HRC ARKANSAS

PrEP

PROVIDER TOOLKIT

HUMAN RIGHTS CAMPAIGN®

DEAR PRESCRIBER OR INDIVIDUAL INTERESTED IN STARTING PrEP,

Enclosed in this packet, you will find information regarding pre-exposure prophylaxis (PrEP) and if you or a patient should begin this regimen. Also included are LGBTQ Competency Resources, patient handouts, billing and coding methods, and payment options for patients to allow the best care possible for patients at risk for HIV.

Southern states face internal disparities based on several factors: geography, legislation, social factors, income barriers, and overall low access to health care services. African American men who engage in homosexual behavior are at the highest risk, followed by their white counterparts. However, gay Latino men and black hetero-sexual woman are also at risk. The south currently makes up 44% of all people living with HIV in the US. Eight of the ten states with the highest rates of new HIV diagnoses are in the South.

The purpose of this toolkit is to allow both patients and physicians the opportunity to learn more about using Truvada® as a way to prevent HIV transmission. We also hope that together we can increase diagnosis of HIV by increasing HIV testing, ensuring patients gain access to care and treatment, teaching the importance of safe sex and condom usage, and supporting behavioral changes.

If you feel like you would like to be part of the PrEP registry so patients can identify you as a provider online, please register online at: **preplocator.org/providers/new/**

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PrEP INFORMATION FOR PROVIDERS AND PATIENTS

FREQUENTLY ASKED QUESTIONS

WHAT IS PrEP?

PrEP stands for Pre-Exposure Prophylaxis. It is a once-daily pill regimen that can help you stay HIV-negative. The only drug that is FDA-approved for PrEP is a prescription medication sold under the brand name Truvada®.

IS PrEP A VACCINE?

There is currently no vaccine for HIV. PrEP medication does not work the same way as a vaccine. When taken as prescribed, PrEP can help block important pathways that the HIV virus uses to infect a person's immune system. The presence of the medication in your bloodstream can often stop the HIV virus from establishing itself and spreading in your body. If you do not take the Truvada® pills every day, there may not be enough medicine in your blood stream to block the virus.

SHOULD I CONSIDER TAKING PrEP?

Only a medical provider can help you answer that question for sure. Generally, PrEP is for anyone at increased risk for contracting HIV, including: anyone who does not have HIV who is in an ongoing relationship with a person living with HIV, anyone who does not consistently use a condom, and anyone who shares injection drug or hormone equipment. Studies have shown that PrEP can be beneficial for people of various gender identities and sexual orientations.

▶ **KEY POINT** PrEP has been shown to be more than...

90% **effective against contracting HIV**

HOW WELL DOES PrEP WORK?

When taken as prescribed, PrEP has been shown to be more than 90 percent effective against contracting HIV. PrEP is much less effective if it is not taken daily. PrEP should be taken once every day, ideally at the same time of day. Daily adherence is essential to maintaining PrEP's effectiveness.

IS PrEP SAFE?

PrEP is safe and generally well tolerated. The drug used for PrEP, Truvada®, has been used to treat people living with HIV since 2004. PrEP can cause mild side effects, including upset stomach, headaches and weight loss, especially at the beginning of the regimen. Rare side effects include kidney (nephrotoxicity) or bone problems (osteoporosis). Talk to a knowledgeable healthcare provider if you are concerned about or experience any of these side effects.

HOW CAN I START PrEP?

If you think you may be at high risk for HIV, talk to your medical provider about PrEP. Any licensed healthcare provider can prescribe PrEP. Most private insurance plans cover PrEP, as does Medicaid, the state-run health insurance program for low-income individuals. If you are uninsured or underinsured, ask your healthcare provider about pharmaceutical patient assistance programs, which may be able to offset the cost of the medication.

WHAT TO EXPECT WHEN STARTING PrEP

If you and your medical provider agree that PrEP might reduce your risk of getting HIV infection, you will need to come in for a general health physical, blood tests for HIV, and tests for other infections that you can get from sex partners. Your blood will also be tested to see if your kidneys and liver are functioning well. If these tests show that PrEP medicines are likely to be safe for you to take and that you might benefit from PrEP, your medical provider may give you a prescription after discussing it with you.

Taking PrEP medicines will require you to follow-up regularly with your medical provider. You will receive counseling on sexual behaviors and blood tests for HIV infection and to see if your body is reacting well to Truvada®. You should take your medicine every day as prescribed, and your medical provider will advise you about ways to help you take it regularly so that it stands the best chance to help you avoid HIV infection. Tell your medical provider if you are having trouble remembering to take your medicine or if you want to stop PrEP.

IF I TAKE PrEP CAN I STOP USING CONDOMS WHEN I HAVE SEX?

You should not stop using condoms because you are taking PrEP. PrEP will not give you any protection against other STDs, like syphilis and gonorrhea. You will get the most protection from HIV and other STIs if you consistently use condoms, even while taking PrEP.

HOW LONG DO I NEED TO TAKE PrEP?

PrEP should be taken every day for as long as you wish to have protection from HIV. For full effectiveness, it takes at least seven days for Truvada® to have a protective effect in the anus and at least twenty days for full effects in the vagina.

If you feel like you want to stop taking PrEP, consult your medical provider. There are several reasons that people stop taking PrEP. If your risk of getting HIV infections becomes low because of changes that occur in your life, you may want to stop taking PrEP. If you find you don't want to take a pill every day or often forget to take your pills, other ways of protecting yourself from HIV infection may work better for you. If you have side effects from the medication that are interfering with your life or if blood tests show that your body is reacting to PrEP in unsafe ways, your medical provider may stop prescribing PrEP for you.

▶ KEY POINTS

PrEP does not protect against other STDs. Do not stop using condoms because of PrEP.

While taking PrEP, remember to follow up regularly with your medical provider.

TRUVADA® MEDICATION INFORMATION SHEET FOR PATIENTS

BRAND NAME: Truvada® (tru-va-duh)

GENERIC NAME: tenofovir disoproxil fumarate and emtricitabine

WHY IS THIS MEDICATION PRESCRIBED?

- Truvada® is now being used to prevent HIV infection.
- When you take Truvada® to prevent HIV infection, medical providers refer to this use as "pre-exposure prophylaxis" or "PrEP".
- Truvada® is one of several medications that are currently used to treat human immunodeficiency virus (HIV) and hepatitis B virus infection.
- Truvada® is sometimes prescribed to some people who do not have HIV infection (for example, those who do not always use condoms or who have a sex partner that has HIV infection) to help reduce their chances of getting HIV infection.

HOW DOES TRUVADA® (PrEP) HELP PREVENT HIV INFECTION?

- HIV is a virus that attacks your body's immune cells (the cells that work to fight infections).
- The 2 medications that make up Truvada® (tenofovir and emtricitabine) block important pathways that viruses use to set up infection.

▶ **KEY POINT** You may be at higher risk of becoming infected with HIV if you miss doses or stop taking Truvada® than if you take it every day.

- When taken as prescribed, PrEP blocks the virus from making copies of itself and spreading throughout the body.
- By itself, PrEP with Truvada® does not work all the time so you should also use condoms during sex for the most protection from HIV infection.

HOW SHOULD THIS MEDICINE BE USED?

- You must take one tablet of Truvada® by mouth every day.
- Follow the directions on your prescription label carefully, and ask your medical provider or pharmacist to explain any part you do not understand.
- Do not stop taking Truvada® without talking to your medical provider. It is important to take PrEP as prescribed to ensure its effectiveness.

WHAT SHOULD I DO IF I FORGET A DOSE?

- Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
- Do not take a double dose to make up for a missed one.

WHAT SPECIAL PRECAUTIONS SHOULD I FOLLOW?

Before taking Truvada® (tenofovir and emtricitabine) you must do the following:

- Tell your medical provider and pharmacist if you are allergic to tenofovir, emtricitabine, or any other medications.
- Tell your medical provider and pharmacist about all prescription and nonprescription medications, (vitamins, nutritional supplements, and herbal products) you are taking. Your medical provider may need to change the doses of your medications or monitor you carefully for side effects.
- Tell your medical provider if you have or have ever had kidney or liver disease.
- Tell your medical provider if you become pregnant or if you are breastfeeding.

WHAT SPECIAL DIETARY INSTRUCTIONS SHOULD I FOLLOW?

- Continue your normal diet unless your medical provider tells you otherwise.

HOW SHOULD I STORE TRUVADA® IN MY HOME?

- You should keep Truvada® in the container it came in, tightly closed, and out of reach of children.
- You must store it at room temperature and away from excessive heat and moisture.
- Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

WHAT SHOULD I DO IN CASE OF EMERGENCY/OVERDOSE?

- In case of overdose, call your local poison control center at 1-800-222-1222. If the person has collapsed or is not breathing, call local emergency services at 911.

WHAT SIDE EFFECTS CAN THIS MEDICATION CAUSE?

You may experience the following side effects while taking Truvada®:

- upset stomach
- headache
- vomiting
- loss of appetite

These side effects usually fade during the first month of taking Truvada® for PrEP. Tell your medical provider if any of these symptoms are severe or do not go away.

Truvada® may cause other side effects. Some side effects can be serious. Call your medical provider immediately if you have any unusual problems while taking this medication or if you have any of the following: fever or chills especially with sore throat, cough, rash or other signs of infection

If you experience a serious side effect, you or your medical provider may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online at fda.gov/Safety/MedWatch or by phone 1-800-332-1088.

MAJOR STUDIES OF PrEP EFFICACY

PrEP was tested in several large studies with men who have sex with men, men who have sex with women, and women who have sex with men. All people in these studies (1) were tested at the beginning of the trial to be sure that they did not have HIV infection, (2) agreed to take an oral PrEP tablet daily, (3) received intensive counseling on safer-sex behavior, (4) were tested regularly for sexually transmitted infections, and (5) were given a regular supply of condoms.

Several studies showed that PrEP reduced the risk of HIV infection. Men who have sex with men who were given PrEP medication to take were 44% less likely to get HIV infection than were those men who took a pill without any PrEP medicine in it (a placebo). Forty-four percent was an average that included men who didn't take the medicine every day and those who did. Among the men who said they took most of their daily doses, PrEP reduced the risk of HIV infection by 73% or more, up to 92% for some.

Among men and women in couples in which one partner had HIV infection and the other partner initially did not ("HIV-discordant" couples), those who received PrEP medication were 75% less likely to become infected than those who took a pill without any medicine in it (a placebo). Among those who said they took most of their daily doses, PrEP reduced the risk of HIV infection by up to 90%.

In one study of men and women who entered the study as individuals (not as couples), PrEP worked for both men and women: those who received the medication were 62% less likely to get HIV infection; those who said they took most of their daily doses, were 85% less likely to get HIV infection.

But in another study, only about 1 in 4 women (<26%) had PrEP medication found in their blood when it was checked. This indicated that few women were actually taking their medication and that study found no protection against HIV infection.

More information on the details of these studies can be found at: **cdc.gov/hiv/prep**

MAJOR STUDIES OF PREP EFFICACY, 2009–2014

iPrEx – THE PRE-EXPOSURE INITIATIVE (2007–2010)

Grant RM, et al; "Preexposure chemo-prophylaxis for HIV prevention in men who have sex with men." NEJM[a] 2010;363(27):2587–99.

- Phase III Clinical trial to test the effecacy of Truvada® as PrEP among gay and bisexual men and transgender women who have sex with men
- 2,499 subjects in Peru (55%), Brazil (15%), Ecuador (12%), USA (9%), Thailand (5%) and South Africa (4%)
- 44% improvement in preventing HIV among subjects
- 92% improvement for those who took the medication as prescribed (daily)

TDF2 STUDY (2007–2009)

Thigpen MC, et al. "Antiretroviral pre-exposure prophylaxis for heterosexual HIV transmission in Botswana." NEJM[a] 2012;367(5):423–34

- Study of Truvada® as PrEP in Botswana
- 1,219 HIV-uninfected, sexually active, healthy male and female subjects 18–39 years of age
- 62% overall improvement in preventing HIV among subjects.
- Separate conclusions for men and women cannot be supported statistically

PARTNERS PrEP STUDY (2008–2010)

Baeten JM, et al. "Antiretroviral pro-phylaxis for HIV prevention in hetero-sexual Men and Women", NEJM[a] 2012;367:399–410.

- Comparative study of efficacy of both tenofovir (TDF), and Truvada® (combination emtricitabine/tenofovir [FTC/TDF])
- 4,747 heterosexual, sero-discordant couples enrolled in Kenya and Uganda
- 75% improvement in preventing HIV among subjects
- 90% improvement for those who took the medication as prescribed (daily)

BANGKOK TENOFOVIR STUDY (2005–2010)

Choopanya K, et al; "Antiretroviral prophylaxis for HIV infection in injecting drug users in Bankok, Thailand (the Bangkok Tenofovir Study): a randomized, double-blind, placebo-controlled phase 3 trial." Lancet 2013;381(9883):2083–90.

- Study at 17 drug-treatment clinics in Bangkok, Thailand
- 2,413 subjects
- 48.9% improvement on HIV prevention for injection drug users (IDUs) who took tenofovir
- 74% improvement for subjects who took medication as prescribed (daily)

FEM-PrEP (2009–2011)

Van Damme L, et al. "Pre-exposure prophylaxis for HIV infection among African women." NEJM[a] 2012;367(5):411–422.

- Multinational study of PrEP with women in Kenya, South Africa, and Tanzania
- 2,120 HIV-negative women
- Equivalent infection rates among women in the treatment group and the placebo group
- The study was discontinued on April 18, 2011 because the preliminary findings failed to show PrEP's efficacy

VOICE (VAGINAL AND ORAL INTERVENTIONS TO CONTROL THE EPIDEMIC) (2009–2011)

Marrazzo J, et al. "Pre-exposure prophylaxis for HIV in women: daily oral tenofovir, oral tenofovir/emtricitabine or vaginal tenofovir gel in the VOICE study (MTN 003)." 20th Conference on Retroviruses and Opportunistic Infections. Atlanta, GA, March 3–6, 2013.

- Multinational study with women in South Africa, Zimbabwe, and Uganda
- 5,029 HIV-negative women
- Equivalent infection rates among women across the various experimental groups
- Discontinued in 2011 due to lack of efficacy. Very poor adherence (<30%) by study participants

ANRS (AGENCE NATIONALE DE RECHERCHE SUR LE SIDA ET LES HÉPATITES VIRALES) IPERGAY TRIAL (2012–2014)

Molina J-M, Capitant C, Charreau I, Myer L, Spire B, Pialoux G, Chidiac C, Delfraissy J-F, Tremblay C. On Demand PrEP With Oral TDF-FTC in MSM: Results of the ANRS Ipergay Trial. Abstract presented to the Conference on Retroviruses and Opportunistic Infections (CROI), February 23–26, 2015, Seattle, Washington.

- Six sites in France and one in Canada, beginning in February 2012 to test PrEP "on demand" (2 pills of Truvada®, before each sexual intercourse, then another pill 24hr later and a forth pill 48hr after the first drug intake)
- 400 MSM
- 86% reduction in HIV infection among subjects
- Study was discontinued in 2014 because the trial had demonstrated such a high rate of efficacy. Further results from the study are pending release and publication.

Notes: (a) New England Journal of Medicine.

IS YOUR CLINIC READY TO OFFER PrEP?

CLINICAL SITE CHECKLIST

The Centers for Disease Control and Prevention has PrEP information and resources specifically for medical providers on their website, **cdc.gov/hiv/risk/prep/index.html**.

- ☐ Clinic is culturally competent to provide care to LGBTQ population
- ☐ Front-desk staff are aware that PrEP is provided and are able to triage patient calls and visits appropriately
- ☐ Clinic staff able to assist with PrEP medication assistance paperwork
- ☐ Healthcare providers willing to prescribe PrEP and have knowledge of:
  - How to take a detailed sexual history of:
    - » Number of sexual partners
    - » Does the patient prefer men, women, or both?
    - » Types of sexual practices (oral, anal, vaginal)
    - » Condom usage
    - » Birth control use
    - » Past history of sexually transmitted infections

Please see pages 17-18 for info on taking a detailed sexual history

▶ KEY POINT

Your clinic must be able to provide culturally competent care to LGBTQ individuals.

- ☐ Laboratory capacity for:
  - » HIV testing every 3 months
  - » Monitoring creatinine clearance every 3-6 months
    - STI screening (chlamydia, gonorrhea, and syphilis) every 3 months, focusing on all exposure sites
  - » Hepatitis A, B, and C screening
  - » Pregnancy testing, for cisgender women
  - » Urinalysis
- ☐ Adherence and risk reduction counseling available on-site

LGBTQ CULTURAL COMPETENCY RESOURCES

Healthy People 2020: Lesbian, Gay, Bisexual, and Transgender Health: **healthypeople.gov/2020 topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health**

National LGBT Health Education Center: A Program of the Fenway Institute: **LGBThealtheducation.org/topic/LGBT-health/**

TAKING A DETAILED SEXUAL HISTORY

Your patients' sexual history is an important part of their overall health and wellness. Taking a sexual history will help guide the physical exam, screening of all exposed sites for sexually transmitted infections (STI) and establish your patients' STI/HIV risk.

THE 5P'S OF SEXUAL HEALTH

- **Partners:** number and gender of partners over a given time
  - **Sample Question:** In the past 12 months, how many sexual partners have you had? Men? Women? Both? Transgender?
- **Practices:** Types of sexual practices — oral, vaginal, anal
  - **Sample Questions:** In the past 12 months, have you had vaginal sex? Oral sex? Anal sex?
  - *For men who have sex with men:* Are you the receptive partner ("the bottom")?
- **Protection from STIs:** Use of condoms and other methods
  - **Sample Questions:** How do you keep yourself from getting infected?
  - Do you use condoms consistently? If not, in which situations are you more likely to use a condom?
- **Past History of STIs:** Establish risk of repeat infections, HIV status and hepatitis risk
  - **Sample Questions:** Have you ever been diagnosed with an STI, such as HIV, herpes, gonorrhea, chlamydia, syphilis, HPV or trichomoniasis? When?
  - Have you had any recurring symptoms or diagnosis?
  - When was your last HIV test?
- **Prevention of Pregnancy:** Desire of pregnancy and use of prevention methods
  - **Sample Questions:** Are you trying to conceive or father a child? Do you want to avoid pregnancy?
  - Are you using contraception or practicing any form of birth control?
  - Do you need any information on birth control or referral?
- **Assess HIV and Hepatitis risk:**
  - **Sample Questions:** Have you or any of your partners been diagnosed with HIV or hepatitis C?
  - Have you or any of your partners injected drugs?

BEST PRACTICES FOR OBTAINING A SEXUAL HISTORY

- Ensure a safe patient environment
- Assure confidentiality
- Be non-judgmental
- Be sensitive and matter-of-fact
- Avoid assumptions

Adapted from A Guide to Taking a Sexual History, Centers for Disease Control and Prevention, cdc.gov/std/treatment/SexualHistory.pdf

INDICATIONS FOR PRESCRIBING PrEP

Men and Transgender Women Who Have Sex with Men

- HIV-positive sexual partner
- Recent bacterial STI (within the past 6 months)
- Multiple sex partners
- History of inconsistent or no condom use[1]
- Commercial sex work

Heterosexual and Bisexual Men and Women

- HIV-positive sexual partner
- Recent bacterial STI (within the past 6 months)
- Multiple sex partners
- History of inconsistent or no condom use[1]
- Commercial sex work

Injection Drug Users

- HIV-positive injecting partner
- Sharing injection equipment
- Recent drug treatment (but currently injecting)[2]

1. *Exception is a monogamous partnership with recently tested, HIV-negative partner*
2. *Recently been in a methadone, buprenorphine, or suboxone treatment program in the past 6 months*

▶ KEY POINTS

1 Provide education about PrEP and other methods that minimize the risk of HIV transmission to both members of an HIV-discordant couple whenever possible.

2 If you prescribe PrEP, include the following in counseling:

- » Importance of adherence to daily doses of medication
- » Importance of continuing condom use after conception to protect against sexually transmitted infections and to add protection against HIV infection

3 Signs and symptoms of acute HIV infection and the need for urgent HIV testing if HIV infection is suspected.

4 If your partner has HIV infection, PrEP may be an option to help protect you from getting HIV infection while you try to get pregnant, during pregnancy, or while breastfeeding.

CONTRAINDICATIONS AND CONSIDERATIONS IN PRESCRIBING PrEP

CONTRAINDICATIONS

- Documented HIV infection
  - » PrEP (TDF/FTC) given to an HIV-infected patient can result in drug resistance
- Creatinine clearance <60 mL/min5

CONSIDERATIONS

There are not absolute contraindications, but please proceed with caution and consider co-management with an infectious diseases specialist in patients:

- With Hepatitis B virus (HBV) infection
- Who are pregnant or are attempting to conceive
  - » Benefits of PrEP in pregnancy: decreased risk of acute HIV during pregnancy and decreased risk of mother-child HIV transmission
  - » Risks of PrEP in pregnancy: No data to suggest PrEP increases risk of birth defects, however there is not enough data to exclude the possibility of harm
- With pre-existing risk factors for chronic kidney disease (>65 years of age, hypertension, diabetes, etc.)
  - » Discuss possibility of kidney disease
  - » Taking concomitant nephrotoxic drugs or drugs that interact with PrEP
  - » Take thorough medication history and consider discussing with a pharmacist
- With osteopenia, osteomalacia, or osteoporosis
  - » Discuss risk of bone loss with tenofovir (TDF)

PRESCRIBING PrEP FOR ADOLESCENTS

Truvada® as PrEP is currently FDA approved for adults only.

As a part of primary health care, HIV screening should be discussed with all adolescents who are sexually active or have a history of injection drug use. Parental/guardian involvement in an adolescent's health care is often desirable but is sometimes contraindicated for the safety of the adolescent.

Data on the effectiveness and safety of PrEP for adolescents are inadequate. The risks and benefits of PrEP for adolescents should be considered carefully in context of local laws and regulations about health care decision-making by minors.

PrEP prescriptions with a recent STI in any type of provider setting do not require parental consent.

▶ KEY POINTS

If PrEP is discontinued, patients with HBV may have rebound viremia.

BONE HEALTH

Decreases in bone mineral density (BMD) have been observed in HIV-infected persons treated with combination antiretroviral therapy (including TDF-containing regimens). However, it is unclear whether this 3%-4% decline would be seen in HIV-uninfected persons taking fewer antiretroviral medications for PrEP. The iPrEx trial (TDF/FTC) and the CDC PrEP safety trial in MSM (TDF) conducted serial dual-emission x-ray absorptiometry (DEXA) scans on a subset of MSM in the trials and determined that a small (~1%) decline in BMD that occurred during the first few months of PrEP either stabilized or returned to normal. There was no increase in fragility (atraumatic) fractures over the 1-2 years of observation in these studies comparing those persons randomized to receive PrEP medication and those randomized to receive placebo.

Therefore, DEXA scans or other assessments of bone health are not recommended before the initiation of PrEP or for the monitoring of persons while taking PrEP. However, any person being considered for PrEP who has a history of pathologic or fragility bone fractures or who has significant risk factors for osteoporosis should be referred for appropriate consultation and management.

▶ KEY POINTS

1. PrEP shows a decreased risk of acute HIV during pregnancy and decreased risk of mother-child HIV transmission.

2. Truvada® as PrEP is currently FDA approved for adults only.

3. Studies show a modest decrease in bone mineral density in patients who started taking PrEP, however this bone loss ws reversible once PrEP is discontinued.

4. DEXA scans are not recommended for starting a patient on PrEP.

PrEP VISIT CHECKLIST

FIRST VISIT CHECKLIST

ASSESSMENT

- ☐ Conduct assessment to determine if the patient is at risk of contracting HIV (see pages 19-20)
  - » Truvada® is not indicated for HIV prophylaxis in individuals who are already living with HIV
- ☐ Assess indications, contraindications, and considerations to PrEP (see pages 21-24)
- ☐ If uninfected individual is not taking other HIV-1 medications or HBV medications
- ☐ Is the patient capable of adhering to a once-daily pill and returning to clinic for refills and lab work every 3 months?
- ☐ If the patient has no symptoms of acute HIV infection or recent (<1month) exposures to HIV
  - » IF YES: Perform both HIV test and a HIV qualitative RNA/NAAT
  - » Patient does not have known renal impairment or eGFR < 60ml/min
- ☐ Patient is counseled that PrEP does not protect against other sexually transmitted infections
  - » Risk-reduction strategies and counseling, such as avoiding intercourse with partners with unknown STI status as well as using condoms consistently, remain important

- ☐ Discuss payment for PrEP (see pages 37-38)

LAB TESTS

- ☐ HIV test: 4th generation antibody/antigen or HIV RNA PCR
  - » The required HIV testing can be accomplished by (1) drawing blood (serum) and sending the specimen to a laboratory for a routine HIV EIA (enzyme-linked immunoassay) or (2) performing a rapid, point-of-care, FDA-approved, fingerstick blood test
  - » Oral rapid tests should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests
  - » Clinicians should not accept patient-reported test results or documented anonymous test results
  - » 3-site STI screening
  - » Oropharyngeal and urine gonorrhea/chlamydia NAAT for all patients
  - » Self-administered rectal and/or vaginal swab gonorrhea/chlamydia NAAT for all patients who participate in receptive anal and/or vaginal sex
  - » Syphilis screening
  - » Hepatitis B and hepatitis C screening
  - » Hepatitis B screening surface antigen, surface antibody, core antibody); consider a full hepatitis B and C panel
  - » Vaccination recommended for those non-immune to hepatitis B or A
  - » Serum Creatinine or Basic Metabolic Panel (preferred) for all patients
  - » Baseline urine analysis to screen for proteinuria

- Pregnancy test for women of childbearing potential
  - Truvada® is a pregnancy B medication; it is often used in pregnant women living with HIV
  - There is limited data on the safety of Truvada® during breastfeeding. Discuss risks and benefits of Truvada® with the patient if pregnant

COUNSELING AND EDUCATION

- ☐ Emphasize adherence to medication
- ☐ Discuss additional risk reduction strategies in addition to PrEP.
- ☐ Emphasize consistent condom usage to prevent other STIs
- ☐ Discuss side effects (gastric pain, nausea, gas) which subsides in 1 to 2 months
- ☐ See Chapter 1 for additional resources to give patients beginning Truvada®
- ☐ Pre-exposure Prophylaxis (PrEP) for HIV Prevention frequently asked questions
- ☐ Truvada® medication information sheet for patients
- ☐ Give hepatitis A, hepatitis B, or HPV vaccines as appropriate

PRESCRIBING TRUVADA® AS PrEP FOR THE FIRST TIME

- ☐ Prescribe Truvada®, 30 day prescription 1 tablet daily with no refills after confirmed HIV negative test result[1]
- ☐ Schedule patient for follow up in 30 days to discuss access, adherences, and side effects

1. *Some providers prefer to have patients do pre-prescription testing and lab work 1 week prior to seeing a healthcare provider to prescribe PrEP. After the 1-week initial lab visit with the clinic, the patient returns the following week to meet a physician to review the patient's history, perform a physical exam, and initiative PrEP.*

▶ **KEY POINT** Truvada® likely requires up to...

3 WEEKS to be fully effective in vaginal mucosa

1 WEEK to be fully effective in rectal mucosa

SUBSEQUENT VISIT CHECKLIST

ASSESSMENT

- ☐ Side effects
- ☐ Symptoms of acute HIV infection
- ☐ Adherence and barriers to medication adherence
- ☐ Discuss continued risk for HIV, sexual activity, and condom usage

LAB TESTS

Every 3 months

- ☐ 4th generation antibody/antigen or HIV RNA PCR
- ☐ The required HIV testing can be accomplished: by (1) drawing blood (serum) and sending the specimen to a laboratory for a routine HIV EIA (enzyme-linked immunoassay) or (2) performing a rapid, point-of-care, FDA-approved, fingerstick blood test
- ☐ Oral rapid tests should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests

- ☐ Clinicians should not accept patient-reported test results or documented anonymous test results
- ☐ 3-site STI screening based on sexual activity
- ☐ Oropharyngeal and urine gonorrhea/chlamydia NAAT for all patients
- ☐ Self-administered rectal and/or vaginal swab gonorrhea/chlamydia NAAT for all patients who participate in receptive anal and/or vaginal sex
- ☐ Syphilis screening
- ☐ Pregnancy test for cisgender women

Every 6 months

- ☐ 4th generation antibody/antigen or HIV RNA PCR
- ☐ 3-site STI screening based on sexual activity
- ☐ Pregnancy test
- ☐ Basic/comprehensive metabolic panel

Annually

- ☐ Urinalysis
- ☐ Hepatitis C screening if indicated

▶ KEY POINT

FIRST FOLLOW UP AFTER
30 DAYS
THEN SUBSEQUENTLY EVERY
90 DAYS

COUNSELING AND EDUCATION AT EVERY VISIT

- ☐ Emphasize adherence to medication
- ☐ Discuss additional risk reduction strategies in addition to PrEP
- ☐ Emphasize consistent condom usage to prevent other STIs
- ☐ Discuss side effects (gastric pain, nausea, gas) which subsides in 1 to 2 months
- ☐ See Chapter 1 for additional resources to give patients beginning Truvada®
- ☐ Pre-exposure Prophylaxis (PrEP) for HIV Prevention frequently asked questions
- ☐ Truvada® medication information sheet for patients
- ☐ Give hepatitis A, hepatitis B, or HPV vaccines as appropriate

PRESCRIBING TRUVADA® AS PrEP AFTER 1 MONTH

- ☐ Prescribe Truvada®, 30 day prescription 1 tablet daily with 2 refills (or 90 days with no refill)
  - Follow-up no later than 3 months
- ☐ Schedule follow-up appointment just prior to end of 90 day prescription
- ☐ Some patients may require more frequent monitoring

PROVIDER FLOWSHEET

STEP 1

INITIAL VISIT

Get labs, assess for PrEP candidacy

▶ FOLLOW UP IN 1 WEEK

STEP 2

1 WEEK FOLLOW UP

Review labs with patients.
Initiate PrEP with 30 day supply.

▶ FOLLOW UP WITHIN 30 DAYS

STEP 3

1 MONTH FOLLOW UP

Review side effects and patients adherence. Give 60-day supply PrEP.

▶ FOLLOW UP IN 2 MONTHS

STEP 4

3 MONTH FOLLOW UP

Labs, review adherence, give 3-month prescription

▶ FOLLOW UP IN 3 MONTHS

MAINTENANCE

See patient every 3 months, repeating labs based on recommendations on right

▶ FOLLOW UP EVERY 3 MONTHS

1st Time PrEP Lab Draw and STI Tests

- Rapid HIV Test
- HIV RNA
- Syphilis
- Gonorrhea/Chlamydia Urine/Rectal/Vaginal/Throat
- Hep B Surface Ab
- HCV Antibody (Hep C Virus Ab)
- HBsAg Screen
- Hep A Ab, IgM
- Comprehensive Metabolic Panel
- Urinalysis
- Pregnancy Test

3 and 9 Month PrEP Lab Draw and STI Tests

- Rapid HIV Test
- HIV RNA
- Syphilis
- Comprehensive Metabolic Panel

PLEASE OFFER

- Gonorrhea/Chlamydia Rectal/Vaginal/Throat
- Pregnancy Test

6 Month PrEP Lab Draw and STI Tests

- Rapid HIV Test
- HIV RNA
- Syphilis
- Gonorrhea/Chlamydia Urine/Rectal/Vaginal/Throat
- Comprehensive Metabolic Panel
- Pregnancy Test

12 Month PrEP Lab Draw and STI Tests

- Rapid HIV Test
- HIV RNA
- Syphilis
- Gonorrhea/Chlamydia Urine/Rectal/Vaginal/Throat
- Comprehensive Metabolic Panel
- Urinalysis
- HCV Antibody (Hep C Virus Ab)
- Pregnancy Test

DISCONTINUING PrEP

Patients may discontinue PrEP medication for several reasons, including personal choice, changed life situations resulting in lowered risk of HIV acquisition, intolerable toxicities, chronic non-adherence to the prescribed dosing regimen despite efforts to improve daily pill-taking, or acquisition of HIV.

Upon discontinuation for any reason, the following should be documented in the health record:

- HIV status at the time of discontinuation
- Reason for PrEP discontinuation
- Recent medication adherence and reported sexual risk behavior

  For persons with incident HIV infection, see Reporting HIV and Other Mandatory Reportable Diseases pages 39-40.

FOR PERSONS WITH ACTIVE HEPATITIS B INFECTION:

If PrEP is no longer needed to prevent HIV infection, a separate determination should be made about whether to continue TDF/FTC as a means of providing TDF to treat HBV infection. Acute flares resulting from the reactivation of HBV infection have been seen in persons living with HIV after the cessation of TDF and other medications used to treat HBV infection. Such flares have not yet been seen in HIV-uninfected persons with chronic active HBV infection who have stopped taking TDF-containing PrEP regimens. Nonetheless, when such patients discontinue PrEP, they should continue to receive care from a clinician experienced in the management of HBV infection so that if flares occur, they can be detected promptly and treated appropriately.

Any person who wishes to resume taking PrEP medications after having stopped should undergo all the same pre-prescription evaluation as a person being newly prescribed PrEP. In addition, a frank discussion should clarify the changed circumstances since discontinuing medication that indicate the need to resume medication.

▶ KEY POINT

Any person looking to resume taking PrEP after having stopped must undergo the same pre-prescription evaluation

BILLING AND CPT CODES

BILLING CODES FOR PrEP

Category	ICD-10	Description
Contact with and (suspected) exposure to communicable diseases	Z20.6	Contact with and (suspected) exposure to HIV (recommended for prescriptions with Medicaid)
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z20.828	Contact with and (suspected) exposure to other communicable diseases
	Z20.89	Contact with and (suspected) exposure to unspecified communicable disease
	Z20.9	Contact with and (suspected) exposure to other viral communicable diseases
High-risk sexual behavior	Z72.51	High-risk heterosexual behavior
	Z72.52	High-risk homosexual behavior
	Z72.53	High-risk bisexual behavior
Other hazardous exposures	Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids
	Z77.9	Other contact with and (suspected) exposure hazardous to health
Contact with hypodermic needle	W46.0XXA	Contact with hypodermic needle (initial encounter)
	W46.0XXD	Contact with hypodermic needle (subsequent encounters)
	W46.1XXA	Contact with contaminated hypodermic needle (initial encounter)
	W46.1XXD	Contact with contaminated hypodermic needle (subsequent encounter)
Long-term prophylaxis	Z79.899	Other Long-Term (current) drug therapy

PAYMENT OPTIONS

Dear Prescriber,

In the following chapter, you will find resources for patients who need assistance in paying for PrEP. Please provide your patient with information about access to the Gilead Advancing Access Co-pay program (see below). You will also find paperwork for the Truvada® Medication Assistance Program and Advancing Access enrollment form for your office to have available to give patients.

Health Insurance and Government Programs

Private Insurance

- Most private insurances cover PrEP.
- Coverage varies based on plan. There may be deductibles and co-payments.

Medicaid

- PrEP prescription costs, medical appointments and lab tests are covered.
- Prior approval is required; approval must be renewed every three months.

GILEAD ADVANCING ACCESS PROGRAM AND CO-PAY COUPON CARD

- Advancing Access provides assistance to appropriate patients who are uninsured or underinsured, or who need financial assistance to pay for PrEP. Program offerings include:
  - » Access to counselors who can help patients and their providers with insurance-related questions, including coverage options.
  - » The Advancing Access Co-pay Coupon Program, which provides co-pay assistance for eligible patients (up to $3,600 in co-pays per year with no monthly limit).
  - » The Advancing Access PAP, which provides Gilead medications at no charge for eligible patients with no other insurance options. Patient must have annual income less than 500% of the FPL (in 2016, $59,400 for a one-person household).
- **Contact**: 1-800-226-2056 or visit gileadadvancingaccess.com/copay-coupon-card

PATIENT ACCESS NETWORK FOUNDATION

- Offers services to people with chronic disease for whom cost limits access to critical medical treatment due to rising deductibles and co-pays.
- Offers one-time grant to cover up to $7,500 of prescription costs for one year.
- Patient must have private insurance, Medicare or Medicaid.
- Patient must have annual income less than 500% FPL (in 2016, $59,400 for a one-person household). If income is above this amount, patient may still qualify if prescription costs exceed 10% of income.
- **Contact:** 1-866-316-7263 or visit panapply.org

REPORTING HIV AND OTHER MANDATORY REPORTABLE DISEASES

RESPONSIBILITY FOR REPORTING

It shall be the duty of every physician, practitioner, nurse; every superintendent or manager of a dispensary, hospital, clinic, nursing or extended care home; any person in attendance on a case of any of the diseases or conditions declared notifiable; or the local health department to report the disease or condition to the Department utilizing the Toll Free Communicable Disease Reporting System (1-800-482-8888) within twenty-four (24) hours.[1]

Any person who determines by laboratory examination that a specimen derived from the human body yields evidence suggestive of a communicable disease shall report, within twenty-four (24) hours, to the Department on the Toll Free Communicable Disease Reporting System microscopical, cultural or other evidence of the presence of any of the diseases declared notifiable.[1]

1. *Arkansas State Board of Health; Rules and Regulations Pertaining to Communicable Disease, 2005*

Electronic reporting forms for the Arkansas Department of Health may be found at the following links:

- **HIV-AIDS-STI Surveillance:** healthy.arkansas.gov/programs-services/topics/hiv-aids-sti-surveillance
- **Adult Case Report Form:** healthy.arkansas.gov/images/uploads/pdf/Adult_Case_Report_Form_2016_Fillable.pdf
- **Mandatory Reportable Diseases List and Instructions:** healthy.arkansas.gov/images/uploads/pdf/List_and_Instructions_Reportable_Diseases_2017.pdf

ARKANSAS REPORTABLE DISEASES LIST

Anaplasmosis
Arboviral, all types
Babesiosis
Blastomycosis
Brucellosis
CD4+ T-Lymphocyte count
Campylobacteriosis
Chagas Disease
Chancroid
Chikungunya
Chlamydial Infections
Coccidioidomycosis
Creutzfeld-Jakob Disease
Cryptosporidiosis
Cyclosporiasis
Dengue virus infections
Diphtheria
Ehrlichiosis
E.coli, Shiga toxin producing
Encephalitis, all types
e.g.: Powassan, EEE, St. Louise, West Nile, WEE
Food poisoning, all types
Giardiasis
Gonorhea
Haemophilus influenzae, invasive
Hansen's Disease (Leprosy)
Hantavirus Pulmonary Syndrome
Hemolytic-uremic Syndrome
HbsAg-positive pregnant female
Hepatitis (A, B, C, or E)
Histoplasmosis
HIV
Influenza (viral type, if known)
Influenza deaths, all ages
Legionellosis
Lyme Disease
Malaria
Measles (Rubeola)
Melioidosis
(Burkholderia pseudomallei)
Meningitis, all types
Mumps
Pertussis
Psittacosis
Rabies, human and animal
Rickettsiosis, Spotted Fever (RMSF)
Rubella, including congenital infection
Salmonellosis (including Typhoid Fever)
Shigellosis (include all isolates)
Staphylococcus aureus infection: Vancomycin-resistant (VRSA)
Streptococcus pneumoniae, Invasive, Indicate antibiotic susceptibility if known
Streptococcal Disease, invasive, group A
Syphilis including congenital infection
Tetanus
Toxic Shock Syndrome
Toxoplasmosis
Trichinellosis
Tuberculosis
Varicella (chickenpox)
Vibriosis (cholera and non-cholera)
West Nile Virus
Yellow Fever
Zika Virus

RESOURCES AND THANKS

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This toolkit was developed by Grant Cagle, an MD/MPH candidate in the class of 2018 at the University of Arkansas for Medical Sciences, as part of a preceptorship with the Human Rights Campaign Arkansas. During his preceptorship, Cagle worked daily with Kendra R. Johnson at the Human Rights Campaign Arkansas and with the Arkansas PrEP Task Force. The PrEP Task Force is comprised of representatives of the Arkansas Department of Health, the Arkansas HIV Planning Group, Arkansas RAPPS, Better Community Development, the Human Rights Campaign Foundation and the University of Arkansas for Medical Sciences Department of Family and Preventive Medicine and University of Arkansas for Medical Sciences College of Public Health.

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NOTES

PrEP TASKFORCE

HUMAN RIGHTS CAMPAIGN®

Arkansas RAPPS

UAMS®

BCD, Inc.
Better Community Development, Inc.
Rebuilding Lives. Restoring Communities