

# HIV Pre-Exposure Prophylaxis (PrEP)

Toolkit

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This toolkit and its appendices are for general information purposes only. The collaborative practice agreement (CPA) is intended to be reviewed by individual organizations for customization. The Pharmacy Society of Wisconsin assumes no responsibility for errors or omissions contained in this toolkit. While every effort has been made to ensure the accuracy of this information, pharmacies and pharmacists should always ensure compliance with all state and federal laws, administrative rules, and regulations. All pharmacies and pharmacists practicing in Wisconsin are responsible for complying with all relevant laws and regulations applicable to their practice setting. In no event shall the Pharmacy Society of Wisconsin be liable for any damages whatsoever arising out of or in connection with the use of this toolkit. The information in this toolkit must not be relied upon as an alternative to legal or medical advice from an appropriately qualified professional.

# **Pre-Exposure Prophylaxis (PrEP) Overview**

### **Introduction & Background**

Pre-Exposure Prophylaxis (PrEP) are medications approved by the FDA for the prevention of human immunodeficiency virus (HIV). Once daily oral emtricitabine/tenofovir disoproxil fumarate (brand name: Truvada®) for PrEP, once daily oral emtricitabine/tenofovir alafenamide (brand name: Descovy®), and bimonthly injectable cabotegravir (brand name: Apretude®) for PrEP have been shown to lower the risk of sexually acquired HIV infection in high-risk adults by up to 99% with high medication adherence and when used in combination with safer sex practices. Additionally, tenofovir-based PrEP regimens have been shown to lower the risk of acquired HIV infection from injection drug use by 74-84% with high adherence. As the public continues to learn about PrEP, pharmacists may be interested in providing PrEP to eligible patients through collaborative practice agreements or unique prescriptive authority. This toolkit will assist pharmacists by equipping them with the knowledge and tools to feel comfortable having a PrEP conversation with their patients.

Although HIV incidence has declined since its discovery in the early 1980s, there are still approximately 30,000 people newly diagnosed with HIV in the United States every year.<sup>1</sup> Of all people for whom PrEP is recommended, only 25% are prescribed a PrEP medication. Additionally, a disproportionately low number of Black/African Americans, Hispanic/Latinos, women, and residents from southern states are prescribed PrEP when indicated<sup>2,3</sup> Since pharmacists are more easily accessible than primary care providers, pharmacies across the country could potentially provide an alternative location for PrEP initiation and continuation for at-risk individuals. PrEP, as a public health initiative, allows pharmacists to be a resource for patients who might have difficulty or an inability to gain access to care. These data demonstrate a demand to expand HIV prevention therapies and pharmacists' ability to meet these needs.

Wisconsin law allows a pharmacist to prescribe PrEP, including ordering and administering all therapy testing, through a collaborative practice agreement (CPA) with a physician. This toolkit will equip you with important tools:

- Who is eligible for PrEP?
- Who should not be prescribed PrEP?
- How do the different PrEP regimens compare?
- How do I talk about sexual health and PrEP with patients?
- What clinical labs and monitoring need to be done with PrEP? How do I go about doing this?

This toolkit is intended to assist pharmacists and their teams with the resources necessary to talk to patients about PrEP, expand direct patient care, and advance pharmacist roles through PrEP advocacy, education, and prescribing.

# **PrEP Eligibility**

The following questions may help identify a patient that is at high risk for HIV infection and may benefit from the use of PrEP:\*

- 1. Has the patient had anal or vaginal sex in the past 6 months?
- 2. Has the patient ever injected drugs?
- 3. Is the patient requesting PrEP because of concerns about acquiring HIV?<sup>2</sup>

\*For a complete list of eligibilities for starting PrEP, refer to the CDC's 2021 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States Guideline<sup>2</sup>

#### Who should NOT be prescribed PrEP at the pharmacy\*\*

- 1. People with HIV or signs/symptoms or acute HIV infection. Patients will need to be tested for HIV before PrEP initiation and every three months thereafter while on oral PrEP or after every two months while receiving intramuscular cabotegravir (CAB) injections.
- 2. People who meet eligibility for post-exposure prophylaxis (PEP) (very recent possible HIV exposure but no signs and symptoms of acute infection)
- 3. People with impaired renal or hepatic function, including hepatitis B infection
- 4. People with osteopenia or osteoporosis
- 5. People who are pregnant or are planning to become pregnant
- 6. Allergy or contraindication to any medicine in PrEP regimen

\*\*Patients who meet these criteria should not be prescribed PrEP at the pharmacy and should instead be referred to their primary care provider for PrEP consideration



# *MSM:* men who have sex with men; *MSW:* men who have sex with women; *WSM:* women who have sex with men Image from: Pre-Exposure Prophylaxis (PrEP). Centers for Disease Control and Prevention.<sup>4</sup>

#### Assessing Indications for PrEP in People Who Inject Drugs



### **Maintenance Regimen Options**

- 1. Emtricitabine/tenofovir disoproxil fumarate (Truvada<sup>®</sup>) 200mg/300mg: 1 tablet by mouth daily (also available as a generic medication)
- 2. Emtricitabine/tenofovir alafenamide (Descovy®) 200mg/25mg: 1 tablet by mouth daily
- 3. Cabotegravir (Apretude<sup>®</sup>): 600 mg IM once every 2 months

**Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada®) Prescribing Guidelines** Emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg is approved for adults and adolescents who weigh at least 35 kg and are at risk for HIV infection through sex or injection drug use.

#### Dosing

Take 1 tablet (containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) once daily with or without food.

*Please note: The strength listed above (200mg/300mg) is the only approved strength for PrEP. These medications may be available in different strengths for the treatment of HIV infection.* 

<u>Lead times to tissue-specific maximum concentration</u> Rectal tissue: 7 days Cervicovaginal tissue: 20 days \*If the patient misses doses and restarts the regimen, be mindful of lead times

#### Emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®) Prescribing Guidelines

Emtricitabine 200mg/tenofovir alafenamide 25mg for PrEP is approved for adults and adolescents who weigh at least 35 kg and are at risk of HIV through sex, except for people assigned female at birth who are at risk of getting HIV from vaginal sex.

#### Dosing

Take 1 tablet (containing 200mg of emtricitabine and 25 mg of tenofovir alafenamide) once daily with or without food

*Please note: The strength listed above (200mg/25mg) is for PrEP only. These medications may be available in different strengths for the treatment of HIV infection.* 

Lead times to tissue-specific maximum concentration

Pharmacokinetic study data related to potential time to tissue-specific maximum concentrations are not yet available as of time of publication.

#### Cabotegravir 600mg/3mL (Apretude®) Prescribing Guidelines

Cabotegravir 600mg/3mL IM injection for PrEP is approved for adults and adolescents who weigh at least 35 kg and are  $\geq$  12 years old and are at risk of HIV through sex. Patients may initiate a cabotegravir oral lead-in prior to IM injections, or they may proceed directly to IM injections without oral lead-in.

Please Note: When cabotegravir injections are discontinued, residual concentrations of the drug may remain in systemic circulation for prolonged periods (12 months or longer). Patients in this situation need careful education and follow-up; daily oral PrEP and other effective HIV prevention methods may be necessary if HIV exposure is anticipated during this time.<sup>2</sup>

#### Dosing

**Oral lead in:** Take 1 tablet [containing 30mg cabotegravir (Vocabria<sup>®</sup>)] by mouth daily with a meal for ~1 month (>28 days)

**Initiation Injections:** Inject 3mL (containing 600 mg cabotegravir) IM once monthly for 2 doses. If using oral lead-in, administer first IM injection on the last day of oral lead-in, or within 3 days after

**Continuation injections:** Inject 3mL (containing 600 mg cabotegravir) IM once every 2 months, starting 2 months after the last initiation injection

<u>Lead times to tissue-specific maximum concentration</u> Pharmacokinetic study data related to potential time to tissue-specific maximum concentrations are not yet available as of time of publication<sup>2</sup>

# **Comparison of Different Regimens for PrEP**

	Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg	Emtricitabine 200 mg/tenofovir alafenamide 25mg	Cabotegravir (30 mg oral & 600 mg IM injection)				
Black Box Warning	<ul> <li>HBV exacerbation upon drug discontinuation</li> <li>Risk of HIV drug resistance</li> </ul>	<ul> <li>HBV exacerbation upon drug discontinuation</li> <li>Risk of HIV drug resistance</li> </ul>	Risk of HIV drug resistance (prolonged due to residual concentrations post- discontinuation of IM injection)				
Contraindications when used for PrEP	<ul> <li>Positive screening for HIV and/or signs &amp; symptoms of acute HIV</li> <li>Allergy or contraindication for PrEP ingredient</li> </ul>						
Common Side Effects (>2% reported)	<ul> <li>Diarrhea</li> <li>Nausea</li> <li>Headache</li> <li>Fatigue</li> <li>Abdominal Pain<sup>5,6</sup></li> </ul>	<ul> <li>Diarrhea</li> <li>Nausea</li> <li>Headache</li> <li>Fatigue</li> <li>Abdominal Pain<sup>5,6</sup></li> </ul>	<ul> <li>Injection site reactions</li> <li>Diarrhea</li> <li>Headache</li> <li>Pyrexia</li> <li>Fatigue</li> <li>Sleep disorders</li> <li>Nausea</li> <li>Dizziness<sup>8</sup></li> </ul>				
Serious Side Effects	<ul> <li>HBV exacerbation upon discontinuation</li> <li>New onset/worsening renal impairment</li> <li>Lactic acidosis/severe hepatomegaly with steatosis</li> <li>Bone loss/mineralization defects<sup>6</sup></li> </ul>	<ul> <li>HBV exacerbation upon discontinuation</li> <li>New onset/worsening renal impairment</li> <li>Lactic acidosis/severe hepatomegaly with steatosis<sup>7</sup></li> </ul>	<ul> <li>Depressive disorders</li> <li>Hepatotoxicity<sup>8</sup></li> </ul>				
Significant Drug-Drug Interactions	<ul> <li>Can increase concentration of tenofovir</li> <li>Some protease inhibitors for HIV</li> <li>Some hepatitis C antiviral agents</li> <li>Can increase concentration of the following: <ul> <li>Didanosine<sup>6</sup></li> </ul> </li> <li>May enhance nephrotoxic effect of tenofovir <ul> <li>NSAIDs (multiple or high-dose)</li> </ul> </li> </ul>	Can decrease concentration of tenofovir • Tipranavir/ ritonavir • Carbamazepine • Oxcarbazepine • Phenobarbital • Phenytoin • Primidone • Rifabutin • Rifapentine • St. John's wort <sup>7</sup> May enhance nephrotoxic effect of TAF • NSAIDs (multiple or high-dose)	Can decrease the concentration of cabotegravir Carbamazepine Oxcarbazepine Phenobarbital Phenytoin Rifampin Rifabutin Rifapentine Can decrease the concentration of the following: Methadone <sup>8</sup> Can decrease the concentration of oral cabotegravir Antacids containing polyvalent cations <sup>9</sup>				
Sex-based Indications	Individuals assigned male or female at birth	Individuals assigned male at birth	Individuals assigned male or female at birth				
Bone Health	Consider assessment of bone mineral density in individuals with a history of pathologic fracture or other risk factors for osteoporosis or bone loss	Less concerning for bone mineral density changes	Less concerning for bone mineral density changes				
Kidney Health	Caution/avoid if CrCl < 60 mL/min Avoid administering with concurrent or recent use of nephrotoxic drugs	Caution/avoid if CrCl < 30 mL/min Less concerning for renal impairment	Caution/avoid if CrCl < 15 mL/min Less concerning for renal impairment				
Cholesterol	May cause small decreases in HDL, LDL, and total cholesterol	May cause small increases in triglycerides	May cause small increases in triglycerides				

# **PrEP Clinical Pearls**

- 1. Symptoms of an acute HIV infection
  - Fatigue, fever, joint/muscle aches, headaches, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin.<sup>2</sup>
- 2. Drug resistance with PrEP
  - If the patient maintains high levels of adherence to both oral and injectable PrEP (>85%), then the likelihood of developing drug resistance and acquiring an HIV infection is low.2
  - All PrEP regimens have a black box warning for the risk of antiretroviral drug resistance if HIV is acquired while utilizing PrEP. This is especially concerning for people who discontinue injectable cabotegravir, as residual concentrations of the drug may remain in systemic circulation for prolonged periods (12 months or longer).2,8
  - Individuals who become infected with HIV-1 while receiving PrEP must transition to a fully active HIV-1 treatment regimen, and an HIV specialist should be consulted.
- 3. Risk reduction for sexually transmitted infections
  - PrEP does not protect against acquiring sexually transmitted infections. Oral and injectable PrEP medications are only indicated for preexposure prophylaxis against acquiring HIV. Patients must continue to use risk reduction strategies such as condom use for sexual exposure and clean needle exchange for injection drug use.<sup>2</sup>
- 4. Likelihood of a false negative rapid HIV test
  - Many HIV tests can miss HIV infection for someone who has been recently infected. It is important to ask if the patient has had any recent exposure to HIV or is experiencing symptoms of an acute HIV infection. If either of these applies, then the decision to initiate or continue PrEP should be delegated to the patient's primary care provider.<sup>2</sup>
- 5. "Seasons of risk" and alternative dosing schemes
  - Oral PrEP can be taken during times when the patient is more at risk of contracting HIV i.e., "seasons of risk." The patient must still be tested for HIV/STIs and complete all proper initiation protocols prior to starting, as well as be mindful of lead times. It is not recommended to stop and restart cabotegravir therapy during "seasons of risk."2
  - Alternative dosing schemes are currently not approved in the United States and will not be discussed in this toolkit.
- 6. Do not make assumptions
  - Avoid assumptions about HIV exposure risk based on your patient's age, appearance, marital status, or any other factor.
  - When communicating with patients, always share and ask for correct pronouns or terminology preferred by the patient. Use those pronouns and patient-friendly language that supports the patient's gender identity and discussion of transmission risk.

# **Special Populations**

#### 1. Hepatitis B

The presence of Hepatitis B is not a contraindication for starting PrEP. However, the decision to initiate or continue PrEP should be decided by the patient's primary care provider.

#### 2. Gender-Affirming Care

No medication approved for PrEP has drug interactions with hormones that will be used in gender-affirming care. The use of gender-affirming medication is not a contraindication for

pharmacists to prescribe PrEP at the pharmacy.

#### 3. Family Planning

Healthcare providers should offer and promote an emtricitabine/tenofovir disoproxil fumarate PrEP regimen, when indicated, for uninfected individuals who are trying to conceive or are pregnant, postpartum, or breastfeeding to prevent HIV acquisition. Safety data during conception, pregnancy, or breastfeeding are limited for injectable cabotegravir. The decision to initiate or continue PrEP should be decided by the patient's primary care provider if the patient is pregnant or breastfeeding.

# How to Have a Conversation About Sexual Health and PrEP with Your Patient<sup>10</sup>

Talking about PrEP can sometimes be an uncomfortable conversation for both you and your patient. Studies have shown that low trust in providers and poor patient-provider relationships have been associated with decreased care retention and decreased patient satisfaction. Many patients have sexual health questions and want your insight but are hesitant about initiating the conversation.

#### Tips to Talk About PrEP<sup>10</sup>

- Remind the patient that it is a safe environment and that they are encouraged to ask questions
  - » "I want to let you know that you are in a safe space and what you tell me is confidential."
  - » "I encourage you to stop at any time and ask me any questions you have about this information."
  - » Utilize a private space in the pharmacy or clinic when talking about PrEP to ensure patient privacy.
  - » Use neutral and inclusive terms such as "partner" and pose your questions in a nonjudgmental manner.
  - » Ensure you and your patient share an understanding of the terms being used to avoid confusion. If you are not familiar with a term your patient used, ask for an explanation.
  - » For more information about vocabulary for conversations about sex, see <u>www.plannedparenthood.org/learn/glossary</u><sup>11</sup>
- Ask open-ended questions to promote dialogue shared decision-making process
  - » "What have you heard about PrEP?"
  - » "What do you expect to be a barrier to any step in the PrEP process?"
  - » Identify skills the patient may lack to remain in care, such as problem solving-skills or low health literacy.
  - » Address any potential challenges to adherence to PrEP before prescribing any medication. Guide the patient to identify changes that would eliminate or reduce barriers they face; congratulate the patient when they are able to overcome or lessen the barriers.
  - » Strategize with the patient to identify new goals and healthy behaviors.
  - » Actively refer patients to relevant clinic support services as needed to provide additional support for retention.
- Consider the patient's perspective:
  - » Explore what might make the patient feel more comfortable (i.e., bringing a supportive friend if they would like, reviewing pamphlets and information during the discussion).
  - » Provide referrals when appropriate and assess patient willingness to complete the referral.

# Steps to PrEP Program Implementation and PrEP Prescribing



#### 1. Screening

- Screening your patient for HIV is the first step to PrEP implementation and prescribing.
- <u>Initial Clinical Evaluation</u>: Patient health history should be reviewed, including signs/ symptoms of acute HIV or sexually transmitted infections (STIs), history of kidney disease, a medication review, and an assessment of indications for PrEP. The provider should also conduct an HIV blood test, evaluate kidney function, conduct a medication review, check for hepatitis B (HBV) infection and hepatitis C (HCV) infection, test for STIs, and conduct a pregnancy test for women.

Note: If your pharmacy has signed the CPA with a provider, refer to the CPA for what point of care services you and your pharmacy can provide the patient

#### 2. PrEP Initiation

- For locations where lab testing results, including HIV tests, are available on the same day as drawn: *The initiation of PrEP may occur on the same day as the initial clinical evaluation.*
- If it is not possible to rule out HIV and normal renal function on the same day as the initial clinical evaluation, initiate PrEP within 7 days of the HIV test to minimize the risk of HIV acquisition between HIV testing and PrEP initiation.

#### 3. Follow-up

- Repeat HIV testing and assess for signs/symptoms of acute infection.
- Assess and provide support for medication adherence and risk-reduction behaviors.
- Order and evaluate lab tests as clinically appropriate (see below for timing).
- Provide a prescription or refill authorization of PrEP for no more than 90 days or until the next follow-up.
- Answer any new questions and provide any new information about PrEP use.

# **Timing of Injectable Cabotegravir Laboratory Tests**

Test	Initiation Visit	1 month visit	Every 2 months	Every 4 months	When stopping cabotegravir
HIV*	Х	Х	Х		Х
STI**	Х			Х	Х

\*HIV-1 RNA assay preferred

\*\* Includes syphilis, gonorrhea, and chlamydia.

This is an example of a practical testing schedule and may differ from CDC guidelines. Please refer to the 2021 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States Guideline for a more complete schedule

# **Timing of Oral PrEP-associated Laboratory Tests**

Initiation Visit	Every 3 months	Every 6 months	Every 12 months	When stopping oral PrEP
Х	Х			Х
Х		If age > 50 or CrCl <90 ml/min at PrEP initiation or as clinically appropriate	Х	х
Х	Х			Х
Х				
Х			Х	
	X X X X X	X X X X X X X X	XXXIf age > 50 or CrCl <90 ml/min at PrEP initiation or as clinically appropriateXXXXXX	XXXIf age > 50 or CrCl <90 ml/min at PrEP initiation or as clinically appropriateXXXXXIf age > 50 or CrCl <90 ml/min at PrEP initiation At PrEP initiation 

\*HIV-1 RNA assay recommended at baseline, but a 3rd or 4th generation point-of-care HIV test for follow-up is appropriate \*\*Includes syphilis, gonorrhea, and chlamydia.

This is an example of a practical testing schedule and may differ from CDC guidelines. Please refer to the 2021 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States Guideline for a more complete schedule

# Implementing a PrEP Workflow in Your Pharmacy

The pharmacy should determine whether to require appointments or accommodate walk-in patients. Pharmacists must effectively communicate and collaborate with other healthcare providers when referring patients in need of follow-up. If initiating point-of-care testing in the pharmacy for purposes of PrEP prescribing, pharmacy workflow changes may be necessary.

- Review intake information and order appropriate tests.
- Develop a workflow for interpreting lab results and follow-up with patients. Consider building a relationship with a lab and having a follow-up workflow for lab results.
- Meet with the patient to review intake information, PrEP education, confirm HIV-negative test result and additional labs, and order PrEP medication if indicated. For any HIV+ test results, provide appropriate linkage to care for HIV treatment.
- Provide supplemental education as appropriate (substance abuse, mental health, needle exchange, naloxone, social support services, additional resources, and clinic referrals).

# **Additional Information and Useful Links**

See page 13 for an example of a PrEP CPA. For additional information on creating a CPA, see the Pharmacy Society of Wisconsin's Collaborative Practice Agreement Toolkit <u>CPA Toolkit web.</u> pdf (pswi.org)<sup>12</sup>

# **Patient Assistance Programs**

The U.S. Preventive Services Task Force issued grade A recommendations on HIV screening and HIV prevention. Under the Affordable Care Act, PrEP must be covered under almost all health insurance plans without additional cost-sharing. For patients without insurance coverage, the following links may be helpful:

- Ready, Set, PrEP (hiv.gov)<sup>13</sup>
- Manufacturer Co-pay Assistance Programs
  - » Gilead (Truvada<sup>®</sup> and Descovy<sup>®</sup>)
    - <u>Gilead Advancing Access® Medication Co-pay Coupon Card</u><sup>14</sup>
       *\*This will not cover generic PrEP medications*
  - » ViiV (Vocabria<sup>®</sup> & Apretude<sup>®</sup>)
    - ° <u>Home | ViiVConnect</u><sup>15</sup>

#### **COLLABORATIVE PRACTICE AGREEMENT**

For authorization of therapy initiation of Pre-Exposure Prophylaxis (PrEP)

#### A. AUTHORITY AND PURPOSE

**I, Dr.** (License # ) authorize the pharmacist(s) name(d) herein, who hold an active license to practice pharmacy in the State of Wisconsin, to initiate therapy and manage patients for Pre-Exposure Prophylaxis (PrEP) pursuant to parameters outlined in this agreement.

#### **B. PARTIES TO THE AGREEMENT**

The following pharmacists agree to the parameters outlined in this agreement and may initiate treatment and manage patients pursuant to the parameters of this agreement

#### Pharmacists:

#### C. PATIENTS

Patients whose therapy may be initiated and managed pursuant to this agreement include those who are seeking Pre-Exposure Prophylaxis (PrEP) therapy.

#### D. PATIENT CARE FUNCTIONS AUTHORIZED

Pharmacist(s) included in section B of this agreement have the authority to initiate and/or manage patients in accordance with this section.

In initiating and/or managing patients, the pharmacist(s) may authorize initiation of drug therapy based on current literature and clinical judgement. See Section J for current prescribing guidelines for PrEP.

#### **D.1. Pre-Exposure Prophylaxis (PrEP)**<sup>1,2</sup>

The pharmacist(s) will evaluate the patient's candidacy for Pre-Exposure Prophylaxis (PrEP) as outlined by 2021 CDC Guideline and Clinical Providers' Supplement of the Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States and other nationally recognized standards of care as supported by current literature.<sup>3-5</sup> This includes pre-therapy initiation testing and recurring testing for HIV, Hepatitis B, STIs, and renal function as outlined by the guidelines. The pharmacist shall question a patient regarding previous adverse events, allergies to food, drugs or other products, current health, immunosuppression, recent receipt of blood or antibody products, pregnancy and underlying conditions before initiation of PrEP. Pharmacist(s) will have the authority to authorize point-of-care testing and authorize initiation of therapy or continuation of therapy which include but are not limited to the following drug classes: nucleoside/nucleotide reverse transcriptase inhibitors or integrase inhibitors approved for use for PrEP for HIV prevention.

#### E. DOCUMENTATION

The pharmacist(s) shall document each initiation or management of therapy authorization in the patient's pharmacy record.

#### F. COMMUNICATION

The pharmacist(s) shall provide the patient's primary care provider with notification in the form of fax or secure electronic communication when the patient's therapy is initiated or continued pursuant to this agreement. In this notification, the pharmacist(s) will include any relevant information that was collected from the patient such as renal function, point of care testing results, or other relevant information.

The pharmacist shall report any new patient complaints and/or deterioration in the patient's condition to the patient's primary care provider immediately after learning of the new condition or as soon as practicable.

If, in the course of questioning the PrEP candidate or initiating/maintaining PrEP therapy, the pharmacist deems the patient in need of additional medical consultation, the pharmacist shall refer the patient to a physician.

#### G. AGREEMENT REVIEW AND DURATION

This authorization shall be valid from \_\_\_\_\_\_ until \_\_\_\_\_ (not to exceed two years), unless revoked sooner in writing.

#### H. RECORD RETENTION

Each signatory to this agreement shall keep a signed copy, written or electronic, of this agreement on file at their primary place of practice. Record of each therapeutic initiation or management opportunity made for a specific patient shall be maintained in the patient's primary record for a period of at least five years

#### I. GUIDELINES

- 1. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States (2021 Update) Clinical Practice Guideline. <u>https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf</u>.
- Preexposure Prophylaxis for the Prevention of HIV Infection in the United States (2021 Update) Clinical Providers Supplement. <u>https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-</u> supplement-2021.pdf.
- 3. Truvada for PrEP Prescribing Information
- 4. Descovy for PrEP Prescribing Information
- 5. Apretude for PrEP Prescribing Information (<u>https://gskpro.com/content/dam/global/hcpportal/en\_US/Prescribing\_Information/Apretude/pdf/APR\_ETUDE-PI-PIL-IFU.PDF</u>)

#### J. AGREEMENT SIGNATURES

#### Signatures:

[Physician name and credentials]	[Physician Signature]	License #	Date	
[Pharmacist name and credentials]	[Pharmacist Signature]	License #	Date	
[Pharmacist name and credentials]	[Pharmacist Signature]	License #	Date	

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- 6. Truvada<sup>®</sup> (emtricitabine and tenofovir disoproxil fumarate). Prescribing information. Gilead; 2020. Available at https://www.gilead.com/-/media/55b14ac03ef94b6f98d5d3c31ea0137b.ashx. Accessed September 20, 2022.
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