

## **HIV Pre-Exposure Prophylaxis (PrEP) Protocol**

### **I. Purpose**

The purpose of this standing order is to prevent people from contracting the Human Immunodeficiency Virus (HIV) in Arkansas by allowing Arkansas-licensed pharmacists to initiate preventative therapy including ordering and/or dispensing treatment medications, along with any necessary supplies for administration, to eligible persons who are HIV negative and at high risk for a HIV infection or show interest in starting HIV pre-exposure prophylaxis (PrEP).

### **II. Authority**

This standing order is issued pursuant to Act 314 of 2023 (HB 1007) (Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to order and/or dispense PrEP medications according to the provisions of Arkansas Code § 17-92-101 and the requirements of this standing order.

### **III. Screening and Assessment**

The Board of Pharmacy will adopt screening assessment and questionnaire (Appendix A) to be used by pharmacists throughout the state. When a patient requests PrEP or point-of-care testing services, or when a pharmacist, in their professional judgment, initiates PrEP or point-of-care testing services, the patient will be assessed for appropriateness of PrEP. If appropriate, administer a rapid HIV test and order and/or dispense PrEP medications.

### **IV. Dispensing Guidelines**

#### **A. Eligibility Criteria**

##### **1. Inclusion:**

- a) Patients  $\geq$  18 years of age
- b) Patients who present interested in starting PrEP, or at substantial risk of acquiring HIV:
  - (1) Sexually active people who have had anal or vaginal sex in the past 6 months and HIV-positive sexual partner (unknown or detectable viral load), bacterial STI in past 6 months, or history of inconsistent or no condom use with sexual partner(s)
  - (2) Persons who inject drugs
    - (a) HIV-positive injecting partner
    - (b) Sharing injection equipment
  - (3) Documented negative HIV antigen/antibody test result within 1 week of initiating PrEP

##### **c) Exclusion:**

- a) Patients interested in Apretude (cabotegravir IM)
- b) Signs and symptoms of an acute HIV infection

- (1) Flu-like symptoms (fever, fatigue, myalgia, skin rash, diarrhea, headache, pharyngitis, cervical adenopathy, arthralgia, or night sweats)
- c) Estimated creatinine clearance < 30 ml/min
- d) Contraindications to medications
- e) Patient self-reports positive HIV status, or if point-of-care HIV test is positive

## **B. Contraindications**

Using for preexposure prophylaxis in patients with unknown or HIV-1 positive status.

Patients with hypersensitivity to emtricitabine, tenofovir alafenamide, tenofovir disoproxil fumarate, or any other component of a formulation

## **C. Product Availability**

PrEP medications that may be dispensed/provided under this standing order. Following dosing below, pharmacists can dispense any commercially available product form (tablet) based on availability and patient preference.

1. Oral emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF) [Truvada]
  - a) Daily dosing schedule: One tablet (FTC 200 mg and TDF 300 mg) once daily
2. Oral FTC/tenofovir alafenamide (TAF) [Descovy]
  - a) Only for patients assigned male at birth (cis-male or trans-female)
  - b) One tablet (FTC 200 mg and TAF 25 mg) once daily

## **D. Warnings/Precautions**

1. Emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF)
  - a) Concerns related to adverse effects:
    - (1) Lactic acidosis/hepatomegaly: Lactic acidosis and severe hepatomegaly with steatosis, sometimes fatal, have been reported with use of nucleoside analogues, alone or in combination with other antiretrovirals. Suspend treatment in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (marked transaminase elevation may/may not accompany hepatomegaly and steatosis).
  - b) Disease-related concerns:
    - (1) Comprehensive prevention program: Pre-exposure prophylaxis (PrEP) should be accompanied by a comprehensive HIV-1 prevention program (eg, risk reduction counseling, access to condoms), with particular emphasis on medication adherence. In addition, regular monitoring (eg, HIV status of patient and partner(s), risk behavior, adherence, adverse effects, sexually transmitted infections that facilitate HIV-1 transmission) is highly recommended. Time from initiation of therapy to maximal protection against HIV-1 is unknown.

2. Emtricitabine (FTC)/tenofovir alafenamide (TAF)

a) Concerns related to adverse effects:

(1) Lactic acidosis/hepatomegaly: Lactic acidosis and severe hepatomegaly with steatosis, sometimes fatal, have been reported with use of nucleoside analogues, alone or in combination with other antiretrovirals. Suspend treatment in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (marked transaminase elevation may/may not accompany hepatomegaly and steatosis).

(2) Renal toxicity: Renal toxicity (acute renal failure, fanconi syndrome, and/or proximal renal tubulopathy) has been reported with use of tenofovir prodrugs; patients with impaired renal function and those with concurrent or recent nephrotoxic therapy (including NSAIDs) are at an increased risk. Discontinue use

in patients who develop clinically significant decreases in renal function or evidence of fanconi syndrome

b) Disease-related concerns:

(1) Chronic hepatitis B **[US BOXED WARNING]**: Acute, severe exacerbations of hepatitis B virus have been reported in HBV-infected patients following discontinuation of antiretroviral therapy. Closely monitor hepatic function with clinic and laboratory follow-up for at least several months in patients with HBV who discontinue this therapy. If appropriate, anti-HBV therapy may be warranted, especially in patients with advanced hepatic disease or cirrhosis (post-treatment HBV exacerbations may lead to hepatic decompensation and liver failure). All patients with HIV should be tested for HBV prior to or when initiating treatment; HBV-uninfected patients should be offered vaccination.

(2) Renal impairment: Use is not recommended in patients with CrCl <30 mL/minute (unless receiving hemodialysis). Safety and efficacy of concurrent administration with an HIV-1 protease inhibitor plus ritonavir or cobicistat has not been established in patients with CrCl <15 mL/minute (with or without hemodialysis).

(3) Comprehensive prevention program: Pre-exposure prophylaxis (PrEP) should be accompanied by a comprehensive HIV-1 prevention program (eg, risk reduction counseling, consistent and correct condom use, regular sexually transmitted infection testing), with particular emphasis on medication adherence.

(4) Resistance risk with pre-exposure prophylaxis: **[US Boxed Warning]**: Confirm HIV-1 negative status immediately before and at least every 3 months during therapy, and upon diagnosis of any other sexually transmitted infection. Do not start PrEP if signs or symptoms of acute HIV-1 infection are present unless HIV-1 negative status is confirmed by a test approved by the Food and Drug Administration (FDA) as an aid to detect HIV-1 infection (including acute or primary infection). Risk of drug resistant HIV-1 variants with PrEP use if patient had undetected acute HIV-1 infection: Some HIV-1 tests do not detect acute HIV-

1 infection. Screen PrEP candidates for signs/symptoms of acute HIV-1 infection and potential exposure events within 1 month of starting PrEP. If signs/symptoms or potential exposure events exist, use a test approved by the FDA for diagnosing acute or primary HIV-1 infection before initiating PrEP. During use of PrEP, if a screening test indicates possible HIV-1 infection or if symptoms of acute HIV-1 infection develop after a potential exposure, convert the HIV-1 PrEP regimen to an HIV-1 treatment regimen until negative infection status is confirmed.

**E. Documentation**

Patient records must be furnished to a health care practitioner designated by the patient upon the request of the patient. Documentation may include but is not limited to assessment and evaluation forms and results of rapid diagnostic test(s). Maintain records of all patients receiving services for two (2) years.

## Appendix A

### Pharmacist Assessment, Evaluation and Prescribing Protocol Form: *PrEP*

PATIENT INFORMATION		
Name:	Date of Birth:	Age:
Preferred Pronouns:	Sex Assigned at Birth (circle): Male or Female	
Address:	City/State/Zip:	
Email Address:	Phone:	
Do you have health insurance? Yes or No If yes, please provide the card when turning in this form.		
Primary Care Provider (Name, Clinic, Phone):		
Medication Allergies?		
Current medications? (prescription, over-the-counter, herbals, topical medications, pain or allergy medication, and any supplements/vitamins)		
Treatments tried for the current indication (if none please indicate N/A):		

Sexual History (optional)		
Are you sexually active with any of the following? Select any/all that apply: <input type="checkbox"/> Men <input type="checkbox"/> Women <input type="checkbox"/> Transgender men <input type="checkbox"/> Transgender women <input type="checkbox"/> Non-binary	Yes	No

Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom.	_____ % of the time Date: __/__/__	
Do you have oral sex? If yes, please select one of the following: <input type="checkbox"/> Giving - you perform oral sex on someone else <input type="checkbox"/> Receiving - someone performs oral sex on you	Yes	No
Do you have vaginal sex? If yes, please select one of the following: <input type="checkbox"/> Receptive - you have a vagina and you use it for vaginal sex <input type="checkbox"/> Insertive - you have a penis and you use it for vaginal sex	Yes	No
Do you have anal sex? <input type="checkbox"/> Receptive - someone uses their penis to have anal sex on you <input type="checkbox"/> Insertive - you use your penis to have anal sex with someone else	Yes	No
Do you inject drugs?	Yes	No
Are you in a relationship with an HIV-positive partner?	Yes	No
Do you exchange sex for money or goods?	Yes	No

<b>Past Medical History</b>		
Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	Yes	No
Are you seeing a provider for management of Hepatitis B?	Yes	No
Have you ever received immunization for Hepatitis B? If yes, when: _____ If not, would you like a vaccine today? Yes or No	Yes	No
Are you seeing a kidney specialist?	Yes	No
Are you currently pregnant or breast-feeding?	Yes	No
Do you take any of the following over-the-counter medications or herbal supplements? <input type="checkbox"/> aspirin <input type="checkbox"/> naproxen (Aleve®) <input type="checkbox"/> ibuprofen (Advil®)	Yes	No
Do you have any other medical problems? If yes, please specify: _____ _____	Yes	No

1. I understand that I must get a HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription. I understand that if I have condomless sex within 2 weeks of my HIV test the results may not be accurate. This could lead to drug resistance if I become HIV positive and I will need a repeat test.
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of acquiring HIV.
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.
4. I understand that I must start taking PrEP within 7 days of my negative HIV test.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Pharmacist Assessment Tool (For pharmacy staff only)

1. Is the patient 18 years of age or older?	
<input type="checkbox"/> Yes: Got to #2	<input type="checkbox"/> No: Do not prescribe PrEP. Refer to local primary care provider (PCP), infectious disease (ID) specialist, or public health clinic
2. Is the patient known to be HIV-positive?	
<input type="checkbox"/> Yes: Do not prescribe PrEP. Refer to local PCP, ID specialist, or public health clinic	<input type="checkbox"/> No: Go to #3
3. Is the patient having any symptoms of an acute HIV infection (fever, fatigue, myalgia, skin rash, diarrhea, headache, pharyngitis, cervical adenopathy, arthralgia, or night sweats)?	
<input type="checkbox"/> Yes: Do not prescribe PrEP. Refer to local PCP, ID specialist, or public health clinic	<input type="checkbox"/> No: Go to #4
4. Does the patient have one or more risk factors present? Select any/all that apply.	
<input type="checkbox"/> Yes: Go to #5 - Oral sex - Vaginal sex - Anal sex - IV drug use - HIV-positive partner - Exchanging sex for money or goods - Sex without condoms - Other: _____	<input type="checkbox"/> No: Patient is requesting PrEP. Go to #5
5. Does the patient have an established PCP for appropriate follow-up? OR - Can the pharmacist directly refer to another local contracted provider or public health clinic for appropriate follow-up?	
<input type="checkbox"/> Yes: Go to #6	<input type="checkbox"/> No: Do not prescribe PrEP. Refer patient to PCP, ID specialist, or public health clinic
6. Does the patient have a history of known Hepatitis B infection (latent or active)?	
<input type="checkbox"/> Yes: Do not prescribe PrEP. Refer to local PCP, ID specialist, or public health clinic	<input type="checkbox"/> No: Go to #7
7. Has the patient received the full Hepatitis B vaccination series? Dates if known: _____	
<input type="checkbox"/> Yes: Go to #9	<input type="checkbox"/> No: Go to #8
8. Review the risks of hepatitis B exacerbation with PrEP with the patient. Offer vaccine if appropriate and go to #9?	

<input type="checkbox"/> Vaccine administered - LOT: _____ Exp: _____	
9. Does the patient use NSAIDs?	
<input type="checkbox"/> Yes: Counsel patient on limiting use due to risk for kidney damage. Descovy preferred. Go to #10	<input type="checkbox"/> No: Go to #10
10. Does the patient have known chronic kidney disease or reduced renal function?	
<input type="checkbox"/> Yes: Do not prescribe PrEP. Refer to local PCP, ID specialist, or public health clinic	<input type="checkbox"/> No: PrEP prescription recommended. Pharmacists must notify both the provider and patient. Go to #11
11. Results of point-of-care HIV test:	
<input type="checkbox"/> Positive: Do not prescribe PrEP. Refer to local PCP, ED, urgent care, ID specialist, or public health clinic. <b>Report result to the Arkansas Department of Health.</b>	<input type="checkbox"/> Negative: Go to #12.
12. Is the patient pregnant or breastfeeding?	
<input type="checkbox"/> Yes: Truvada is preferred. Go to #13	<input type="checkbox"/> No: Go to #13
13. Is the patient cis-female or transgender-male?	
<input type="checkbox"/> Yes: Truvada is preferred. Go to #14	<input type="checkbox"/> No: Go to #14
14. Is the patient at risk for decreased bone mineral density or on medications that affect bone mineral density?	
<input type="checkbox"/> Yes: Descovy is preferred.	<input type="checkbox"/> No: Use either Descovy or Truvada

**Diagnosis of Patient**

PrEP recommended

PrEP not recommended

Refer to PCP, ID Specialist, or Public Health Clinic



**Prescription:**

PrEP Therapy		
Truvada	Dispense: <input type="checkbox"/> 200 mg/ 300 mg #30 No Refills	Sig: Take 1 (one) tablet by mouth daily
<b>OR</b>		
Descovy	Dispense: <input type="checkbox"/> 200 mg/ 25 mg #30 No Refills	Sig: Take 1 (one) tablet by mouth daily

Patient: \_\_\_\_\_

Prescribing Pharmacist: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Follow up with PCP, ID Specialist, or Public Health Clinic

References:

*PREEXPOSURE PROPHYLAXIS for the PREVENTION of HIV INFECTION in the UNITED STATES - 2021 UPDATE a CLINICAL PRACTICE GUIDELINE.*; 2021. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

Lexicomp: Evidence-Based Drug Referential Content. Wolterskluwer.com. Published 2023. Accessed August 10, 2023. <https://www.wolterskluwer.com/en/solutions/lexicomp>

## Provider Notification

Pharmacy Name: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_

Pharmacy Phone: \_\_\_\_\_ Pharmacy Fax: \_\_\_\_\_

Dear Provider \_\_\_\_\_ (name), (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (fax)

Your patient \_\_\_\_\_ (name) \_\_\_\_/\_\_\_\_/\_\_\_\_ (DOB) has initiated HIV Pre-Exposure Prophylaxis (PrEP) at our pharmacy.

The regimen initiated on \_\_\_\_\_ (Date) consists of:

Checked medication was prescribed:
<input type="checkbox"/> Truvada 200 mg/300 mg tablet: Take 1 tablet by mouth once daily
<b>OR</b>
<input type="checkbox"/> Descovy 200 mg/25 mg tablet: Take 1 tablet by mouth once daily

We recommend an in-clinic office visit with you or another provider after starting PrEP. Listed below are some key points to know about PrEP and which labs are recommended to monitor.

### Provider pearls:

- Truvada is not recommended for CrCl < 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada is safe in pregnancy.
- Recommend referring Hepatitis B positive patients to an infectious disease or gastroenterology specialist if started on PrEP.
- A positive STI test is not a contraindication to PrEP.

### Follow-up lab work:

- HIV antigen/antibody
- HIV-1 RNA (if available)
- Hepatitis B screening
- Hepatitis C antibody
- Comprehensive metabolic panel
- Syphilis screening
- Pregnancy test as appropriate
- STI screening (chlamydia, gonorrhea at affected sites)

If you have further questions, please contact the pharmacy. For more information about PrEP, please visit the CDC website at [www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf](http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf), or call 1-855-HIV-PREP.

## Patient Information

### Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency (HIV)

Pharmacy Name: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_

Pharmacy Phone Number: \_\_\_\_\_

Medications: You MUST start these within 7 days of your negative HIV test.

Checked medication was prescribed:
<input type="checkbox"/> Truvada 200 mg/300 mg tablet: Take 1 tablet by mouth once daily
<b>OR</b>
<input type="checkbox"/> Descovy 200 mg/25 mg tablet: Take 1 tablet by mouth once daily

#### Key points:

- Take medications everyday. If you miss a dose, take it as soon as you remember.
  - If it is close to the time for your next dose, just that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without asking your doctor or pharmacist.
- The most common side effects from these medications are stomach upset and headache. Taking medications with food can help with stomach upset.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PrEP.

#### Follow-up and Next Steps:

1. Contact your PCP to let them know you have been prescribed PrEP. They will need to order labs and see you within 4 weeks.
2. Our pharmacist will contact your doctor to let them know what labs are recommended. .

## HIV Post-Exposure Prophylaxis (PEP) Protocol

### I. Purpose

The purpose of this standing order is to prevent people from contracting the Human Immunodeficiency Virus (HIV) in Arkansas by allowing Arkansas-licensed pharmacists to initiate preventative therapy including ordering and/or dispensing treatment medications, along with any necessary supplies for administration, to eligible person who are HIV negative and at risk for a HIV infection or show interest in starting HIV post-exposure prophylaxis (PEP).

### II. Authority

This standing order is issued pursuant to Act 314 of 2023 (HB 1007) (Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to order and/or dispense PEP medications according to the provisions of Arkansas Code § 17-92-101 and the requirements of this standing order.

### III. Screening and Assessment

The Board of Pharmacy will adopt screening assessment and questionnaire (Appendix A) to be used by pharmacists throughout the state. When a patient requests PEP or point-of-care testing services, or when a pharmacist in their professional judgment decides to initiate PEP or point-of-care testing services, the patient will be assessed for appropriateness of PEP.

### IV. Dispensing Guidelines

#### A. Eligibility Criteria

1. Inclusion:
  - a) Individuals  $\geq$  13 years of age
  - b) Exposure to a source individual known to be HIV-positive. Exposure of:
    - (1) Vagina, rectum, eye, mouth, other mucous membranes, non-intact skin, percutaneous contact  
**WITH**
    - (2) Blood, semen, vaginal secretions, rectal secretions, breast milk, any body fluid visibly contaminated with blood
  - c) If exposure is from a source with an unknown HIV status, PEP may be considered and antiretroviral agents may be prescribed.
2. Exclusion:
  - a) Exposure occurred  $>$  72 hours ago
  - b) Individuals  $<$  13 years of age
  - c) Patient self-reports positive HIV status, or if point-of-care HIV test is positive
  - d) Known or suspected reduced renal function
  - e) Patients with any contraindications to PEP medications
  - f) Patients with a potential exposure who have been consistently adherent to PrEP

## B. Contraindications

Concurrent use of dolutegravir with dofetilide.

Patients with hypersensitivity to dolutegravir, emtricitabine, tenofovir alafenamide, tenofovir disoproxil fumarate, or any other component of a formulation

## C. Product Availability

PEP medications that may be dispensed/provided under this standing order. Following dosing below, pharmacists can dispense any commercially available product form (tablet) based on availability and patient preference.

Dosage Forms:

1. Oral emtricitabine (FTC) [Emtriva]
  - a) Capsule: 200 mg
  - b) Oral Solution: 10 mg/mL
2. Oral emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF) [TRUVADA]
  - a) Tablet: 200 mg/300 mg
3. Oral dolutegravir (DTG) [TIVICAY]
  - a) Tablet: 50 mg
4. Oral raltegravir (RAL) [ISENTRESS]
  - a) Tablet: 400 mg (film-coated, to be swallowed)
  - b) Chewable Tablets: 100 mg (scored)
5. Oral tenofovir disoproxil fumarate (TDF) [Viread]
  - a) Tablets (film coated): 150 mg, 200 mg, 300 mg

Dosing (all prescription will be for 30 day supply):

1. Adult Dosing ( $\geq 18$ ):
  - a. Truvada 200 mg/300 mg: Take one tablet by mouth once daily  
**PLUS**
  - b. Tivicay 50 mg: Take one tablet by mouth once daily  
**OR**
  - c. Isentress 400 mg: Take one tablet by mouth twice daily
2. Pediatric Dosing (13-17):

If  $\geq 40$  kg:

  - a. Isentress 400 mg: Take one tablet by mouth twice daily  
**PLUS**
  - b. Truvada 200 mg/300 mg: Take one tablet by mouth once daily

If < 40 kg:

a. Isentress

Recommended Dosing for Raltegravir (Isentress)		
Weight (kg)	Tablet (twice daily)	Chewable Tablet (Twice Daily)
20 to <25	150 mg	1.5 x 100 mg
25 to <28	400 mg	1.5 x 100 mg
28 to <40	400 mg	2 x 100 mg
≥ 40	400 mg	3 x 100 mg

b. Tenofovir disoproxil fumarate (TDF)

Recommended Dosing of Tenofovir	
Weight (kg)	Tablets (once daily)
22 to 27	200 mg
28 to 34	250 mg
≥ 35	300 mg

c. Emtricitabine

- i. Oral solution: 6 mg/kg (max 240 mg) by mouth
- ii. Capsule: 200 mg by mouth if weight > 33 kg

**D. Warnings/Precautions**

1. Emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF) [TRUVADA]

a) Concerns related to adverse effects:

(1) Lactic acidosis/hepatomegaly: Lactic acidosis and severe hepatomegaly with steatosis, sometimes fatal, have been reported with use of nucleoside analogues, alone or in combination with other antiretrovirals. Suspend treatment in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (marked transaminase elevation may/may not accompany hepatomegaly and steatosis).

b) Disease-related concerns:

(1) Renal impairment: Use is not recommended in patients with CrCl <30 mL/minute (unless receiving hemodialysis). Safety and efficacy of concurrent administration

with an HIV-1 protease inhibitor plus ritonavir or cobicistat has not been established in patients with CrCl <15 mL/minute (with or without hemodialysis).

## 2. Dolutegravir (DTG) [TIVICAY]

### a) Concerns related to adverse effects:

- (1) Hepatotoxicity: Hepatic adverse events, including elevated serum liver biochemistries, hepatitis, and acute liver failure, have been reported; these events have occurred in patients without underlying hepatic disease or other risk factors. Patients with hepatitis B or C may be at increased risk for worsening or development of increased transaminases; sometimes these increases were consistent with immune reconstitution syndrome or hepatitis B reactivation (particularly when anti-hepatitis therapy was withdrawn). Drug-induced liver injury has been reported with dolutegravir in combination with abacavir and lamivudine. Monitor patients for signs/symptoms of hepatotoxicity.
- (2) Hypersensitivity reactions: Rash, constitutional findings, and organ dysfunction (eg, liver injury) have been reported. Discontinue immediately if signs of hypersensitivity (eg, severe rash, rash with fever, malaise, fatigue, muscle/joint aches, blistering or peeling of skin, oral blisters/lesions, conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema, difficulty breathing) occur. Monitor

clinical status and liver function tests, and initiate supportive therapy as appropriate. If hypersensitivity occurs, do not reinstitute therapy with dolutegravir.

### b) Disease-related concerns:

- (1) Hepatic impairment: Not recommended for use in patients with severe hepatic impairment (has not been studied).
- (2) Renal impairment: Use with caution in integrase strand transfer inhibitor (INSTI)-experienced patients with severe renal impairment; decreases in dolutegravir concentrations were observed and may result in loss of therapeutic effect and development of resistance to dolutegravir or other coadministered antiretroviral agents.

### c) Dosage form specific issues:

- (1) Product interchangeability: Dolutegravir tablets and soluble tablets for oral suspension (Tivicay PD) are not bioequivalent and not interchangeable on a milligram-per-milligram basis. If a patient switches from one formulation to another, adjust dose for the new dosage formulation. Incorrect dosing may result in underdosing, loss of therapeutic effect, and possible development of resistance, or adverse reactions from increased exposure to dolutegravir.

### d) Other warnings/precautions:

- (1) False elevations in serum creatinine: May inhibit tubular secretion of creatinine without affecting actual renal glomerular function; observed onset was within the first 4 weeks of therapy followed by stability through at least 96 weeks. Use caution when interpreting serum creatinine values in patients with medical conditions or receiving drugs needing to be monitored with estimated CrCl.

3. Raltegravir (RAL) [ISENTRESS]

a) Concerns related to adverse effects

(1) Myopathy: Grade 2 to 4 creatine kinase (CK) increases have been observed and myopathy and rhabdomyolysis have been reported; use caution in patients with a history of rhabdomyolysis, myopathy, or increased serum creatine kinase or who have risk factors for CK elevations and/or skeletal muscle abnormalities, including taking other drugs known to cause myopathy or rhabdomyolysis.

(2) Skin and hypersensitivity reactions: Severe, life-threatening or fatal cases of Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported. Hypersensitivity reactions (rash, constitutional symptoms, organ dysfunction) have also been reported. Discontinue immediately if a severe skin reaction or hypersensitivity symptoms develop. Monitor clinical status, including liver transaminases.

b) Dosage form specific issues:

(1) Chewable tablet: Contains phenylalanine; avoid or use with caution in patients with phenylketonuria.

(2) Tablets and oral suspension: Raltegravir film-coated tablets and chewable tablets or oral suspension are not bioequivalent and are not substitutable on a mg/mg basis.

**E. Documentation**

Patient records must be furnished to a health care practitioner designated by the patient upon the request of the patient. Documentation may include, but is not limited to assessment and evaluation forms and results of rapid diagnostic test(s). Maintain records of all patients receiving services for two (2) years.



## Appendix A

### Pharmacist Assessment, Evaluation and Prescribing Protocol Form: *PEP*

<b>PATIENT INFORMATION</b>			
Name:	Date of Birth:	Weight:	Age:
Preferred Pronouns:	Sex Assigned at Birth (circle): Male or Female		
Address:	City/State/Zip:		
Email Address:	Phone:		
Do you have health insurance? Yes or No If yes, please provide the card when turning in this form.			
Primary Care Provider (Name, Clinic, Phone):			
Medication Allergies?			
Current medications? (prescription, over-the-counter, herbals, topical medications, pain or allergy medication, and any supplements/vitamins)			
Treatments tried for the current indication (if none please indicate N/A):			

<b>Exposure History</b>			
Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	Yes	No	Not Sure
What was the date of the exposure?	__/__/__		
What was the approximate time of the exposure?	__:__ AM/PM		
Was your exposure due to unwanted physical contact or sexual assault?	Yes	No	Not Sure
Was your exposure due to an occupational exposure (needle-stick)?	Yes	No	Not Sure

Was the exposure through contact with any of the following body fluids? Select any/all that apply: <input type="checkbox"/> Blood <input type="checkbox"/> Tissue fluids <input type="checkbox"/> Semen <input type="checkbox"/> Vaginal secretions <input type="checkbox"/> Saliva <input type="checkbox"/> Tears <input type="checkbox"/> Sweat <input type="checkbox"/> Other Please specify if other: _____	Yes	No	Not Sure
Did you have vaginal or anal intercourse without a condom?	Yes	No	Not Sure
Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	Yes	No	Not Sure
Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	Yes	No	Not Sure
Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	Yes	No	Not Sure
Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? Select any/all that apply: <input type="checkbox"/> persons with known HIV infection <input type="checkbox"/> men who have sex with men with unknown HIV status <input type="checkbox"/> persons who inject drugs <input type="checkbox"/> sex workers	Yes	No	Not Sure
Did you have another encounter that is not included above that could have exposed you to high risk body fluids listed above? If yes, please specify: _____	Yes	No	Not Sure

<b>Past Medical History</b>		
Have you ever been diagnosed with HIV?	Yes	No
Are you seeing a provider for management of Hepatitis B?	Yes	No
Have you ever received immunization for Hepatitis B? If yes, when: _____ If not, would you like a vaccine today? Yes or No	Yes	No
Are you seeing a kidney specialist?	Yes	No
Are you currently pregnant or breast-feeding?	Yes	No
Do you take any of the following over-the-counter medications or herbal supplements? <input type="checkbox"/> Orlistat (Alli®) <input type="checkbox"/> aspirin <input type="checkbox"/> naproxen (Aleve®) <input type="checkbox"/> ibuprofen (Advil®) <input type="checkbox"/> antacids (Tums® and Rolaids®) <input type="checkbox"/> multivitamins containing iron, calcium, magnesium, zinc, or aluminum	Yes	No
Do you have any other medical problems? If yes, please specify: _____ _____	Yes	No

## Pharmacist Assessment Tool (For pharmacy staff only)

1. Is the patient less than 13 years old?	
<input type="checkbox"/> Yes: Do not prescribe PEP. Refer to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease (ID) specialist, or public health clinic	<input type="checkbox"/> No: Go to #2
2. Is the patient a survivor of sexual assault?	
<input type="checkbox"/> Yes: Continue on with the algorithm (Go to #3) and then refer to the ED for a sexual assault workup.	<input type="checkbox"/> No: Go to #3
3. Did the patient have an occupational exposure (needle stick)?	
<input type="checkbox"/> Yes: Continue on with the algorithm (Go to #4) and ask patient how medications are being billed.	<input type="checkbox"/> No: Go to #4
4. Is the patient known to be HIV-positive?	
<input type="checkbox"/> Yes: Do not prescribe PEP. Refer to local PCP, ID specialist, or public health clinic	<input type="checkbox"/> No: Go to #5. Conduct HIV test
5. When did the exposure occur?	
<input type="checkbox"/> > 72 hours ago: PEP not recommended. Do NOT prescribe PEP. Refer patient to local PCP, ID specialist, or public health clinic	<input type="checkbox"/> ≤ 72 hours ago: Go to #6
6. Was the exposure from a source known to be HIV-positive? (If known to be negative - Do not prescribe PEP)	
<input type="checkbox"/> Yes: Go to #7	<input type="checkbox"/> Not sure: Go to #8
7. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids?	
Please check any/all that apply: <input type="checkbox"/> Blood <input type="checkbox"/> Semen <input type="checkbox"/> Vaginal secretions <input type="checkbox"/> Rectal secretions <input type="checkbox"/> Breast milk <input type="checkbox"/> Any body fluid that is visibly contaminated with blood  If any boxes are check, go to #10.	Please check any/all that apply (Note: only applicable if not visibly contaminated with blood): <input type="checkbox"/> Urine <input type="checkbox"/> Nasal Secretions <input type="checkbox"/> Saliva <input type="checkbox"/> Sweat <input type="checkbox"/> Tears <input type="checkbox"/> None of the above  Go to #8
8. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?	
<input type="checkbox"/> Yes: Go to #10	<input type="checkbox"/> No: Go to #9
9. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?	

<input type="checkbox"/> Yes: Please check all that apply and go to #10: <input type="checkbox"/> Was the source person known to be HIV-positive? <input type="checkbox"/> Were there cuts/openings/sores/ulcers on the oral mucosa? <input type="checkbox"/> Was blood present? <input type="checkbox"/> Has this happened more than once without PEP treatment? <input type="checkbox"/> None of the above	<input type="checkbox"/> No: Use clinical judgment. Risk of acquiring HIV is low. If clinical determination is to prescribe PEP then continue to #10
10. Does the patient have an established PCP for appropriate follow-up? OR - Can the pharmacist refer for appropriate follow-up?	
<input type="checkbox"/> Yes: Go to #11	<input type="checkbox"/> No: Do not prescribe PEP. Refer patient to PCP, ED, urgent care, ID specialist, or public health clinic
11. Does the patient have a history of known Hepatitis B infection (latent or active)?	
<input type="checkbox"/> Yes: Do not prescribe PEP. Refer to local PCP, ED, urgent care, ID specialist, or public health clinic	<input type="checkbox"/> No: Go to #12
12. Has the patient received the full Hepatitis B vaccination series? Dates if known: _____	
<input type="checkbox"/> Yes: Go to #14	<input type="checkbox"/> No: Go to #13
13. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #14.	
<input type="checkbox"/> Vaccine administered - LOT: _____ Exp: _____	
14. Does the patient have known chronic kidney disease or reduced renal function?	
<input type="checkbox"/> Yes: Do not prescribe PEP. Refer to local PCP, ED, urgent care, ID specialist, or public health clinic	<input type="checkbox"/> No: Go to #15
15. Results of point-of-care HIV test:	
<input type="checkbox"/> Positive: Do not prescribe PEP. Refer to local PCP, ED, urgent care, ID specialist, or public health clinic. <b>Report result to the Arkansas Department of Health.</b>	<input type="checkbox"/> No: Go to #16
16. Does the patient take any medications that interact with PEP medications?	
<input type="checkbox"/> Yes: <ul style="list-style-type: none"> <li>- Prescribe PEP if minor interaction that can be avoided by separating medications.</li> <li>- Do not prescribe PEP if major interaction. Refer to local PCP, ED, urgent care, ID specialist, or public health clinic</li> </ul>	<input type="checkbox"/> No: PEP prescription recommended. Pharmacists must notify both the provider and patient.

**Diagnosis of Patient**

- PEP recommended
 PEP not recommended  
 Refer to PCP, ED, Urgent Care, ID Specialist, or Public Health Clinic

## Prescription:

<b>Non-pregnant Patients PEP Therapy</b>		
Truvada	Dispense: <input type="checkbox"/> 200 mg/ 300 mg #30 No Refills	Sig: Take 1 (one) tablet by mouth daily for 30 days
<b>AND</b>		
Tivicay	Dispense: <input type="checkbox"/> 50 mg #30 No Refills	Sig: Take 1 (one) tablet by mouth daily for 30 days
<b>Pregnant Patients OR Patients between 13-18 weighing <math>\geq</math> 40 kg PEP Therapy</b>		
Truvada	Dispense: <input type="checkbox"/> 200 mg/ 300 mg #30 No Refills	Sig: Take 1 (one) tablet by mouth daily for 30 days
<b>AND</b>		
ISENTRESS	Dispense: <input type="checkbox"/> 400 mg #60 No Refills	Sig: Take 1 (one) tablet by mouth twice daily for 30 days
<b>Pediatric Patients weighing &lt;40 kg PEP Therapy (See chart above for dosing)</b>		
Isentress	Dispense: <input type="checkbox"/> No Refills	Sig:
<b>AND</b>		
Emtricitabine	Dispense: <input type="checkbox"/> No Refills	Sig:
<b>AND</b>		
Tenofovir (TDF)	Dispense: <input type="checkbox"/> No Refills	Sig:

Patient: \_\_\_\_\_

Prescribing Pharmacist: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Follow up in 4-6 weeks with PCP, Urgent Care, ID Specialist, or Public Health Clinic

**References:**

Dominguez KL, Smith DK, Thomas V, et al. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016. Cdc.gov. Published April 2016. Accessed August 10, 2023. <https://stacks.cdc.gov/view/cdc/38856> Lexicomp: Evidence-Based Drug Referential Content. Wolterskluwer.com. Published 2023. Accessed August 10, 2023. <https://www.wolterskluwer.com/en/solutions/lexicomp>

## Provider Notification for Adults and Pediatric Patients Weighing >40kg

Pharmacy Name: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_

Pharmacy Phone: \_\_\_\_\_ Pharmacy Fax: \_\_\_\_\_

Dear Provider \_\_\_\_\_ (name), (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (fax)

Your patient \_\_\_\_\_ (name) \_\_\_\_/\_\_\_\_/\_\_\_\_ (DOB) has initiated treatment for HIV Post-Exposure Prophylaxis (PEP) at our pharmacy.

The regimen initiated on \_\_\_\_\_ (Date) consists of:

Checked medications were prescribed:
<input type="checkbox"/> Truvada 200 mg/300 mg tablet: Take 1 tablet by mouth once daily for 30 days
<b>AND ONE OF THE FOLLOWING</b>
<input type="checkbox"/> Tivicay 50 mg tablet: Take 1 tablet by mouth once daily for 30 days
<b>OR</b>
<input type="checkbox"/> Isentress 400 mg tablet: Take 1 tablet by mouth twice daily for 30 days

We recommend an in-clinic office visit with you or another provider within 4-6 weeks of starting PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

### Provider pearls:

- Truvada needs renal dose adjustments for CrCl < 50 mL/min. Please contact the pharmacy if this applies to your patient.
- NSAIDs should be avoided while patients are taking PEP to avoid drug-drug interactions with Truvada.
- Discontinuation of Truvada can cause reactivation of hepatitis B. We recommend you refer Hepatitis B positive patients to an ID or gastroenterology specialist.
- If your patient has risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after completion of the 30-day PEP course.

### Follow-up lab work at 4-6 weeks:

- HIV antigen/antibody
- Hepatitis B surface antigen and surface antibody
- Hepatitis C antibody
- Comprehensive metabolic panel
- Treponema pallidum antibody as appropriate
- Pregnancy test as appropriate
- STI screening (chlamydia, gonorrhea at affected sites)

If you have further questions, please contact the pharmacy. For more information about PEP, please visit the CDC website at [cdc.gov/hiv/basics/pep.html](http://cdc.gov/hiv/basics/pep.html) or call PEpline at 1-888-448-4911

**Patient Information for Adults and Pediatric Patients weighing >40kg**  
**Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency (HIV)**

Pharmacy Name: \_\_\_\_\_  
Pharmacy Address: \_\_\_\_\_  
Pharmacy Phone Number: \_\_\_\_\_

Medications: You MUST start these within 72 hours of your exposure

Checked medications were prescribed:
<input type="checkbox"/> Truvada 200 mg/300 mg tablet: Take 1 tablet by mouth once daily for 30 days
<b>AND ONE OF THE FOLLOWING</b>
<input type="checkbox"/> Tivicay 50 mg tablet: Take 1 tablet by mouth once daily for 30 days
<b>OR</b>
<input type="checkbox"/> Isentress 400 mg tablet: Take 1 tablet by mouth twice daily for 30 days

**Key points:**

- Take medications everyday. If you miss a dose, take it as soon as you remember.
  - If it is close to the time for your next dose, just that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without asking your doctor or pharmacist.
- The most common side effects from these medications are stomach upset and headache. Taking medications with food can help with stomach upset.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

**Follow-up and Next Steps:**

1. Contact your PCP to let them know you have been prescribed PEP. They will need to order labs and see you in the next 4-6 weeks.
2. Our pharmacist will contact your doctor to let them know what follow up labs are recommended.
3. If you think you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

## Provider Notification for Pediatric Patients weighing <40 kg

Pharmacy Name: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_

Pharmacy Phone: \_\_\_\_\_ Pharmacy Fax: \_\_\_\_\_

Dear Provider \_\_\_\_\_ (name), (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (fax)

Your patient \_\_\_\_\_ (name) \_\_\_\_/\_\_\_\_/\_\_\_\_ (DOB) has initiated treatment for HIV Post-Exposure Prophylaxis (PEP) at our pharmacy.

The regimen initiated on \_\_\_\_\_ (Date) consists of:

Checked medications were prescribed and instructions as written below:
<input type="checkbox"/> Isentress
<b>AND</b>
<input type="checkbox"/> Emtriva
<b>AND</b>
<input type="checkbox"/> Viread

We recommend an in-clinic office visit with you or another provider within 4-6 weeks of starting PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

### Provider pearls:

- Truvada needs renal dose adjustments for CrCl < 50 mL/min. Please contact the pharmacy if this applies to your patient.
- NSAIDs should be avoided while patients are taking PEP to avoid drug-drug interactions with Truvada.
- Discontinuation of Truvada can cause reactivation of hepatitis B. We recommend you refer Hepatitis B positive patients to an ID or gastroenterology specialist.
- If your patient has risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after completion of the 30-day PEP course.

### Follow-up lab work at 4-6 weeks:

- HIV antigen/antibody
- Hepatitis B surface antigen and surface antibody
- Hepatitis C antibody
- Comprehensive metabolic panel
- Treponema pallidum antibody as appropriate
- Pregnancy test as appropriate
- STI screening (chlamydia, gonorrhea at affected sites)

If you have further questions, please contact the pharmacy. For more information about PEP, please visit the CDC website at [cdc.gov/hiv/basics/pep.html](http://cdc.gov/hiv/basics/pep.html) or call PEPLine at 1-888-448-4911.



## Patient Information for Pediatric Patients weighing <40 kg

### Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency (HIV)

Pharmacy Name: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_

Pharmacy Phone Number: \_\_\_\_\_

Medications: You MUST start these within 72 hours of your exposure

Checked medications were prescribed and instructions as written below:
<input type="checkbox"/> Isentress
<b>AND</b>
<input type="checkbox"/> Emtriva
<b>AND</b>
<input type="checkbox"/> Viread

#### Key points:

- Take medications everyday. If you miss a dose, take it as soon as you remember.
  - If it is close to the time for your next dose, just that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without asking your doctor or pharmacist.
- The most common side effects from these medications are stomach upset and headache. Taking medications with food can help with stomach upset.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

#### Follow-up and Next Steps:

4. Contact your PCP to let them know you have been prescribed PEP. They will need to order labs and see you in the next 4-6 weeks.
5. Our pharmacist will contact your doctor to let them know what follow up labs are recommended.

If you think you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

## Appendix B

### HIV Pre-Exposure and Post-Exposure Prophylaxis Financial Assistance

1. **Ready, Set, PrEP** program provides free pre-exposure HIV-prevention medications to patients who qualify. Patients can apply for this program if they do not have health insurance coverage for prescription drugs, have taken an HIV test and received a negative result before starting the program, have a prescription for PrEP, and live in the United States, including tribal lands or territories. The enrollment form can be downloaded to complete (<https://readyssetprep.hiv.gov/>) or by calling toll-free (855) 447-8410.
2. **Advancing Access**® is a program offered by the drug manufacturer, Gilead. This program is for patients who have insurance or not. Gilead is the manufacturer of Truvada (PrEP and PEP) and Descovy (PrEP). The enrollment form can be downloaded to complete (<https://www.gileadadvancingaccess.com/hcp/>) or by calling toll free (800) 226-2056.
3. **MerckHelps**™ is a program that provides drug products free of charge to eligible patients. Patients who do not meet the insurance requirements to receive HIV prevention medications may still qualify if they attest that they have special circumstances of financial and medical hardship, and their income meets the program criteria. Isentress is used for HIV post-exposure prophylaxis. The enrollment form can be completed by downloading a form (<https://www.merckhelps.com/ISENTRESS>) or by calling toll-free (800) 727-5400.
4. **ViiVConnect Savings Card Program** offers eligible patients savings off their out-of-pocket expenses for Tivicay (PEP). This program is for patients who have commercial insurance. If a patient does not have commercial insurance, he may be eligible for the ViiV Healthcare PAP. Applying can be done using a mobile application (<https://myviivcard.com/get-a-card/>) for commercial insurance or online (<https://www.viivconnect.com/for-providers/financial-support/medications/>) for patient assistance program (PAP).
5. **The Patient Advocate Foundation (PAF) Co-Pay Relief Program** provides direct payment for co-pays, co-insurance, and deductibles for patients who need financial assistance. Once the application is completed, assistance is immediately accessible. Application can be completed online (<https://copays.org/pharmacies/>) or by calling toll-free (866) 512-3861.

## Appendix C

### HIV Pre-Exposure and Post-Exposure Prophylaxis Referral to Care

1. **Arkansas RAPPS** (Reach, Affirm, Positive, Progressive, Systems) is a non-profit community-based organization that provides HIV-prevention training, HIV and Hepatitis C screenings, access to care and treatment options, health services navigation, and events to encourage de-stigmatization of HIV and other sexually transmitted infections. They offer tele-health appointments with a physician. <https://www.arrapps.org/> or call 501-379-8357.
2. **UAMS HealthNow** offers telemedicine appointments seven days a week from 8 a.m. to 8 p.m. After a sex history with the provider, the patient is tested for HIV. If negative, the provider prescribes PrEP medications three months at a time. The patient will be tested for HIV every three months. <https://uamshealth.com/healthnow/teleprep/> or call 501-686-7000.
3. **The HIV Testing Sites & Care Services Locator** is a location-based search tool that allows you to search for testing services, housing providers, health centers, and other service providers. <https://locator.hiv.gov/>
4. **Please PrEP Me** is a location -based search tool that allows you to search for testing services, insurance coverage, health centers, and other service providers. <https://prelocator.org/>
5. **Engaging Arkansas Communities (EAC)** is a comprehensive prevention program that provides support resources. EAC partners with Q Care Plus who provides options like virtual provider visits and at-home HIV testing kits. <https://qcareplus.com/engaging-arkansas-communities/>
6. **ARcare 's Positive Connection Access Centers** offer HIV Case Management and Rapid HIV Testing Services. [Find a Location - ARcare](#). Positive Connections also offer an FDA-approved, oral swab test mailed to eligible participants FREE of charge. [Get Tested - ARcare](#)

# Arkansas Department of Health (ADH) Mandatory Reportable Diseases List and Instructions

The "Rules and Regulations Pertaining to Reportable Disease" adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the Laws of the State of Arkansas including, without limitation, Ark. Code Ann. §§ 20-7-101 et seq. Section III, states "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 clinical or private laboratory; 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..."

**The following diseases/conditions (*suspected or confirmed*) are to be reported immediately to the ADH:**

Anthrax***	Meningococcal infection**	Poliomyelitis***	Variola (Smallpox)***
Botulism (all types)***	Novel Coronavirus***	Q Fever***	Middle Eastern Respiratory Syndrome (MERS; MERS-CoV)
Chemical agents of terrorism***	Novel influenza A virus**	Tularemia**	Severe Acute Respiratory Syndrome (SARS; SARS-CoV-1)
Emerging threat agents***	Plague ( <i>Yersinia pestis</i> )**	Typhus***	Viral hemorrhagic fevers***

**TO REPORT DISEASES IMMEDIATELY VIA TELEPHONE, CALL 1-501-661-2381 (8:00 AM - 4:30 PM)  
AFTER HOURS, HOLIDAYS AND WEEKENDS, PLEASE CALL 1-800-554-5738**

**All outbreaks of diseases on this list or any unusual outbreak/cluster should be reported immediately by phone to the ADH. All unusually drug resistant infections should be reported within 24 hours to the ADH.**

The following diseases of public health significance are to be reported to the Arkansas Department of Health within 24 hours of diagnosis. Reports should include: 1) the reporter's name, location and phone number; 2) the name and onset date of the disease; 3) the patient's name, address, phone number, age, sex and race; 4) the attending physician's name, location and phone number; 5) any pertinent clinical, laboratory, and treatment information. Report by fax to 501-661-2428; or by phone to 501-280-4115.

Acute flaccid myelitis (AFM)	Histoplasmosis
Alpha-gal syndrome	HIV (human immunodeficiency virus)* (qualitative, quantitative, and genotyping included even if no virus is detected)
Anaplasmosis ( <i>Anaplasma phagocytophilum</i> )	Influenza deaths/hospitalizations, all ages†
Arboviral, neuro and non-neuroinvasive	Legionellosis
Babesiosis	Leptospirosis
<i>Bacillus cereus</i>	Listeriosis**
<i>Bacillus</i> species that cannot be ruled out as <i>B. anthracis</i> or <i>B. cereus</i> biovar anthracis**	Lyme disease
Blastomycosis	Malaria
Brucellosis**	Measles (rubeola)
CD4+ T-lymphocyte count	Melioidosis ( <i>Burkholderia pseudomallei</i> )**
Campylobacteriosis**	Meningitis, all types**
<i>Candida auris</i> **	Mpox (monkeypox)
Carbapenemase producing organisms (CPO)**	Multisystem inflammatory syndrome (MIS)
Chagas disease	Mumps
Chancroid	Pertussis
Chikungunya	Psittacosis
Chlamydial infections	Rabies, human and animal; plus mammalian animal bites‡
Coccidioidomycosis (caused by <i>Coccidioides</i> )	Rickettsiosis, spotted fever (RMSF)
COVID-19 (SARS-CoV-2)	Rubella, including congenital infection
Creutzfeld-Jakob disease	Salmonellosis (including typhoid fever)**
Cryptococcosis	Shigellosis**
Cryptosporidiosis	<i>Streptococcus</i> infection, invasive, including <i>S. pneumoniae</i> , <i>S. pyogenes</i> /group A; indicate antibiotic susceptibility if known.
Cyclosporiasis	Syphilis, including congenital infection*
Dengue virus infections	Tetanus
Diphtheria	Toxic shock syndrome
Ehrlichiosis	Toxoplasmosis
<i>E. coli</i> , Shiga toxin producing**	Trichinellosis
Encephalitis, all types (including Powassan, California, EEE, St. Louis, West Nile, WEE)	Tuberculosis
Food poisoning, all types	Vancomycin-intermediate/resistant <i>Staphylococcus aureus</i> (VISA/VRSA)**
Giardiasis	Varicella (chickenpox), disease or death
Glanders ( <i>Burkholderia mallei</i> )**	Vibriosis (cholera and non-cholera)**
Gonorrhoea	West Nile virus
<i>Haemophilus influenzae</i> , invasive**	Yellow fever
Hansen's disease (leprosy)	Yersiniosis, non-pestis (any species)
Hantavirus pulmonary syndrome	Zika virus
Hemolytic-uremic syndrome (HUS)	
Hepatitis (type A, B, C, or E) viruses	
Hepatitis B surface antigen (HBsAg) positive in pregnant woman	

## **REPORTABLE OCCUPATIONAL AND ENVIRONMENTAL DISEASES AND OTHER CONDITIONS**

(For acute disease consultation on the diseases listed below please call the Poison Control Center at: **800-376-4766**)

- Asbestosis
- Blood lead levels\*\*\*\*
- Byssinosis
- Chemical exposure, all types
- Clinical radiation adverse event
- Elevated blood heavy metal (e.g.: mercury, arsenic, cadmium)
- Pesticide exposure
- Pneumoconiosis (coal workers)
- Mesothelioma
- Silicosis
- Suspected unintentional radiation exposure

**\* Any pregnant woman infected with AIDS, HIV or Syphilis must be reported indicating the trimester of pregnancy. This applies each time the woman becomes pregnant.**

**\*\* Non-viral isolates must be submitted to the ADH Laboratory for further testing. For enteric, if no isolate is available, please send raw stool.**

**\*\*\* Isolates must be retained and ADH contacted to determine whether sample needs to be submitted for further testing.**

**\*\*\*\* Blood lead levels over 3.5 µg/dl for patients 72 months old and younger and levels over 10 µg/dl for patients 73 months and older.**

† Web reporting for influenza is available at: <https://flureport.adh.arkansas.gov>

‡ <https://www.healthy.arkansas.gov/programs-services/topics/rabies-animal-bites>

Other diseases not named in this list may at any time be declared notifiable as the necessity and public health demand, and these regulations shall apply when so ordered by the Director.

**TO REPORT DISEASES IN THE SECOND LIST ABOVE, PLEASE  
FAX THE DISEASE REPORT TO 1-501-661-2428**



**Please Print Legibly**

**Reporting facility:** \_\_\_\_\_ **Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip Code:** \_\_\_\_\_ **Phone:** (\_\_\_\_) \_\_\_\_ - \_\_\_\_\_

**Reporter name:** \_\_\_\_\_ **Reporter phone:** (\_\_\_\_) \_\_\_\_ - \_\_\_\_\_

**Physician Last name:** \_\_\_\_\_ **First:** \_\_\_\_\_ **phone:** (\_\_\_\_) \_\_\_\_ - \_\_\_\_\_

**Disease or Condition:** \_\_\_\_\_ **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Patient Last name:** \_\_\_\_\_ **First:** \_\_\_\_\_ **Date of birth:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Address:** \_\_\_\_\_ **Phone:** (\_\_\_\_) \_\_\_\_ - \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip:** \_\_\_\_\_ **County:** \_\_\_\_\_

**Gender:** Male  Female

**Race:** American Indian/Alaskan  Asian  Black

**Ethnicity:** Hispanic  Not Hispanic

Hawaiian/Pac Islander  White  Other  \_\_\_\_\_

**Method of diagnosis:** clinical  laboratory  **Specific test name** \_\_\_\_\_ **Result:** \_\_\_\_\_

**Specimen (blood, CSF, sputum, stool, etc.):** \_\_\_\_\_ **Date lab specimen collected:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Food handler:** Yes  No  Unknown

**Child/worker in a daycare:** Yes  No

**Healthcare worker:** Yes  No  Unknown

**Pregnant:** Yes  No  **Due Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Nursing home:** Yes  No  Unknown

**Jail:** Yes  No

**Is this part of an outbreak/cluster?:** Yes  No  Unknown  **Number of cases linked to this case:** \_\_\_\_\_

**Was the patient hospitalized** Yes  No  Unknown

**Admission date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Discharge date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Reason seen:** \_\_\_\_\_

**Died:** Yes  No  Unknown

**Other Lab Results, Treatments or Additional Comments:** (Please include test name, source, result and dates)

**Disease or Condition-Specific Information (Please complete if appropriate)**

**If Hepatitis:**

**Hep A IgM antibody:** Positive  Negative  Not Done

**LFT collection date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Hep B IgM antibody:** Positive  Negative  Not Done

**Total bilirubin:** \_\_\_\_\_

**Hep B surface antigen:** Positive  Negative  Not Done

**SGOT (AST):** \_\_\_\_\_

**Hep C antibody:** Positive  Negative  Not Done

**SGPT (ALT):** \_\_\_\_\_

**(Signal to cut off ratio:** \_\_\_\_\_)

**Was patient jaundiced** Yes  No

**Does patient have previous diagnosis of Hepatitis** Yes  No

**Was patient symptomatic** Yes  No

**If Tickborne Disease:**

**Diagnostic Tests:** IgG titer: \_\_\_\_\_ IgM titer: \_\_\_\_\_ PCR: \_\_\_\_\_

**Symptoms:** Fever  Rash  Myalgia  Headache  Anemia  Leukopenia  Thrombocytopenia

**Elevated hepatic transaminases**  Other \_\_\_\_\_

**If Influenza: please report online at: <https://FluReport.ADH.Arkansas.gov>**

**Test Performed:** Rapid antigen: \_\_\_\_\_ PCR result: \_\_\_\_\_ Other: \_\_\_\_\_

**Vaccinated this season** Yes  No  Unknown

**If yes, Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_