

## HIV Pre-Exposure Prophylaxis (PrEP) Collaborative Drug Therapy Agreement Protocol

**Authorized Prescriber:** \_\_\_\_\_, MD, MPH is an active, licensed physician authorized to prescribe medications in Washington State. The authority granted here is within the scope of their current practice.

**Pharmacists:** The pharmacists who are party to this agreement, \_\_\_\_\_, are licensed pharmacists who work at \_\_\_\_\_ in \_\_\_\_\_, **WA**.

**Time Period:** This agreement will remain in effect for two years unless rescinded earlier in writing by either the authorized practitioner or by the individual pharmacist(s). Any changes in the protocol or procedures described below must be made via a substitute written agreement.

**Type of Prescriptive Authority:** To help prevent HIV infection, this agreement enables the pharmacists to both initiate and modify drug therapy for patients/customers 35kg and over who are at risk for HIV to obtain PrEP medication, and to provide appropriate, ongoing monitoring. The pharmacists are hereby authorized to prescribe and administer medications and order labs necessary for HIV pre-exposure prophylaxis (PrEP) with emtricitabine-tenofovir disoproxil fumarate according to the protocol below. Under consultation with the Authorized Prescriber only; the pharmacists are also authorized to prescribe emtricitabine and tenofovir alafenamide.

This protocol is in accordance with local standard of care, and the laws and regulations of the State of Washington (RCW Chapter 18.64; WAC 246-945-350). Pharmacists providing HIV PrEP services under this protocol will follow these procedures as the standard of care.

### Protocol:

1. When a patient requests HIV PrEP or is referred to the pharmacy for HIV PrEP consultation, the pharmacist initially will:
  - Assess the patient's risk for HIV acquisition;
  - Assess the patient's underlying medical conditions, current medications, drug allergies, immunization history, and risk for bacterial sexually transmitted infections (STI);
  - Assess for signs and symptoms of acute HIV infection (i.e., fever, particularly if accompanied with sore throat, persistent fatigue, rash, or diarrhea, and sexual- or injection- exposure in the last 4-6 weeks);
  - If the patient has signs or symptoms of acute HIV infection, the pharmacist must not prescribe PrEP but instead take the following actions immediately:
    - Order lab test for HIV Antigen/Antibody and HIV RNA.
    - Contact the local health jurisdiction and refer the patient to the health center for confirmatory testing and linkage to care:
    - Notify the Authorized Prescriber.
2. Also at the initial visit, **for patients without signs or symptoms of acute HIV**, the pharmacist will conduct counseling specific to PrEP, and this will include:
  - Current knowledge of benefits and risks of PrEP.
  - Education about PrEP medication.
  - Information on other methods to protect against HIV transmission.

- Information on methods to protect against bacterial STI and STI screening recommendations.
  - Counsel on medication use, dosing, side effects, expectations, labs required.
  - Discuss the importance of adherence, discuss potential barriers and develop adherence plan.
  - Emphasize the importance of condom use for STI prevention and, if applicable, safer syringe practices.
3. If the patient has a medical history of kidney disease or osteoporosis, the pharmacist will refer the patient to a primary care provider for evaluation prior to initiating PrEP and notify the Authorized Prescriber that this was done.
4. If the patient has **no** signs or symptoms of acute HIV infection, the pharmacist must, at the initial visit conduct or order the tests as indicated below. In lieu of conducting or ordering the tests below, the pharmacist may accept results conducted by an external healthcare provider or referring agency.
- Conduct a whole blood rapid HIV test.
  - Order laboratory screening tests, including:
    - HIV antigen/antibody test
    - Renal function (creatinine)
    - Hepatitis B serologic tests (i.e., Hepatitis B surface antigen and surface antibody)
    - Pregnancy test, if applicable (i.e. patient has uterus and has not undergone menopause)
    - Screening for gonorrhea and chlamydia at exposed anatomical sites, including:
      1. For men and trans persons who have sex with men: the pharynx, urethra (urine testing), rectum and vagina.
      2. For cisgender women: the vagina.
    - Screening for syphilis
5. Assuming no contra-indications as described above, the pharmacist will dispense PrEP as follows:
- Prescribe emtricitabine-tenofovir disoproxil fumarate with the directions “Take 1 tablet by mouth daily.”
6. As soon as the initial test results are available, the pharmacist must review and evaluate the test results, notify the patient, and take the following actions for medical evaluation and follow-up as detailed below. For patients with test results from external healthcare providers or referring agencies, pharmacists must take the following actions or confirm that the following actions have been taken.
- Positive or indeterminate whole blood rapid HIV test or HIV rapid antibody test results – the pharmacist must take the following actions immediately:
    - Do not prescribe PrEP and/or Advise the patient to stop taking PrEP (FTC/TDF).
    - Notify the patient and refer him/her to the local health jurisdiction for treatment.

- Report the case to the local health jurisdiction within 3 working days.
  - Notify the Authorized Prescriber.
- Creatinine clearance <60ml/min - the pharmacist must refer the patient for primary care evaluation and contact the Authorized Prescriber to discuss plan for PrEP continuation.
- Positive pregnancy test - the pharmacist must refer the patient for primary care evaluation and advise the patient to continue PrEP.
- Positive hepatitis B antigen - the pharmacist must refer the patient for primary care evaluation and contact the Authorized Prescriber to discuss plan for PrEP continuation.
- Negative Hepatitis B surface antibody and negative Hepatitis B surface antigen – the pharmacist must offer the patient Hepatitis B vaccine, as part of pharmacist’s scope of practice, and advise the patient to continue PrEP.
- Positive gonorrhea or chlamydia test – the pharmacist must report cases to the local health jurisdiction within 3 working days and provide treatment. When notifying the patient, the pharmacist should also recommend they refer their partner(s) to the health department for partner care (HIV and STI testing).
  - Providing treatment: The pharmacists shall follow the protocol outlined below or the most current CDC recommended treatment guidelines.
    1. Gonorrhea:
      - a. For patients with uncomplicated genital, rectal, or pharyngeal gonorrhea who weigh <150kg (300 pounds), the pharmacist will provide ceftriaxone, 500 mg as a single intramuscular injection. If chlamydia co-infection has not been ruled out with a negative test, provide doxycycline 100mg orally twice daily.
      - b. Counsel patient to abstain from sexual activity for 7 days.
      - c. If patient weighs >150kg (300 pounds), the pharmacist will provide ceftriaxone 1 gram as a single muscular injection.
      - d. If the patient is allergic to penicillin, refer to the appropriate health department for treatment.
      - e. If the patient is pregnant and chlamydia infection has not been ruled out, do not treat with doxycycline. Provide azithromycin 1 gram orally in a single dose and refer patient to their healthcare provider.
      - f. If the patient is a woman of childbearing age who is not using highly effective contraception (hormonal or IUD) or had a negative pregnancy test, do not treat with doxycycline. Provide azithromycin 1 gram orally in a single dose.
    2. Chlamydia:
      - a. For patients with uncomplicated genital, rectal or pharyngeal chlamydia: provide doxycycline, 100 mg orally twice daily for 7 days.
      - b. Counsel patient to abstain from sexual activity until completion of the 7 days.

- c. Pregnant patients should not be given doxycycline. ; if pregnant, provide azithromycin 1 gram orally in a single dose and refer patient to their healthcare provider).
  - d. If the patient is a woman of childbearing age who is not using highly effective contraception (hormonal or IUD) or had a negative pregnancy test, do not treat with doxycycline. Provide azithromycin 1 gram orally in a single dose.
  - e. If the patient is allergic to doxycycline, pharmacist can provide azithromycin, 1 gram orally in a single dose.
- Positive syphilis test -- the pharmacist must refer the patient to the local health jurisdiction for treatment and report cases to the local health jurisdiction within 3 working days.
7. For all patients prescribed and whom the pharmacist continues to prescribe PrEP, the pharmacist must conduct follow-up assessments at a minimum of every 3 months, specifically:
- Every 3 months, repeat the HIV antigen/antibody testing and bacterial STD screening for syphilis, gonorrhea, and chlamydia. The pharmacist may accept lab results for HIV and bacterial STD screening tests conducted by an external healthcare provider or referring agency.
  - Every 6 months repeat creatinine blood test. The pharmacist may accept creatinine lab results conducted by an external healthcare provider or referring agency.
  - At every follow-up, reassess any barriers to adherence and provide counseling support as appropriate.
  - If at any time the patient indicates that they have stopped PrEP for 1 month or longer, the pharmacist will initiate care as if the patient is newly starting PrEP. The pharmacist will screen for AHI, repeat the whole blood rapid HIV test, the HIV antigen/antibody test, the bacterial STD screening for syphilis, gonorrhea, and chlamydia STI tests, and collect information on why PrEP was discontinued.
  - If at any time the patient has signs and symptoms suggestive of acute HIV infection, the pharmacist must take the actions outlined in section 1, subsection 4 above.
  - If at any time the patient has a positive HIV antigen/antibody test, the pharmacist must take the actions outlined in section 6, subsection 1 above.
  - During any consultation, the pharmacist may also provide patients with recommended vaccines, HIV/STI prevention counseling, contraception counseling, and appropriate over-the-counter medication.

**Documentation and Quality Assurance:** The pharmacist will document each prescription in the prescription record, patient drug profile, patient medical chart, or in a separate log book.

**Primary Care:** The patient should ideally establish care with a primary care provider within a year after beginning PrEP. If the patient does not have a primary care provider, the pharmacist will offer assistance locating a primary care provider. For patients who already have a primary care provider, the pharmacist will notify the primary care provider of the medications provided if the patient consents to release of the information. Patients who do not engage in primary care can continue to receive PrEP as described above.

**Quality Assurance:** On at least a semi-annual basis, the authorized prescriber and the pharmacist will meet (in-person, by videoconference or by phone) to perform a quality assurance review of procedures, test results, and follow-up, according to mutually acceptable criteria. This review will include both individual case review of a pre-determined sub-set of cases as well as an aggregate review of overall retention rates (proportion of patients receiving needed follow-up testing, etc.). The prescriber and pharmacist will also maintain a relationship that facilitates the pharmacist contacting the prescriber as needed and receiving a timely response. The authorized prescriber will be available for general questions and concerns related to PrEP in addition to specific patient concerns.

**If at any time the authorized prescriber becomes aware of the need to discuss a specific patient or decision, particularly in the case of an unforeseen event or error, the pharmacist will be available in a timely manner to discuss the concern. The authorized prescriber or pharmacist may also request additional periodic meetings to review specific cases and address questions. To contact the authorized prescriber with questions, concerns, or to discuss a patient:**

- **Office phone** \_\_\_\_\_
- **Pager** \_\_\_\_\_
- **Call by cell phone or text a general message requesting a call back at** \_\_\_\_\_
- **Email:** \_\_\_\_\_

**Training:** The pharmacist who participates in this protocol must have completed training covering the procedures listed above in addition to the HIV PrEP clinical practice guidelines and clinical supplement. The pharmacist listed on this agreement will also take personal responsibility to maintain up-to-date knowledge about HIV and PrEP. A pharmacist performing venipuncture must hold a Medical Assistant-Phlebotomist Certification through the Washington State Department of Health.

**Laboratory Samples:** For all testing under this protocol, the pharmacist must obtain samples, per package insert or manufacturer's instructions, via finger stick, venipuncture. Alternatively, the pharmacist may instruct the patient to go to a laboratory collection facility. Rectal, pharyngeal, and vaginal swabs and urine for bacterial STI testing will be self-obtained by the patient according to instructions the pharmacist provides.

Signed and agreed to this \_\_\_\_\_ day of \_\_\_\_\_, in the year of \_\_\_\_\_, in \_\_\_\_\_, WA by:

**Authorized Practitioner:**

\_\_\_\_\_

[Signature Block]

**Pharmacists:**

Signed and agreed to this \_\_\_\_\_ day of \_\_\_\_\_, in the year of \_\_\_\_\_, in \_\_\_\_\_, WA by:

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