each visit
- **Every 6 months**
  - Check serum creatinine
- **Every 12 months**
  - Check Hepatitis C antibody



When a patient cannot come in for an office visit, but the provider has reason to anticipate stable medication adherence, prescribing extra medication without a recent HIV antibody test may be preferable to reduce the likelihood of a lapse in PrEP.

# Positive HIV test

- What if a patient tests positive for HIV while on PrEP?
  - Discontinue PrEP to avoid development of HIV resistance
  - Start the patient on HIV antiretroviral treatment as soon as possible
  - Order HIV genotype

# Discontinuing PrEP

- It is recommended that patients continue PrEP as long as the risk of infection persists
- For persons who initiate PrEP because their partner has HIV, PrEP should be continued until their partner has achieved a stably suppressed viral load (typically occurs by 6 months after initiating antiretroviral therapy)
- When a person decides to discontinue PrEP, treatment should be continued for 2-30 days after their last sexual exposure (2 days for cisgender men who have sex with men; 30 days for all other populations)
- HIV testing should be performed at the time of PrEP discontinuation

# Summary

- Pre-exposure prophylaxis (PrEP) with antiretroviral therapy (ART) is associated with marked reductions in HIV transmission in several populations
- Available regimens: single tablet once daily oral agents (Truvada, Descovy); injectable therapy with long-acting cabotegravir which is administered every month for 2 months and then every 2 months
- For most patients, once daily Truvada is recommended as it is the most widely studied regimen and has been evaluated in all patient populations
- If taken as prescribed, Truvada can reduce the risk of sexual HIV transmission by nearly 100%
- Truvada should be avoided in patients with reduced kidney function (GFR<60) or osteoporosis
- Patients receiving PrEP should have regular follow-up (ideally every 3 months for oral regimen)

# References

- UpToDate:
  - *HIV pre-exposure prophylaxis*
  - *Management of nonoccupational exposures to HIV and hepatitis B and C in adults*
- CDC
- AAFP
  - *Preexposure Prophylaxis for the Prevention of HIV Infection: Recommendation Statement*
- USPSTF guidelines
- New York Times
  - *Expert Panel Recommends New Options for H.I.V. Prevention*
- California Department of Public Health (CDPH)
  - *Quick Clinical Guide: HIV PrEP*
- HIVinfo.NIH.gov
  - *Pre-Exposure Prophylaxis*



# Questions?

Thank you!