COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Third Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Statewide Protocol Work Group Meeting Agenda
August 16, 2024
1:30PM

TOPIC **PAGES**

Call to Order: Cheri Garvin, RPh, Chairman
- Welcome & Introductions

Approval of Agenda

Call for Public Comment: The work group will receive public comment at this time. The work group will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

Agenda Items:
- Review draft amendments of HIV PrEP statewide protocol **2-49**
- Review all other current statewide protocols and offer recommendations to amend, if necessary, to ensure consistency with standard of care **50-147**

Adjourn

Agenda Topic: Review draft amendments of HIV PrEP statewide protocol

Background:

VDH requested amendments to the HIV PrEP statewide protocol to align with current CDC recommendations and include the injectable formulation Apretude®. Board of Pharmacy staff and VDH staff collaborated on draft amendments using Oregon's current version of its oral PrEP statewide protocol as the foundation and inserted draft language regarding use of Apretude.

Included in Agenda Packet:

- Draft amendments to Virginia's HIV PrEP statewide protocol - pages 3-27
- Virginia's current HIV PrEP statewide protocol - pages 28-37
- Oregon's current HIV PrEP statewide protocol (revised in 2023) - pages 38-49

Action Needed:

- Motion to recommend amendments to HIV PrEP statewide protocol as presented or amended.

~~**Adopted: 9/24/2021**~~

Revised: _____

Effective Date: ~~**12/22/2021**~~

VIRGINIA BOARD OF PHARMACY

Preventive Care

HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol

Consistent with the manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- ~~standardized~~ PrEP Self-Screening Patient Intake Form ~~(pg. 2-3)~~
- Assessment and Oral Treatment Care Pathway consisting of:
    - Oral PrEP Algorithm A for Initiation with Appendix A or
    - Oral PrEP Algorithm B for Continuation with Appendix B and
    - Table 1 Oral PrEP Required Labs
- Assessment and Injectable Treatment Care Pathway consisting of:
    - Injectable PrEP Algorithm A for Initiation with Appendix A or
    - Injectable PrEP Algorithm B for Continuation with Appendix B and
    - Table 2 Injectable PrEP Required Labs
- ~~Utilize the~~ Recommended Regimen and Communication Examples
- ~~Utilize the standardized~~ PrEP Prescription Template and Provider Notification Form~~Fax (pg.10)~~

PHARMACIST EDUCATION AND TRAINING

- Prior to issuing a prescription to initiate treatment with, dispensing, or administering controlled substances for prep~~ost~~-exposure prophylaxis under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.

*Note: A pharmacy may create and use an electronic format for the PrEP Patient Intake Form,

PrEP Assessment and Treatment Care Pathway, and PrEP Provider Fax if the information is identical to the forms included in this protocol.

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL- Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other_____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Section 1: Reason for HIV PrEP and Eligibility

You do not have to indicate reason; please review and answer the question at the bottom of this box:	
▪ I want to start PrEP ▪ I want to keep taking PrEP ▪ I had sex in the past 6 months ▪ I do not always use condoms when I have sex ▪ I had gonorrhea, chlamydia, or syphilis in the past 6 months	▪ I have had sex with someone living with HIV ▪ I have had sex with one or more partners and did not know their HIV status ▪ I injected drugs in the past 6 months ▪ I shared injection equipment (any)
1a. Is your answer YES to one of the above statements?	□ Yes □ No □ Unsure
1b. Are you UNDER 183 years old?	□ Yes □ No
1c. Do you weigh LESS than 77 pounds (35 kg)?	□ Yes □ No

Commented [CJ1]: Should these statements be combined? 1a states I must answer yes to one of the statements.

Section 2: HIV Testing, PrEP, and HIV Post-Exposure (PEP) Histories; Acute HIV Symptom Review

2a. Have you ever had a positive, reactive, detected, or indeterminate test for HIV?	□ yes □ no
2b. Have you had any of the following in the last 4 weeks: fever, feeling very tired, muscle or joint aches or pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms?	□ yes □ no
2c. Are you taking PrEP now or in the past? • If now, which PrEP medicine?_____. Skip question 1d and continue to question 1e. • If in the past, what was your reason for stopping? _____	□ yes □ no
2d. Are you currently finishing a course of PEP after a possible HIV exposure?	□ yes □ no
2e. When was your last sex, injection drug use, or other possible exposure to HIV?	□ Less than 72 hours (3 days) ago □ More than 72 hours (3 days), but less than 4 weeks ago □ More than 4 weeks ago

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL- Protected Health Information)

Section 3: Brief Medial History to Determine which PrEP Medication may be Best for You

3a. Have you ever been told you have kidney disease (e.g., kidney failure, poor kidney function)?	□ yes □ no
3b. Have you been told you have a bone disease (e.g. osteoporosis, osteopenia, low bone mineral density, etc.?	□ yes □ no
3c. Have you ever had Hepatitis B infection? Have you ever received an immunization for Hepatitis B? If yes, when: Date(s): #1___/___/___ #2 ___/___/___ #3 ___/___/___ If No, would you like a Hepatitis B immunization today?	□ yes □ no □ unsure □ yes □ no □ unsure □ yes □ no □ unsure
3d. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no □ does not apply
3e. Please list the names of other prescriptions (medicines), over-the-counter, herbal, or supplement products that you take so that the pharmacist can check for drug interactions with PrEP. Please note doses and use of any nonsteroidal anti-inflammatory medicines (NSAIDS): ibuprofen (Advil/Motrin), naproxen (Aleve), meloxicam, celecoxib, diclofenac and any estradiol containing gender-affirming hormone medicines: _____ _____ _____ _____	
3f. Please list any other medical problems or questions you would the pharmacist to know: _____ _____	

Section 4: Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my oral PrEP prescription filled and every 60 days to receive injectable PrEP medication. The pharmacist must document a negative HIV test to fill my PrEP prescription. • I may be able to have tests performed at the pharmacy. • I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last7 days. (The pharmacist must document a negative HIV test result within the last 7 days before prescribing PrEP. If that is the only lab result available, then the pharmacist can only prescribe up to a 30-day supply until other labs are done. When all needed lab results are given to the pharmacist, then the pharmacist may be able to prescribe up to a 90-day supply each time.) ○ I brought my labs in today. • I understand that if I have condomless sex within 4 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.	□ Yes □ No □ Yes □ No
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. • I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate. • I understand screening for gonorrhea and chlamydia should be done at each possible site of exposure via urine (genital) and swab (throat and rectum) collections.	□ Yes □ No
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses AS DIRECTED. Missing doses increases the risk of getting HIV.	□ Yes □ No

Patient Signature: _____ **Date:** _____

Commented [CJ2]: Should language regarding appropriateness of administering injection under these circumstances also be inserted?

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

ALGORITHM A: PrEP INITIATION (Review Relevant Questions on Patient In-Take Form)

1) PrEP INDICATION AND ELIGIBILITY

- Review Patient Intake Form #1a

- Review Patient Intake Form #1b or #1c

If NO to both, proceed.

If YES to either, refer. → Refer

2a) CURRENT HIV STATUS

- Review Patient Intake Form #2a and HIV test results from Section 4.

If NO history of HIV, proceed.

If YES has history of HIV , refer. → Refer

HIV TEST

- HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive

*HIV Ag/Ab blood test must be RESULTED within 7 days prior to prescribing and dispensing

- HIV RNA test resulted: □ detected □ indeterminate □ not detected □ result pending □ none

May order HIV RNA at initial intake (preferred) and as appropriate thereafter

If NO current HIV or
HIV Ag/Ab Test non-reactive HIV or
RNA Test not detected, proceed.

If YES possibly living with HIV or
HIV Ag/Ab Test result reactive or indeterminate or
HIV RNA Test result detected or indeterminate, refer & report. → Refer & Report

- A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation.

(See Communication Example A)

3) ASSESS FOR POSSIBLE HIV AQUISITION WITHIN THE PAST 4 WEEKS

-Review Patient Intake Form #2b, 2c, 2d, and 2e

- Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.
- Could have acute HIV with negative screening HIV Ag/Ab result

-Consider calling the HIV Warmline (888) 448- 4911 for guidance if unclear

Time of last potential exposure:	**☐ ≤ 72 hours**	**☐ >72 hours to ≤ 4 weeks**		**☐ > 4 weeks**
Symptoms of possible acute HIV infection:	HIV Post-Exposure Prophylaxis (PEP) → PEP Protocol	**If NO symptoms:** -Eligible for up to a 30-day supply of PrEP -Order HIV RNA test now -Counsel on acute retroviral syndrome symptoms	**If YES to symptoms, refer** (Communication Example B) → Refer	

4) MEDICAL and MEDICATION HISTORY

- Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f

Kidney Disease
- Review Patient Intake form #3a

☐ **YES** → Refer

☐ **NO**

Bone Mineral Density
- Review Patient Intake form #3b

☐ **YES** → Refer

☐ **NO**

Hepatitis B Status
- Review Patient Intake Form #3c

- Tenofovir disoproxil fumarate 300mg/Emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabne 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare.
- People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.

Hepatitis B History → Refer

Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via VIIS

☐ **YES**

☐ **NO**
-Offer Hep B Vaccine series.
-Order Hep B Surface Antigen (see Table 1)

Pregnancy
- Review Patient Intake form #3d

Pregnancy and breastfeeding are not contraindications for PrEP. → Refer PRN

Medication
- Review Patient Intake form # 3e, 3f

Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density.
- Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage.
- Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.

5) LABORATORY RESULTS- See Appendix A and Table 1 for detailed information on labs	
-Hepatitis B Vaccine series or	□ completed
-Hepatitis B serologies resulted:	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Serum creatinine	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Lipid Panel (F/TAF only)	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Syphilis/Treponemal antibody	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
Are all required Baseline labs resulted (see Tables 2 and 3)?	□ **YES** □ **NO**

6) DETERMINE DURATION OF PrEP PRESCRIPTION

-Required BASELINE labs resulted? □ **YES** □ **NO**

-Was last possible exposure to HIV > 4 weeks ago (Patient intake Form #2e, Step 3 above)? □ **YES** □ **NO**

If **YES**,	If **NO**,
- Pharmacist may prescribe PrEP for up to a **90-day** supply	- Pharmacist may prescribe PrEP for up to a **30-day** supply - Patient needs to complete all required labs within 30 days by the next refill

APPENDIX A PrEP INITIATION 4) LABORATORY- Required Baseline Labs

Hepatitis B Status

-Confirm vaccination or order lab at intake only
-Counsel about the risk of Hep B flare if stopping PrEP if living with an unknown previous or current Hep B infection.
-Do not start PrEP if has current Hepatitis B infection
Please see: https://www.cdc.gov/hepatitis/HBV/PDFs/serologicChartv8.pdf for further information

Step 1:**Hepatitis B Vaccine** □ YES	•Confirmation of being fully vaccinated for hepatitis B via ALERT • Attempt to obtain past Hep B surface antibody result to confirm protection after completion of vaccine series or order to check Negative Hep B Surface
□ NO	•Lack of vaccination is not a contraindication for PrEP •Counsel on risk factors for Hepatitis B and recommend vaccination. OAR 855-019-0280.
Step 2: Hepatitis B surface antigen If no Hep B Vaccination, order Hepatitis B serologies □ non-reactive all OR only surface antiGEN and core antiBODY	□ reactive or indeterminate surface AntiGEN or core AntiBODY Refer and Report

[1]

Lipid Panel - Order lab at intake & every 6 months for patients on F/TAF.

Renal Function Status -Order lab at intake & annually thereafter If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start, order every 6 months

□ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ CrCl < 30 mL/min	□ CrCl is < 60 ml/min, do NOT use F/TDF • Consider F/TAF (Descovy®) in cis-gender men and TGW with risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min.
	□ CrCL is < 60 ml/min AND not a candidate for F/TAF (i.e., vaginal sex is an HIV exposure risk) * -or- □ CrCL is < 30 ml/min* Refer • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease

Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Report [1,2]
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Urinalysis test result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Report [1,2]
Hepatitis C Ab----Optional Recommended for: -MSM minimum annually -TGW minimum annually -PWID every 3 to 6 months □ reactive □ indeterminate □ non-reactive	□ reactive, positive, detected or indeterminate Pharmacist may proceed with prescribing PrEP Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[2]

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.

[2] County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Summary of Comments on Part 3 Oral Algorithms-Appendices-Table 1.pdf

Page: 3

Number: 1 Author: Caroline Juran Subject: Sticky Note Date: 8/1/2024 9:14:38 AM
What additional guidance is needed here regarding lipid panel?

Number: 2 Author: Caroline Juran Subject: Sticky Note Date: 8/1/2024 9:19:46 AM
Need to revise with VA links.

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

ALGORITHM B: PrEP CONTINUATION

1) HIV TEST

HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive

*HIV Ag/Ab must be RESULTED within 7 days prior to prescribing and dispensing

HIV RNA test resulted □ detected □ indeterminate □ not detected □ result pending □ none

May order HIV RNA as appropriate

If HIV Ag/Ab Test non-reactive or HIV RNA Test not detected, then proceed. ↓

If HIV Ag/Ab Test result reactive or indeterminate, or HIV RNA Test result detected or indeterminate, then refer & report. → Refer & Report

- A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation.

(See Communication Example A)

2) ASSESS FOR POSSIBLE ACUTE HIV INFECTION WITHIN THE PAST 4 WEEKS

Review Patient Intake form #2b, 2c, 2d, 2e

- Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.
- Could have acute HIV with negative screening HIV Ag/Ab result

-Consider calling the HIV Warmline (888) 448- 4911 for guidance

☐ **No symptoms** ↓

☐ **Symptoms**
-Eligible for PrEP for up to a 30-day supply.
-Order HIV RNA and repeat HIV Ag/Ab within 7 days of the next prescription
-Counsel on acute retroviral syndrome
-May refer → Refer PRN
(See Communication Example C)

3) MEDICAL and MEDICATION HISTORY

- Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f

Kidney Disease - Review Patient Intake form #3a		**Bone Mineral Density** - Review Patient Intake form #3b		**Hepatitis B Status** Review Patient Intake Form #3c, 3d -Counsel about the risk of Hep B flare if stopping PrEP if living with an unknown previous or current Hep B infection. • Tenofovir disoproxil fumarate 300mg/Emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabne 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. • People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.		**Pregnancy** Review Patient Intake form #3e	**Medication** Review Patient Intake form # 3f
☐ **YES** → Refer	☐ **NO** ↓	☐ **YES** → Refer	☐ **NO** ↓	Hepatitis B History ☐ **YES** → Refer	Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via ALERT IIS ☐ **YES** ↓ / ☐ **NO** -Offer Hep B Vaccine series.		Pregnancy and breastfeeding are not contraindications for PrEP. → Refer PRN ↓	Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use. ↓

4) LABORATORY RESULTS- See Appendix B and Table 1 for detailed information on labs

-See **Table 1: REQUIRED PrEP Labs**

-Serum creatinine □ resulted, ok for protocol □ resulted, needs referral □ no result yet

-Syphilis/Treponemal antibody □ resulted, ok for protocol □ resulted, needs referral □ no result yet

-Gonorrhea/Chlamydia □ resulted, ok for protocol □ resulted, needs referral □ no result yet

-Lipid Panel (F/TAF only) □ resulted, ok for protocol □ resulted, needs referral □ no result NO

-Required PrEP Continuation labs resulted ? □ YES ↓ □ No ↓

5) DETERMINE DURATION OF PrEP PRESCRIPTION

-Required BASELINE labs resulted? □ YES □ NO

If **YES**,
- Pharmacist may prescribe PrEP for up to a **90- day** supply

If **NO**,
- Pharmacist may prescribe PrEP for up to a **30-day** supply
- Patient needs to complete all required labs within 30 days by the next refill

APPENDIX B- PrEP CONTINUATION 4) LABORATORY- Required Baseline Labs [1]

Lipid Panel - Order lab at intake & every 6 months for patients on F/TAF.

Renal Function Status -Order lab at intake & annually thereafter If ≥ 50 yrs old or CrCl < 90 ml/min at PrEP start, order every 6 months

□ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ CrCl < 30 mL/min	□ CrCl is < 60 ml/min, do NOT use F/TDF • Consider F/TAF (Descovy®) in cis-gender men and TGW with risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min.
	□ CrCL is < 60 ml/min AND not a candidate for F/TAF (i.e., vaginal sex is an HIV exposure risk) * -or- □ CrCL is < 30 ml/min* -• Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease Refer

Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Reort [1,2]
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Report [1,2]
Hepatitis C Ab----Optional Recommended for: -MSM minimum annually -TGW minimum annually -PWID every 3 to 6 months □ reactive □ indeterminate □ non-reactive	□ reactive, positive, detected or indeterminate Pharmacist may proceed with prescribing PrEP Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA. [2]

[2] County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Number: 1 Author: Caroline Juran Subject: Sticky Note Date: 8/1/2024 9:18:55 AM
What additional guidance is needed here regarding lipid panel?

Number: 2 Author: Caroline Juran Subject: Sticky Note Date: 7/27/2024 12:59:09 PM
Need to update with VDH links.

Table 1: Oral PrEP Required Labs

Lab Data	BASELINE	In 1 month	Every 3 months	Every 6 months	Every 12 months	When stopping oral PrEP
HIV Ag/Ab 4th generation test	X Required within 7 days before the start	X If first prescription is for 30 days	X Within 7 days before each new prescription			X
HIV RNA[1]	X		X			X
Hepatitis B -Review vaccine Status and serologies	X					
Chlamydia Screening	X		MSM/TGW	X		MSM/TGW
Gonorrhea Screening	X		MSM/TGW	X		MSM/TGW
Syphilis Screening	X		MSM/TGW	X		MSM/TGW
SCr and calculated creatinine clearance	X			X If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start	X	
Hepatitis C Ab *	MSM/ TGW, PWID				MSM/ TGW, PWID	
HCG pregnancy test*	X					
Lipid Panel (F/TAF only)	X			X		

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1]HIV RNA is highly recommended at baseline, especially in certain situations, and if symptoms of possible acute retroviral syndrome develop while taking PrEP. It is recommended every 3 months as part of PrEP monitoring however; it is not a required test and should not be a barrier to prescribing PrEP.

HIV INJECTABLE Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway (CONFIDENTIAL-Protected Health Information)

ALGORITHM A: PrEP INITIATION (Review Relevant Questions on Patient In-Take Form)

1) PrEP INDICATION AND ELIGIBILITY
- Review Patient Intake Form #1a

- Review Patient Intake Form #1b or #1c **If NO to both, proceed.**	**If YES to either, refer.** → Refer

2a) CURRENT HIV STATUS
- Review Patient Intake Form #2a and HIV test results from Section 4.

If NO history of HIV, proceed.	**If YES** has history of HIV , refer. → Refer

HIV TEST
- HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive
*HIV Ag/Ab blood test must be RESULTED within 7 days prior to prescribing and dispensing
- HIV RNA test resulted: □ detected □ indeterminate □ not detected □ result pending □ none
May order HIV RNA at initial intake (preferred) and as appropriate thereafter

If NO current HIV or HIV Ag/Ab Test non-reactive HIV or RNA Test not detected, proceed.	**If YES** possibly living with HIV or HIV Ag/Ab Test result reactive or indeterminate or HIV RNA Test result detected or indeterminate, refer & report. • A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A) → Refer & Report

3) ASSESS FOR POSSIBLE HIV AQUISITION WITHIN THE PAST 4 WEEKS
-Review Patient Intake Form #2b, 2c, 2d, and 2e
• Acute HIV symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.
• Could have acute HIV with negative screening HIV Ag/Ab result
-Consider calling the HIV Warmline (888) 448- 4911 for guidance if unclear

Time of last potential exposure:	☐ **≤ 72 hours**	☐ **>72 hours to ≤ 4 weeks**		☐ **> 4 weeks**
Symptoms of possible acute HIV infection:	HIV Post-Exposure Prophylaxis (PEP) → PEP Protocol	**If NO symptoms:** -Eligible for up to a 30-day supply of PrEP -Order HIV RNA test now -Counsel on acute retroviral syndrome symptoms	**If YES to symptoms, refer** (Communication Example B) → Refer	

4) MEDICAL and MEDICATION HISTORY
- Review Patient Intake Form #3d, 3e and 3f

Pregnancy - Review Patient Intake form #3d	**Medication** - Review Patient Intake form # 3e, 3f
Pregnancy and breastfeeding are not contraindications for PrEP. → Refer PRN	Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.

5) LABORATORY RESULTS- See Appendix A for detailed information on labs
-Syphilis/Treponemal antibody □ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia □ resulted, ok for protocol □ resulted, needs referral □ no result yet
Are all required Baseline labs resulted (see Tables 2 and 3)? □ **YES** □ **NO**

6) DETERMINE DURATION OF PrEP PRESCRIPTION
-Required BASELINE labs resulted? □ **YES** □ **NO**
-Was last possible exposure to HIV > 4 weeks ago (Patient intake Form #2e, Step 3 above)? □ **YES** □ **NO**

If **YES**, - Pharmacist may start injectable PrEP initiation with subsequent injection at 1 month.	If **NO**, - Pharmacist may prescribe PrEP for up to a **30-day** supply - Patient needs to complete all required labs within 30 days by the next refill

APPENDIX A- PrEP INITIATION 4) LABORATORY- Required Baseline Labs	
Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Report [1,2]
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Urinalysis test result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.

[2] County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

ALGORITHM B: INJECTABLE PrEP CONTINUATION

1) HIV TEST

HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive

*HIV Ag/Ab must be RESULTED within 7 days prior to prescribing and dispensing

HIV RNA test resulted □ detected □ indeterminate □ not detected □ result pending □ none

May order HIV RNA as appropriate

HIV Ag/Ab Test non-reactive HIV RNA Test not detected	HIV Ag/Ab Test result reactive or indeterminate HIV RNA Test result detected or indeterminate • A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A)

Refer & Report

2) ASSESS FOR POSSIBLE ACUTE HIV INFECTION WITHIN THE PAST 4 WEEKS

Review Patient Intake form #2b, 2c, 2d, 2e

• Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.

• Could have acute HIV with negative screening HIV Ag/Ab result

-Consider calling the HIV Warmline (888) 448- 4911 for guidance

□ **No symptoms**	□ **Symptoms** -Eligible for PrEP for up to a 30-day supply. -Order HIV RNA and repeat HIV Ag/Ab within 7 days of the next prescription -Counsel on acute retroviral syndrome -May refer (See Communication Example C)

Refer PRN

3) MEDICAL and MEDICATION HISTORY

- Review Patient Intake Form #3d, 3e, and 3f

Pregnancy Review Patient Intake form #3e	**Medication** Review Patient Intake form # 3f
Pregnancy and breastfeeding are not contraindications for PrEP.	

Refer PRN

4) LABORATORY RESULTS- See Appendix B for detailed information on labs

-See **Table 1: REQUIRED PrEP Labs**

-Syphilis/Treponemal antibody □ resulted, ok for protocol □ resulted, needs referral □ no result yet

-Gonorrhea/Chlamydia □ resulted, ok for protocol □ resulted, needs referral □ no result yet

-Required PrEP Continuation labs resulted ? □ YES □ NO

5) DETERMINE DURATION OF PrEP PRESCRIPTION

-Required BASELINE labs resulted? □ YES □ NO

If **YES**, - Pharmacist may start injectable PrEP initiation with subsequent injection at 1 month.	If **NO**, - Pharmacist may prescribe PrEP for up to a **30-day** supply - Patient needs to complete all required labs within 30 days by the next refill

Summary of Comments on Part 4 Injectable algorithms - appendices - table 2 DRAFT.pdf

Page: 3

Number: 1 Author: Caroline Juran Subject: Sticky Note Date: 8/1/2024 10:21:37 AM
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APPENDIX B- PrEP CONTINUATION 4) LABORATORY- Required Baseline Labs	
Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Reort [1,2]
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.

[2] County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

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Table 2: INJECTABLE PrEP
Required Labs

Lab Data	BASELINE	In 1 month	Every 2 months	Every 4 months	Every 6 months	Every 12 months	When stopping CAB
HIV Ag/Ab 4th generation test	X Required within 7 days before the start	X	X				X
HIV RNA[1]	X	X	X				X
Chlamydia Screening	X			MSM/TGW	Heterosexually active women and men only	X	MSM/TGW
Gonorrhea Screening	X			MSM/TGW	Heterosexually active women and men only	X	MSM/TGW
Syphilis Screening	X			MSM/TGW	Heterosexually active women and men only	X	MSM/TGW

MSM = men who have sex with men; TGW = transgender women; X = all PrEP patients

[1]HIV RNA is highly recommended at baseline, especially in certain situations, and if symptoms of possible acute HIV develop while taking PrEP. It is recommended every 3 months as part of PrEP monitoring; however, it is not a required test and should not be a barrier to prescribing PrEP.

HIV PrEP RECOMMENDED REGIMENS:

Emtricitabine/Tenofovir DF **(F/TDF; Truvada®):**	**Emtricitabine/Tenofovir Alafenamide** **(F/TAF; Descovy®):**	**Cabotegravir** **(CAB; Apretude®):**
Dose: 200/300 mg once daily	**Dose:** 200/25 mg once daily	**Dose:** 600 mg/3 ml injected intramuscularly (ventrogluteal via Z-track injection technique method preferred) now, then repeat at 1 month, then every 2 months thereafter *
FDA-Approved for: all HIV exposure risk indications	**FDA-Approved for**: use by men and transgender women only	**FDA-Approved for**: all HIV risk exposure risk indications, except if injection substance use is the only HIV risk
Preferred if: pregnancy/breastfeeding, vaginal exposure risks, substance use risks	**Not recommended for**: HIV risk via vaginal sex or if injection substance use is the only HIV risk	**Preferred if**: renal insufficiency, risk of renal insufficiency (e.g., uncontrolled hypertension or uncontrolled blood glucose), and/or bone density concerns for cisgender women
Not preferred if: concomitant nephrotoxic medications, or risks for/known renal insufficiency or osteopenia/osteoporosis	**Preferred if**: renal insufficiency, risk of renal insufficiency (e.g. uncontrolled hypertension or uncontrolled blood glucose), and/or bone density concerns for men or transgender women ONLY	**Cost:** no generic, may require prior authorization, patient may be eligible for manufacturer assistance program -or- copay card
Cost: available as a generic, lower-cost option	**Cost:** no generic, may require prior authorization, patient may be eligible for manufacturer assistance program -or- copay card	

*Apretude® resources:

Dosing and Administration Guide - https://apretudehcp.com/resources

Video for Preparing and Administering Apretude® - https://apretudehcp.com/resources

HIV PrEP COMMUNICATION EXAMPLES:

Example A Reactive, positive, indeterminate, -or- detected result for: HIV Ag/Ab -or- HIV RNA	Your HIV test is [reactive, positive, -or- indeterminate]. This is not a diagnosis of HIV infection, but you do need further testing to confirm if this is a true result. Do you want to go to your Primary Care Provider, urgent care clinic, local health department, or an HIV specialist for further evaluation? It is important that you STOP taking PrEP now as it is an incomplete treatment for HIV and can lead to drug resistance in the future. Until you know your HIV test results/status, please use condoms during sex and/or use sterile injection equipment, not share with others. You may start PrEP again with a PrEP provider if it is determined that this was a false result and you do NOT have an HIV infection. I can help you make an appointment for further evaluation.
Example B Concerns for acute HIV infection NOT on PrEP	Based on the [symptoms AND last possible exposure to HIV] that you reported, there is a chance that this is a sign of a recent HIV infection. These symptoms are also general and could be related to the flu, COVID19, or another viral illness. I would like to recheck the regular HIV screening test and add another test that looks directly for the virus before we can START PrEP. These tests should be done at 2 to 4 weeks after your possible exposure. I cannot prescribe PrEP today, but we can get you started once we have these other lab results. You should also consider if you want to see your PCP, PrEP provider, or urgent care clinic for evaluation, possible other viral illness testing, and follow-up of your symptoms. They could also start you on PrEP if they decide it's appropriate to start now. Please let me know if you want a referral and/or would like me to refer you to a community organization[1] that can help link you to care and evaluation.
Example C Concerns for acute HIV infection ON PrEP	Based on the [symptoms AND last possible exposure to HIV] that you reported, there is a chance that this is a sign of recent HIV infection. These symptoms are also very general and could be related to the flu, COVID19, or another viral illness. I would like to screen for HIV and add another test that looks directly for the virus. These should be done at 2 to 4 weeks after your possible exposure. While we wait for those lab results, I can prescribe up to a 30-day supply for this refill. You should also consider if you want to see your PCP, PrEP provider, or urgent care clinic for evaluation, possible other viral illness testing, and follow-up of your symptoms. Please let me know if you want a referral and/or would like me to refer you to a community organization[1] that can help link you to care and evaluation.
Example D Reactive, positive, -or- indeterminate result for: Gonorrhea -or- Chlamydia -or- Syphilis	There were [reactive, positive, -or- indeterminate] results for [gonorrhea, chlamydia, and/or syphilis]. This is not a diagnosis of [gonorrhea, chlamydia, and/or syphilis], but you need further evaluation and possibly testing to confirm if this is a true result. Please keep taking your PrEP, do not stop PrEP. Please use condoms during sexual activity until you have been evaluated and/or treated by a clinical provider. I can help you make an appointment for further evaluation/treatment to a Primary Care Provider, urgent care clinic, or local health department.

Commented [CJ1]: Do we have organizations we can insert or should this reference be removed?

Commented [CJ2]: Do we have organizations we can insert or should this reference be removed?

PrEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Note: Pharmacist may not prescribe and must refer patient if HIV test reactive or indeterminate

Rx

□ **Truvada® (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**
- □ Take one tablet by mouth daily for 30 days, #30, 0 refills
- □ Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

□ **Descovy® (emtricitabine/tenofovir alafenamide) 200/25mg tablets**
- □ Take one tablet by mouth daily for 30 days, #30, 0 refills
- □ Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

□ **Apretude® (cabotegravir (CAB;):**
- □ **Pharmacist to Administer:** 600 mg/3 ml injected intramuscularly (ventrogluteal via Z-track injection technique method preferred) now, then repeat at 1 month, then every 2 months thereafter

Written Date: _____

Expiration Date: (This prescription expires 90 days from the written date) _____

Pharmacist Name: _____ Pharmacist Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

□ Patient Referred

□ Hepatitis B Vaccination administered:

Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes: _____

_____

_____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Provider Notification
Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____
Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH/PharmD. This regimen was filled/administered on _____/_____/_____ (Date) for a _____ day supply and follow-up HIV testing is recommended in approximately _____ days _____/_____/_____ (Date)

This regimen consists of the following (check one):

- □ Truvada® (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily
- □ Descovy® (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - Take one tablet by mouth daily
- □ Apretude® (cabotegravir)
  - 600 mg/3 ml injected intramuscularly (ventrogluteal via Z-track injection technique method preferred) now, then repeat at 1 month, then every 2 months thereafter

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• HIV RNA:	___/____/_____	□ *detected* □ *indeterminate* □ not detected	□ *Yes*
• Hepatitis B surface antigen:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
• Hepatitis C antibody:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
• Syphilis/Treponemal antibody:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• Gonorrhea/Chlamydia:	____/____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ non-reactive	Pharyngeal test result: □ *reactive* □ *indeterminate* □ non-reactive	Rectal test result: □ *reactive* □ *indeterminate* □ non-reactive	
• Renal function (CrCl):	____/____/_____	_____ mL/min	□ *Yes*
□ CrCl >60mL/min	□ CrCl 30mL/min - 60mL/min	□ *CrCl <30mL/min*	
• HCG:	____/____/_____	□ *positive* □ *indeterminate* □ negative	□ *Yes*
• Lipid Panel (Descovy®):	____/____/_____	□ within normal limits □ abnormal	□ *Yes*

- Signs/symptoms of acute retroviral syndrome (□ *Present* □ Not Present) AND potential HIV exposure in the last 4 weeks (□ *Yes*□ *No)* and not on PrEP (□ *Yes* □ No).
- Exposure risk less than 72 hours ago? □ *Yes* □ No □ *Yes*

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- PrEP is prescribed for up to a 90 day supply for each prescription to align with appropriate lab monitoring guidelines.
- Truvada® is not recommended for CrCl less than 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 oral option. Apretude® is not recommended for CrCl less than 15 mL/min so may be best consideration for altered renal function.
- Truvada® and Descovy® are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada® is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacist monitoring of HIV PrEP and transition of care:

- The pharmacist prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and other baseline and treatment monitoring lab results as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

VIRGINIA BOARD OF PHARMACY

Preventive Care

HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol

Consistent with the manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
- Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-9)
- Utilize the standardized PrEP Provider Fax (pg.10)

PHARMACIST EDUCATION AND TRAINING

- Prior to issuing a prescription to initiate treatment with, dispensing, or administering controlled substances for post-exposure prophylaxis under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.

*****Note: A pharmacy may create and use an electronic format for the PrEP Patient Intake Form, PrEP Assessment and Treatment Care Pathway, and PrEP Provider Fax if the information is identical to the forms included in this protocol.

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Do you answer yes to any of the following? □ yes □ no

1. Do you sexually partner with men, women, transgender, or non-binary people?
2. 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 __/__/__ last sex without a condom
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. Do you have vaginal sex? • Receptive- you have a vagina and you use it for vaginal sex • Insertive- you have a penis and you use it for vaginal sex
5. Do you have anal sex? • Receptive- someone uses their penis to perform anal sex on you • Insertive- you use your penis to perform anal sex on someone else
6. Do you inject drugs?
7. Are you in a relationship with an HIV-positive partner?
8. Do you exchange sex for money or goods? (includes paying for sex)
9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex?

Medical History: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	□ yes □ no
2. Do you see a (healthcare provider) for management of Hepatitis B?	□ yes □ no
3. Have you ever received an immunization for Hepatitis B? If yes, when: • If no, would you like a Hepatitis B immunization today? □ yes □ no	□ yes □ no Date of vaccine __/__/__
4. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
6. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ no

Testing and Treatment:

1. I understand that I must get an 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 may be able to have tests performed at the pharmacy. • I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks. ○ I brought my labs in today □ Yes □ No • I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.	□ Yes □ No
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. • I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.	□ Yes □ No
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.	□ Yes □ No

Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.

Please list any questions you have for the pharmacy staff:

Patient Signature: _____ **Date:** _____

Name_____ Date of Birth_____ Age_____ Today's Date_____

Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

Risk Factor:	Notes and considerations
1. Sexual partners	• MSM activity is highest risk for HIV. • Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.
2. Estimated condom use _____% of the time __/__/__ last sex without a condom	• Condomless sex greatly increases risk of HIV and STIs. • For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP). • Condomless sex within last 14 days, repeat HIV test in one month.
3. Oral sex	• Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals. • STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.
4. Vaginal sex	• Receptive vaginal sex can be high risk for HIV. • Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.
5. Anal sex	• Receptive anal sex has the most risk of HIV of any sex act. • Insertive anal sex has high risk for HIV. • STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.
6. Injection drug use	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
7. HIV-positive partner	• People living with HIV who have undetectable viral loads will not transmit HIV. • For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.
8. Exchanging sex for money or goods	• People who buy or sell sex are at high risk for HIV.
9. Popper and/or methamphetamine use	• Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV. • Recommend adequate lubrication in persons who use poppers for sex.

1. Is one or More Risk Factor Present: □ **yes** □ ***no***

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

Testing:

The pharmacist must verify appropriate labs are complete. Pharmacist may order any necessary labs that are not complete. *Italics* below indicate need for referral.

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen) test: *Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing.* NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing.	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
• Syphilis/Treponemal antibody: *Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing.*	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
• Hepatitis B surface antigen: *Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician.*	_____/_____/_____	□ *positive* □ negative	□ *Yes*
• Hepatitis C surface antigen: *Positive surface antigen indicates either acute or chronic Hepatitis C and PrEP should be referred to county health or a specialist physician.*	_____/_____/_____	□ *positive* □ negative	□ *Yes*
• Pregnancy: *Positive result indicates pregnancy and PrEP should be referred to county health or a specialist physician.*	_____/_____/_____	□ *positive* □ negative	□ *Yes*
• Gonorrhea/Chlamydia: Urinalysis result: □ *reactive* □ *indeterminate* □ negative; Pharyngeal test result: □ *reactive* □ *indeterminate* □ negative; Rectal test result: □ *reactive* □ *indeterminate* □ negative. *All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment.*	_____/_____/_____		□ *Yes*
• Renal function (CrCl): SCr _____mg/dL	_____/_____/_____	_____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min*	□ *Yes*
CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Emtricitabine and tenofovir alafenamide indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Emtricitabine and tenofovir alafenamide.*			
• <u>ALT/AST:</u> <u>Baseline + at 4-6 weeks recommended.</u>	_____/_____/_____	ALT_____u/L AST_____u/L	
• Signs/symptoms of STI not otherwise specified:	_____/_____/_____	□ *Present*	□ *Yes*
• Condomless sex in past two weeks	_____/_____/_____	□ *Yes*	□ *Yes*

2. Is HIV ab/ag 4th gen test complete? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes <u>and</u> non-reactive: Proceed to question #3
- *If yes <u>and</u> reactive or indeterminate: RPH many NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

3. Are all required labs complete? □ **yes** □ ***no***

- If yes, pharmacist may prescribe PrEP and next labs due in 90 days. Proceed to next section: Medical History.
- If no, pharmacist may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

Sample language for reactive or indeterminate tests:

Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.

Sample language for reactive (indeterminate) STI tests:

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

Medical History: The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

Medical history factor	**Notes and considerations**
	REFERRAL CONDITIONS
1. Positive HIV test *Needs Referral:* □ *yes* □ no	• A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. • Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.
2. Presence of Hepatitis B infection *Needs Referral:* □ *yes* □ no	• Emtricitabine and tenofovir disoproxil fumarate and Emtricitabine and tenofovir alafenamide are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare. • People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.
3. Impaired kidney function (<30mL/min) *Needs Referral:* □ *yes* □ no	• Emtricitabine and tenofovir disoproxil fumarate is approved for patients with a CrCl >60mL/min. • Consider Emtricitabine and tenofovir alafenamide in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.
4. Other medications *Needs Referral:* □ *yes* □ no	• Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density. • For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Emtricitabine and tenofovir alafenamide over Emtricitabine and tenofovir disoproxil fumarate.
	CONSIDERATIONS
5. NSAID use Precaution- Counseled on limiting use: □ yes □ no	• Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
6. Hepatitis B vaccinated If not, would the patient like to be vaccinated? □ yes □ no	• Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP. • Counsel on risk factors for Hepatitis B and recommend vaccination. • If patient would like to be vaccinated, proceed according to the Statewide Vaccine Protocol or 54.1-3408(I) of the Code of Virginia.
7. Pregnant or breastfeeding	• Pregnancy and breastfeeding are not contraindications for PrEP. • Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence.

- Emtricitabine and tenofovir disoproxil fumarate is preferred due to better data in these populations.

4. Are one or More Referral Condition(s) Present? □ *yes* □ no

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to initiate treatment in accordance with this protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*
- If no, HIV PrEP is recommended and pharmacists are authorized to initiate treatment and dispense PrEP in accordance with this protocol. Proceed to next sections: Regimen Selection and Prescription.

Regimen Selection:

Considerations*	Preferred regimen
Cis-gender male or male to female transgender woman. • Both Emtricitabine and tenofovir disoproxil fumarate and Emtricitabine and tenofovir alafenamide are FDA approved in these populations. May prescribe based on patient preference.	May choose Emtricitabine and tenofovir disoproxil fumarate or Emtricitabine and tenofovir alafenamide
Cis-gender female or female to male transgender man. • Only Emtricitabine and tenofovir disoproxil fumarate is FDA approved in these populations. • If patient has low bone mineral density or renal function that would preclude Emtricitabine and tenofovir disoproxil fumarate use, but has risk factors for HIV, refer the patient to a specialist for PrEP management.	Emtricitabine and tenofovir disoproxil fumarate
NSAID use • If patient is male or a male to female transgender woman, consider Emtricitabine and tenofovir alafenamide	Emtricitabine and tenofovir alafenamide
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. • If patient is male or male to female transgender woman, consider Emtricitabine and tenofovir alafenamide	Emtricitabine and tenofovir alafenamide
Patient has decreased bone mineral density or on medications that affect bone mineral density. • If patient is male or male to female transgender woman, consider Emtricitabine and tenofovir alafenamide.	Emtricitabine and tenofovir alafenamide
Patient is pregnant or breastfeeding • Emtricitabine and tenofovir alafenamide has not been studied in these populations. Emtricitabine and tenofovir disoproxil fumarate is approved in these populations.	Emtricitabine and tenofovir disoproxil fumarate

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/PEP and alternative dosing regimens (i.e. PrEP on demand, PrEP 2-1-1)
- Individualized strategies for optimum adherence
- Behaviorally based adherence improvement strategies, such as pairing medication with established part of daily routine, pill boxes, reminder for daily dose
- Signs/symptoms of acute HIV infection and recommended actions
- Appropriate counseling regarding on-going risk for HIV and other STI acquisition
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care.
- The importance and requirement of testing for HIV, renal function, hepatitis B, hepatitis C and sexually transmitted diseases

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Pharmacy Board Regulation 18VAC110-21-46.

Referrals to primary care provider:

- (note 1) If a patient tests positive for HIV infection or has signs or symptoms of acute HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 2) If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 3) If a patient test has abnormal renal values and/or signs of acute renal injury, refer for urgent evaluation.

- (note 4) If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 5) If a patient tests positive for Hepatitis C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 6) If a female patient becomes pregnant while on PrEP, refer for care.

Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been initiated treatment for HIV Pre-Exposure Prophylaxis (PrEP) by _____. This regimen was filled on _____/_____/_____ (Date) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

This regimen consists of the following (check one):

- ☐ Emtricitabine/tenofovir disoproxil fumarate 200/300mg; One tablet by mouth daily for 90 days
- ☐ Emtricitabine/tenofovir alafenamide 200/25mg tablets; Take one tablet by mouth daily for 90 days

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
• Syphilis/Treponemal antibody:	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
• Hepatitis B surface antigen:	_____/_____/_____	□ *positive* □ negative	□ *Yes*
• Gonorrhea/Chlamydia:	_____/_____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ negative	Pharyngeal test result: □ *reactive* □ *indeterminate* □ negative	Rectal test result: □ *reactive* □ *indeterminate* □ negative	
• Renal function (CrCl): □ CrCl >60mL/min	_____/_____/_____ □ CrCl 30mL/min - 60mL/min	_____ mL/min □ *CrCl <30mL/min*	□ *Yes*
• Signs/symptoms of STI not otherwise specified:	_____/_____/_____	□ *present*	□ *Yes*
• Condomless sex in past two weeks	_____/_____/_____	□ *yes*	□ *Yes*

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- Emtricitabine and tenofovir disoproxil fumarate is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Emtricitabine and tenofovir alafenamide may be a better option.
- Emtricitabine and tenofovir disoproxil fumarate and Emtricitabine and tenofovir alafenamide are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Emtricitabine and tenofovir disoproxil fumarate.
- Emtricitabine and tenofovir disoproxil fumarate is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacy monitoring of HIV PrEP:

- The pharmacy initiating treatment and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a Pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a Pharmacist licensed and located in Oregon may prescribe pre-exposure prophylaxis (PrEP) drug regimen.
- The prescribing Pharmacist is responsible for all laboratory tests ordered, resulted and for reporting as required.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
- Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-10)
- Utilize the standardized PrEP Prescription Template *optional* (pg. 11)
- Utilize the standardized PrEP Provider Fax (pg.12)

PHARMACIST TRAINING/EDUCATION:

- Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

REFERENCES

- Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2021 Update. Accessed February 14, 2023. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- PrEP | HIV Basics | HIV/AIDS | CDC. Published July 11, 2022. Accessed February 14, 2023. https://www.cdc.gov/hiv/basics/prep.html

Patient Information

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Name on Documents_____ Name _____

Sex Assigned at Birth (circle) M / F / Intersex Gender:_____ Are you transgender? (circle) Y/N/_____

Pronouns: She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, _____

Street Address _____

Phone ( ) _____ Email Address _____

Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____

Do you have health insurance? Yes / No Insurance Provider Name _____

Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if ORAL PrEP may benefit you, be safe for you, and what lab screenings are recommended before starting or continuing on PrEP.

Section 1: Reason for HIV Pre-Exposure Prophylaxis (PrEP) and Eligibility

You do not have to indicate reason; please review and answer the question at the bottom of this box: ▪ I want to start PrEP ▪ I want to keep taking PrEP ▪ I had sex in the past 6 months ▪ I do not always use condoms when I have sex ▪ I had gonorrhea, chlamydia, or syphilis in the past 6 months ▪ I have had sex with someone living with HIV ▪ I have had sex with one or more partners and did not know their HIV status ▪ I injected drugs in the past 6 months ▪ I shared injection equipment (any)	
1a. Is your answer YES to one of the above statements?	☐ Yes ☐ No ☐ Unsure
1b. Are you UNDER 13 years old?	☐ Yes ☐ No
1c. Do you weigh LESS than 77 pounds (35 kg)?	☐ Yes ☐ No

Section 2: HIV Testing, PrEP, and HIV Post-Exposure Prophylaxis (PEP) Histories; Acute HIV Symptom Review

2a. Have you ever had a positive, reactive, detected, or indeterminate test for HIV?	☐ Yes ☐ No
2b. Have you had any of the following in the last 4 weeks: fever, feeling very tired, muscle or joint aches or pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms?	☐ Yes ☐ No
2c. Are you taking PrEP now or in the past? • If now, which PrEP medicine?_____. Skip question 2d and continue to question 2e. • If in the past, what was your reason for stopping? _____	☐ Yes ☐ No
2d. Are you currently finishing a course of PEP after a possible HIV exposure?	☐ Yes ☐ No
2e. When was your last sex, injection drug use, or other possible exposure to HIV?	☐ Less than 72 hours (3 days) ago ☐ More than 72 hours (3 days), but less than 4 weeks ago ☐ More than 4 weeks ago

Section 3: Brief Medical History to Determine Which PrEP Medication May Be Best for You

3a. Have you been told you have kidney disease (e.g. kidney failure, poor kidney function)?	☐ Yes ☐ No
3b. Have you been told you have a bone disease (e.g. osteoporosis, osteopenia, low bone mineral density, etc.?	☐ Yes ☐ No
3c. Have you ever had Hepatitis B infection? --Have you been vaccinated for Hepatitis B? If Yes, Date(s): #1 ___/___/___ #2 ___/___/___ #3 ___/___/___ If No, do you want to start the Hepatitis B vaccination today?	☐ Yes ☐ No ☐ Unsure ☐ Yes ☐ No ☐ Unsure ☐ Yes ☐ No
3d. Are you pregnant, breastfeeding or planning to become pregnant? --If no, what are you using to prevent pregnancy? _____	☐ Yes ☐ No ☐ Does not apply

3e. Please list the names of other prescriptions (medicines), over-the-counter, herbal, or supplement products that you take so that the pharmacist can check for drug interactions with PrEP. Please note doses and use of any non-steroidal anti-inflammatory medicines (NSAIDS): ibuprofen (Advil/Motrin), naproxen (Aleve), meloxicam, celecoxib, diclofenac and any estradiol containing gender-affirming hormone medicines:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

3f. Please list any other questions or medical concerns you would like to the pharmacist to know:

Section 4: What to Expect on Oral PrEP

The biggest risks of PrEP are:

1. Starting PrEP when you do not know that HIV is already there **and**
2. Staying on PrEP after contracting HIV. PrEP medicines are also used to *treat* HIV, but it's not full treatment. If someone starts the PrEP medicine while living with HIV -*or*- contracts HIV while taking PrEP, then the medicines in PrEP might not work for treatment.

Please be aware that:

1. HIV testing must be done every 3 months while taking PrEP. The pharmacist must document a negative HIV test result within the last 7 days before prescribing PrEP. If that is the only lab result available, then the pharmacist can only prescribe up to a 30-day supply until other labs are done. When all needed lab results are given to the pharmacist, then the pharmacist may be able to prescribe up to a 90-day supply each time.
2. Screenings for gonorrhea, chlamydia, and syphilis must be done at least every 6 months while taking PrEP. Undiagnosed sexually transmitted infections (STIs) may increase the risk of contracting HIV, even while you are taking PrEP, and PrEP does NOT protect against other STIs. Screening for gonorrhea and chlamydia must be done at each possible site of exposure via urine (genital) and swab (throat and rectum) collections.
3. Missing doses of PrEP increases the risk of contracting HIV. PrEP works the best when taken AS DIRECTED by the pharmacist. Please talk to your pharmacist if you are having trouble taking your PrEP and/or getting labs done.

Patient Signature:_____ Date:_____

ALGORITHM A: PrEP INITIATION

1) PrEP INDICATION AND ELIGIBILITY
- Review Patient Intake Form Questions #1a, 1b & 1c

Is the patient < 13 years old[i] Is the Patient < 77 lbs[ii] ☐ **NO**	☐ **YES** → Refer

2a) CURRENT HIV STATUS
- Review Patient Intake Form #2a and HIV test results

☐ **NO** history of HIV	☐ **YES** has history of HIV → Refer

2b) HIV TEST
- HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive

*HIV Ag/Ab blood test must be RESULTED within 7 days prior to prescribing and dispensing

- HIV RNA test resulted: □ detected □ indeterminate □ not detected □ result pending □ none

May order HIV RNA at initial intake (preferred) and as appropriate thereafter

☐ **NO** current HIV HIV Ag/Ab Test non-reactive HIV RNA Test not detected	☐ **YES** possibly living with HIV HIV Ag/Ab Test result reactive or indeterminate HIV RNA Test result detected or indeterminate → Refer and Report •A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A)

3) ASSESS FOR POSSIBLE HIV AQUISITION WITHIN THE PAST 4 WEEKS
-Review Patient Intake Form #2b, 2c, 2d, and 2e
•Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.
•Could have acute HIV with negative screening HIV Ag/Ab result
-Consider calling the HIV Warmline (888) 448- 4911 for guidance if unclear

Time of last potential exposure:	☐ **≤ 72 hours**	☐ **>72 hours to ≤ 4 weeks**		☐ **> 4 weeks**
Symptoms of possible acute HIV infection:	HIV Post-Exposure Prophylaxis (PEP) → PEP Protocol	☐ **NO symptoms** -Eligible for up to a 30-day supply of PrEP -Order HIV RNA test now -Counsel on acute retroviral syndrome symptoms	☐ **YES symptoms** (Communication Example B) → Refer	

4) MEDICAL and MEDICATION HISTORY
- Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f

Kidney Disease - Review Patient Intake form #3a		**Bone Mineral Density** - Review Patient Intake form #3b		**Hepatitis B Status** - Review Patient Intake Form #3c •Tenofovir disoproxil fumarate 300mg/Emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabne 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. • People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.		**Pregnancy** - Review Patient Intake form #3d	**Medication** - Review Patient Intake form # 3e, 3f
☐ **YES** → Refer	☐ **NO**	☐ **YES** → Refer	☐ **NO**	Hepatitis B History → Refer	Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via ALERT IIS ☐ **YES**	☐ **NO** -Offer Hep B Vaccine series. -Order Hep B Surface Antigen (see Table 1)	Pregnancy and breastfeeding are not contraindications for PrEP. → Refer PRN	Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.

5) LABORATORY RESULTS- See Appendix A for detailed information on labs	
-Hepatitis B Vaccine series	□ completed
or	
-Hepatitis B serologies resulted:	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Serum creatinine	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Syphilis/Treponemal antibody	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
Are all required Baseline labs resulted (Tables 2 and 3 below)?	□ **YES** □ **NO**

6) DETERMINE DURATION OF PrEP PRESCRIPTION	
-Required BASELINE labs resulted?	□ **YES** □ **NO**
-Was last possible exposure to HIV > 4 weeks ago (Patient intake Form #2e, Step 3 above)?	□ **YES** □ **NO**
If **YES**, - RPH may prescribe PrEP for up to a **90- day** supply	If **NO**, - RPH may prescribe PrEP for up to a **30-day** supply - Patient needs to complete all required labs within 30 days by the next refill

ALGORITHM B: PrEP CONTINUATION

1) HIV TEST

HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive

*HIV Ag/Ab must be RESULTED within 7 days prior to prescribing and dispensing

HIV RNA test resulted □ detected □ indeterminate □ not detected □ result pending □ none

May order HIV RNA as appropriate

HIV Ag/Ab Test non-reactive HIV RNA Test not detected	HIV Ag/Ab Test result reactive or indeterminate HIV RNA Test result detected or indeterminate •A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A) Refer & Report

2) ASSESS FOR POSSIBLE ACUTE HIV INFECTION WITHIN THE PAST 4 WEEKS

Review Patient Intake form #2b, 2c, 2d, 2e

•Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.

•Could have acute HIV with negative screening HIV Ag/Ab result

-Consider calling the HIV Warmline (888) 448- 4911 for guidance

☐ **No symptoms**	☐ **Symptoms** -Eligible for PrEP for up to a 30-day supply. -Order HIV RNA and repeat HIV Ag/Ab within 7 days of the next prescription -Counsel on acute retroviral syndrome -May refer (See Communication Example C) Refer PRN

3) MEDICAL and MEDICATION HISTORY

- Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f

Kidney Disease - Review Patient Intake form #3a		**Bone Mineral Density** - Review Patient Intake form #3b		**Hepatitis B Status** Review Patient Intake Form #3c, 3d -Counsel about the risk of Hep B flare if stopping PrEP if living with an unknown previous or current Hep B infection. •Tenofovir disoproxil fumarate 300mg/Emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabne 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. • People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.		**Pregnancy** Review Patient Intake form #3e	**Medication** Review Patient Intake form # 3f
☐ **YES** Refer	☐ **NO**	☐ **YES** Refer	☐ **NO**	Hepatitis B History ☐ **YES** Refer	Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via ALERT IIS ☐ **YES** / ☐ **NO** -Offer Hep B Vaccine series.		Pregnancy and breastfeeding are not contraindications for PrEP. Refer PRN	Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.

4) LABORATORY RESULTS- See Appendix B for detailed information on labs

-See **Table 1: REQUIRED PrEP Labs**

-Serum creatinine □ resulted, ok for protocol □ resulted, needs referral □ no result yet

-Syphilis/Treponemal antibody □ resulted, ok for protocol □ resulted, needs referral □ no result yet

-Gonorrhea/Chlamydia □ resulted, ok for protocol □ resulted, needs referral □ no result yet

- Required PrEP Continuation labs resulted ? □ YES □ NO

5) DETERMINE DURATION OF PrEP PRESCRIPTION

-Required BASELINE labs resulted? □ YES □ NO

If **YES**, - RPH may prescribe PrEP for up to a **90- day** supply	If **NO**, - RPH may prescribe PrEP for up to a **30-day** supply - Patient needs to complete all required labs within 30 days by the next refill

RECOMMENDED REGIMENS:

Note: There are other FDA-Approved medications available and may be other dosing strategies for PrEP. Daily dosing of emtricitabine / tenofovir DF (Truvada®) and emtricitabine / tenofovir alafenamide (Descovy®) are the only regimens permitted for pharmacist prescribing at this time.	
Emtricitabine/Tenofovir DF (F/TDF; Truvada®): **Dose:** 200/300 mg once daily **FDA-Approved for**: all HIV exposure risk indications **Preferred if**: pregnancy/breastfeeding, vaginal exposure risks, substance use risks **Not preferred if:** concomitant nephrotoxic medications, or risks for/known renal insufficiency or osteopenia/osteoporosis **Cost:** available as a generic, lower-cost option	**Emtricitabine/Tenofovir alafenamide(F/TAF; Descovy®):** **Dose:** 200/25 mg once daily **FDA-Approved for**: use by men and transgender women only **Not recommended for**: HIV risk via vaginal sex or if injection substance use is the only HIV risk **Preferred if**: renal insufficiency, risk of renal insufficiency (e.g. uncontrolled hypertension or uncontrolled blood glucose), and/or bone density concerns for men or transgender women ONLY **Cost:** no generic, may require prior authorization, patient may be eligible for manufacturer assistance program -or- copay card

COMMUNICATION EXAMPLES:

Example A Reactive, positive, indeterminate, -or- detected result for: HIV Ag/Ab -or- HIV RNA	Your HIV test is [reactive, positive, -or- indeterminate]. This is not a diagnosis of HIV infection, but you do need further testing to confirm if this is a true result. Do you want to go to your Primary Care Provider, urgent care clinic, county health department, or an HIV specialist for further evaluation? It is important that you STOP taking PrEP now as it is an incomplete treatment for HIV and can lead to drug resistance in the future. Until you know your HIV test results/status, please use condoms during sex and/or use sterile injection equipment, not share with others. You may start PrEP again with a PrEP provider if it is determined that this was a false result and you do NOT have an HIV infection. I can help you make an appointment for further evaluation.
Example B Concerns for acute HIV infection NOT on PrEP	Based on the [symptoms AND last possible exposure to HIV] that you reported, there is a chance that this is a sign of a recent HIV infection. These symptoms are also general and could be related to the flu, COVID19, or another viral illness. I would like to recheck the regular HIV screening test and add another test that looks directly for the virus before we can START PrEP. These tests should be done at 2 to 4 weeks after your possible exposure. I cannot prescribe PrEP today, but we can get you started once we have these other lab results. You should also consider if you want to see your PCP, PrEP provider, or urgent care clinic for evaluation, possible other viral illness testing, and follow-up of your symptoms. They could also start you on PrEP if they decide it's appropriate to start now. Please let me know if you want a referral and/or would like me to refer you to a community organization[1] that can help link you to care and evaluation.

Continued on next page →

Example B Concerns for acute HIV infection ON PrEP	Based on the [symptoms AND last possible exposure to HIV] that you reported, there is a chance that this is a sign of recent HIV infection. These symptoms are also very general and could be related to the flu, COVID19, or another viral illness. I would like to screen for HIV and add another test that looks directly for the virus. These should be done at 2 to 4 weeks after your possible exposure. While we wait for those lab results, I can prescribe up to a 30-day supply for this refill. You should also consider if you want to see your PCP, PrEP provider, or urgent care clinic for evaluation, possible other viral illness testing, and follow-up of your symptoms. Please let me know if you want a referral and/or would like me to refer you to a community organization[1] that can help link you to care and evaluation.
Example D Reactive, positive, -or- indeterminate result for: Gonorrhea -or- Chlamydia -or- Syphilis	There were [reactive, positive, -or- indeterminate] results for [gonorrhea, chlamydia, and/or syphilis]. This is not a diagnosis of [gonorrhea, chlamydia, and/or syphilis], but you need further evaluation and possibly testing to confirm if this is a true result. Please keep taking your PrEP, do not stop PrEP. Please use condoms during sexual activity until you have been evaluated and/or treated by a clinical provider. I can help you make an appointment for further evaluation/treatment to a Primary Care Provider, urgent care clinic, or county health department.

Table 1: PrEP Laboratory Requirements
REQUIRED:

Lab Data	BASELINE	In 1 month	Every 3 months	Every 6 months	Every 12 months
HIV Ag/Ab 4th generation test	X Required within 7 days before the start	X If first prescription is for 30 days	X Within 7 days before each new prescription		
HIV RNA[1]	X		X		
Hepatitis B -Review vaccine Status and serologies	X				
Chlamydia Screening	X		X MSM/TGW	X	
Gonorrhea Screening	X		X MSM/TGW	X	
Syphilis Screening	X		X MSM/TGW	X	
SCr and calculated creatinine clearance	X			X If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start	X
OPTIONAL:					
Hepatitis C Ab *	X MSM/TGW, PWID		X PWID	X PWID	X MSM/TGW, PWID
HCG pregnancy test*	X				

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1]HIV RNA is highly recommended at baseline, especially in certain situations, and if symptoms of possible acute retroviral syndrome develop while taking PrEP. It is recommended every 3 months as part of PrEP monitoring however, it is not a required test and should not be a barrier to prescribing PrEP.

APPENDIX A- ALGORITHM A: PrEP INITIATION 4) LABORATORY- Required Baseline Labs

Hepatitis B Status

-Confirm vaccination or order lab at intake only
-Counsel about the risk of Hep B flare if stopping PrEP if living with an unknown previous or current Hep B infection.
-Do not start PrEP if has current Hepatitis B infection
Please see: https://www.cdc.gov/hepatitis/HBV/PDFs/serologicChartv8.pdf for further information

Step 1:**Hepatitis B Vaccine** □ YES	•Confirmation of being fully vaccinated for hepatitis B via ALERT • Attempt to obtain past Hep B surface antibody result to confirm protection after completion of vaccine series or order to check Negative Hep B Surface
□ NO	•Lack of vaccination is not a contraindication for PrEP •Counsel on risk factors for Hepatitis B and recommend vaccination. OAR 855-019-0280.
Step 2: Hepatitis B surface antigen If no Hep B Vaccination, order Hepatitis B serologies □ non-reactive all OR only surface antiGEN and core antiBODY	□ reactive or indeterminate surface AntiGEN or core AntiBODY Refer and Report

Renal Function Status

Order lab at intake and annually thereafter If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start, order every 6 months

□ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ CrCl < 30 mL/min	□ CrCl is < 60 ml/min, do NOT use F/TDF • Consider F/TAF (Descovy®) in cis-gender men and TGW with risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min.
	□ CrCL is < 60 ml/min AND not a candidate for F/TAF (i.e., vaginal sex is an HIV exposure risk) * -or- □ CrCL is < 30 ml/min* Refer • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease

Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D above) Refer & Report [1,2]
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis test result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D above) Refer & Report [1,2]
Hepatitis C Ab----Optional Recommended for: -MSM minimum annually -TGW minimum annually -PWID every 3 to 6 months □ reactive □ indeterminate □ non-reactive	□ reactive, positive, detected or indeterminate Pharmacist may proceed with prescribing PrEP Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.

[2] County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

APPENDIX B- ALGORITHM B: PrEP CONTINUATION 4) LABORATORY- Required Baseline Labs

Renal Function Status

Order lab at intake and annually thereafter If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start, order every 6 months

□ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ CrCl < 30 mL/min	□ CrCl is < 60 ml/min, do NOT use F/TDF • Consider F/TAF (Descovy®) in cis-gender men and TGW with risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min.
	□ CrCL is < 60 ml/min AND not a candidate for F/TAF (i.e., vaginal sex is an HIV exposure risk) * -or- □ CrCL is < 30 ml/min* -• Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease Refer

Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D above) Refer & Reort [1,2]
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D above) Refer & Report [1,2]
Hepatitis C Ab----Optional Recommended for: -MSM minimum annually -TGW minimum annually -PWID every 3 to 6 months □ reactive □ indeterminate □ non-reactive	□ reactive, positive, detected or indeterminate Pharmacist may proceed with prescribing PrEP Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.

[2] County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Note: RPh may not prescribe and must refer patient if HIV test reactive or indeterminate

Rx

☐ **Truvada® (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**
- ☐ Take one tablet by mouth daily for 30 days, #30, 0 refills
- ☐ Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

☐ **Descovy® (emtricitabine/tenofovir alafenamide) 200/25mg tablets**
- ☐ Take one tablet by mouth daily for 30 days, #30, 0 refills
- ☐ Take one tablet by mouth daily for 90 days, #90, 0 refills

Written Date: _____

Expiration Date: (This prescription expires 90 days from the written date) _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:

Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH. This regimen was filled on _____/_____/_____ (Date) for a _____ day supply and follow-up HIV testing is recommended in approximately _____ days _____/_____/_____ (Date)

This regimen consists of the following (check one):

- ☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily
- ☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - Take one tablet by mouth daily

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• HIV RNA:	___/____/_____	□ *detected* □ *indeterminate* □ not detected	□ *Yes*
• Hepatitis B surface antigen:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
• Hepatitis C antibody:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
• Syphilis/Treponemal antibody:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• Gonorrhea/Chlamydia:	____/____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ non-reactive	Pharyngeal test result: □ *reactive* □ *indeterminate* □ non-reactive	Rectal test result: □ *reactive* □ *indeterminate* □ non-reactive	
• Renal function (CrCl):	____/____/_____	_____ mL/min	□ *Yes*
□ CrCl >60mL/min	□ CrCl 30mL/min - 60mL/min	□ *CrCl <30mL/min*	
• HCG:	____/____/_____	□ *positive* □ *indeterminate* □ negative	□ *Yes*
• Signs/symptoms of acute retroviral syndrome (□ *Present* □ Not Present) AND potential HIV exposure (□ *Yes* □ No) in the last 4 weeks <u>and</u> not on PrEP (□ *Yes* □ No).			□ *Yes*
• Exposure risk less than 72 hours ago? □ *Yes* □ No			□ *Yes*

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- PrEP is prescribed for up to a 90 day supply for each prescription to align with appropriate lab monitoring guidelines.
- Truvada® is not recommended for CrCl less than 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® and Descovy® are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada® is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacist monitoring of HIV PrEP and transition of care:

- The pharmacist prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and other baseline and treatment monitoring lab results as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

Agenda Topic: Review all other current statewide protocols and offer recommendations to amend, if necessary, to ensure consistency with standard of care

Protocols Included in Agenda Packet:

- Pharmacist Protocol for Testing and Initiating Treatment for COVID-19 Virus Infection
- Pharmacist Emergency Contraception Statewide Protocol
- Pharmacist Epinephrine Statewide Protocol
- Pharmacist Protocol for Testing and Initiating Treatment for Acute Group A Streptococcus Bacteria Infection
- HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol
- Pharmacist Protocol for Testing and Initiating Treatment for Influenza
- Pharmacist Statewide Protocol to Lower Out-of-Pocket Expenses
- Pharmacist Naloxone or Other Opioid Antagonist Statewide Protocol
- Pharmacist Prenatal Vitamin Statewide Protocol
- Pharmacist Hormonal Contraceptive Statewide Protocol
- Tuberculin Skin Testing One-Step Protocol
- Tuberculin Skin Testing Two-Step Protocol
- Pharmacist Statewide Protocol for Tobacco Cessation
- Pharmacist Protocol for Testing and Initiating Treatment for Suspected Acute Uncomplicated Lower Urinary Tract Infection in Women
- Pharmacist Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older
- Vaccine Statewide Protocol for Persons Ages Three (3) through Seventeen (17)

Action Needed:

- Motion to recommend amendments to specific statewide protocols or take no action.

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for COVID-19 Virus Infection

Pursuant to the United States Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) for the emergency use of PAXLOVID, a pharmacist may prescribe Paxlovid for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with mild-to-moderate coronavirus disease 2019 (COVID-19) who are at high risk for progression to severe COVID-19 under the following conditions:

- Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and

- Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

PATIENT INCLUSION CRITERIA AND TREATMENT

Pharmacists shall complete the Paxlovid Patient Assessment Form in Appendix A to assist in determining patient eligibility and appropriate treatment.

RECORDKEEPING

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for COVID-19 pursuant to this Protocol and shall document the results and dispensing of Paxlovid in the prescription record, including documentation of the following:

- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antiviral therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

PAXLOVID PATIENT ASSESSMENT FORM FOR PHARMACIST

PATIENT INFORMATION

Patient Name:	Date:
Address:	Date of Birth:
Tel.:	Email:

PATIENT ELIGIBILITY SCREENING

□ Yes □ No	Patient meets limitations of authorized use for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
□ Yes □ No	Patient informed to AVOID going into the pharmacy for pick-up (use Drive-Thru, Curbside, Delivery).
□ Yes □ No	Date of Positive Test (Home Test Accepted) and Symptom Onset is within 5 days. Record date of positive test:_____
□ Yes □ No	Renal Function within 12 months is known. Record eGFR:_____
□ Yes □ No	Hepatic Function normal (must be within 12 months, Child-Pugh Class C-Use NOT recommended).
□ Yes □ No	Full Medication List Obtained (including OTCs/herbal supplements)
□ Yes □ No	Reviewed for potential drug interactions and NO dose adjustments/medication modifications are needed.
□ Yes □ No	Modifications to other medications are needed. Pharmacist will not prescribe and will refer for evaluation by a physician, advance practice registered nurse, or physician assistant.
□ Yes □ No	Paxlovid FDA EUA Fact Sheet given to patient at time of pharmacist prescribing.

THERAPY OPTIONS

❑ Paxlovid Tablets (Standard Dose, eGFR ≥60mL/min):	Dispense: 30 tablets No refills	Sig: Take 2 pink (Nirmatrelvir 150 mg) tablets and 1 white (Ritonavir 100 mg) tablet by mouth together twice daily for five days.
❑ Paxlovid Tablets (Renal Dose, eGFR ≥30 to <60mL/min):	Dispense: 20 tablets No refills	Take 1 pink (Nirmatrelvir 150 mg) tablet and 1 white (Ritonavir 100 mg) tablet by mouth together twice daily for five days.
❑ Paxlovid NOT prescribed. Referred for evaluation by a physician, advance practice registered nurse, or physician assistant.		

PHARMACIST PERFORMING ASSESSMENT AND/OR INITIATING TREATMENT

Printed Name:	License Number:

Signature Date

Adopted: 9/9/2020
Effective Date: 1/3/2021
Revised: 11/28/2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Emergency Contraception Statewide Protocol

A pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Self-administered hormonal emergency contraception (EC) provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, or dispensing of a self-administered hormonal EC under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use or standard protocol and shall have completed at least one hour of continuing education specific to the prescribing of EC.

PATIENT INCLUSION CRITERIA

Patients eligible for self-administered hormonal EC under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Emergency Contraception Self-Screening Questionnaire****** indicating the last day of unprotected intercourse was within the previous 5 days (120 hours) and who the pharmacist has determined is eligible for a hormonal emergency contraceptive, consistent with the most current version of the Centers for Disease Control and Prevention *US Medical Eligibility Criteria for Contraceptive Use, Classifications for Emergency Contraception.*

*****Note: A pharmacy may create and use an electronic emergency contraception self-screening questionnaire if the collection of patient information and assessment process is identical to the Virginia Emergency Contraception Self-Screening Questionnaire.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT be eligible for EC shall be referred to a healthcare practitioner and may not receive EC under this statewide protocol. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

DRUG INCLUSION CRITERIA

The following drug formulations are included in this EC statewide protocol:

Dedicated Approved EC – One Tablet Regimens

Plan B One-Step	1 tablet	1.5mg levonorgestrel	OTC
Levonorgestrel	1 tablet	1.5mg levonorgestrel	OTC
Next Choice One Dose	1 tablet	1.5mg levonorgestrel	OTC
Ella	1 tablet	30mg ulipristal	Rx only

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed.

Oral Contraceptive Pills

Brand	Tablets per dose (2 doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)*	Status
Alesse	5 pink tablets	100	0.50	Rx only
Aviane	5 orange tablets	100	0.5	Rx only
Levlen	4 light-orange tablets	120	0.6	Rx only
Levlite	5 pink tablets	100	0.5	Rx only
Levora	4 white tablets	120	0.60	Rx only
Lo/Ovral	4 white tablets	120	0.60	Rx only
Low-Ogestrel	4 white tablets	120	0.60	Rx only
Nordette	4 light-orange tablets	120	0.60	Rx only
Ogestrel	2 white tablets	100	0.50	Rx only
Ovral	2 white tablets	100	0.50	Rx only
Tri-Levlen	4 yellow tablets	100	0.50	Rx only
Triphasil	4 yellow tablets	120	0.50	Rx only
Trivora	4 pink tablets	120	0.50	Rx only
Ovrette	20 yellow tablets	0	0.75	Rx only

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrol, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed. Estrogen containing regimens are not preferred and should be used only when other options are not available.

Anti-nausea Treatment Options for use with EC

Drug	Dose	Timing of Administration	Status
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25mg tablets	1 hour before first EC dose; repeat if needed in 24 hours	OTC
Diphenhydramine hydrochloride (Benadryl)	One or two 25mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Dimenhydrinate (Dramamine)	One or two 50mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Cyclizine hydrochloride (Marezine)	One 50mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours	OTC

ADDITIONAL PRESCRIBING AND DISPENSING CONSIDERATIONS

- For women who weigh more than 165 lbs, levonorgestrel may be less effective than ulipristal acetate.*****
- Levonorgestrel may be preferable for women who need EC due to missed or late pills, patch, or ring.*****
- Starting hormonal birth control immediately after taking ulipristal acetate may make it ineffective.*****
- For women with prescription insurance coverage, OTC drugs may be covered by the health carrier when prescribed for the patient.*****
- Ella may be more effective if it has been more than 72 hours since the last day of unprotected intercourse.
- Pharmacist must counsel the patient on the proper use of the EC and side effects, to include providing written educational materials.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER AND COUNSELING

1. If the pharmacist initiates treatment with or dispenses or administers a self-administered hormonal EC, the pharmacist shall notify the patient's primary care provider and obstetrician/gynecologist (OB/GYN). If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located; and,
2. Additionally, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

***Per the American Society for Emergency Contraception.**

Adopted: 9/9/2020
Effective Date: 1/3/2021

Virginia Emergency Contraception Self-Screening Questionnaire

Timing is an essential element of the effectiveness of emergency contraception (EC). EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.

Patient's Name_____**Date**___

Healthcare Provider's Name_____

Healthcare Provider's Telephone or Email address_____

Date of Birth _____ **Age** _____ **Weight** _____

What was the date of you last women's health clinical visit? _____

Any allergies to medications? _____

Number of hours/days since last unprotected intercourse _____

Internal use only

☐ Verified DOB with valid photo ID BP Reading _____/_____

☐ Drug Prescribed: _____

Sig: _____

Pharmacist's Name: _____

Pharmacy's Name and Address: _____

Pharmacy's Phone: _____

☐Patient Referred

Reason(s):_____

Notes:_____

_____

_____

Adopted: 9/9/2020
Effective Date: 1/3/2021
Revised: 11/28/2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Epinephrine Statewide Protocol

Consistent with the epinephrine manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Epinephrine auto-injector; or,
- Injectable epinephrine, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such epinephrine.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering epinephrine under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognition and management of anaphylaxis.

PATIENT INCLUSION CRITERIA

Patients eligible for epinephrine under this protocol:

- Any person, 18 years of age or older, demonstrating signs and symptoms of anaphylaxis or at risk for experiencing anaphylaxis, e.g., patients reporting having previously been prescribed epinephrine for treatment of possible anaphylaxis or reporting a diagnosis of allergies that may result in anaphylaxis.

COUNSELING

The pharmacist shall counsel the patient or the patient's agent on how to properly recognize and mangage anaphylaxis, including proper administration of the epinephrine.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for Acute Group A Streptococcus Bacteria Infection

Pursuant to § 54.1-3303.1, a pharmacist may initiate CLIA-waived point-of-care testing for acute Group A streptococcal (GAS) pharyngitis and, when diagnostically confirmed, initiate the dispensing of antibiotics to treat the infection for persons 18 years of age or older.

A pharmacist may not initiate assessment or testing unless sufficient antibiotics are readily available to treat acute GAS pharyngitis infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antibiotic therapies under this Protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy. Additionally, the pharmacist shall maintain knowledge of the Infectious Disease Society of America (IDSA) and the Centers for Disease Control and Prevention (CDC)'s current guidelines for the treatment of acute GAS pharyngitis. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

PATIENT INCLUSION CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotic therapy to treat acute GAS pharyngitis infection shall treat patients according to current IDSA and CDC guidelines.

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula); and,
- Reported symptom onset < 96 hours before time of presentation.

PATIENT EXCLUSION CRITERIA

Any individual who meets **any** of the following criteria:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced

glomerulonephritis;

- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- A patient who has taken antibiotics for sore throat or upper respiratory infection in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Severe symptoms of respiratory distress, including:
    - Muffled voice;
    - Drooling;
    - Stridor;
    - Respiratory distress;
    - "Sniffing" or "tripod" positions;
    - Fever and rigors;
    - Severe unilateral sore throat;
    - Bulging of the pharyngeal wall/floor or soft palate;
    - Trismus;
    - Crepitus;
    - Stiff neck; or
    - History of penetrating trauma to oropharynx; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

Pharmacists shall assess a patient based on the inclusion and exclusion criteria based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

FURTHER CONDITIONS

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status
- Current medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's acute GAS pharyngitis status.

- If positive, the pharmacist may proceed to consideration for immediate antibiotic therapy treatment.
- If negative, the pharmacist shall counsel the patient or caregiver pursuant to the Counseling section of this Protocol or refer the patient, if clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions:

- Mild allergic reactions to penicillin (amoxicillin)
- Mild allergic reactions to cephalosporins (cephalexin)
- Severe allergic reactions to penicillin (amoxicillin and cephalexin)
- Allergic reactions to macrolides (azithromycin and clarithromycin)
- Allergic reactions to clindamycin
- History of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.)

DRUG INCLUSION CRITERIA

The pharmacist may initiate one the following medication regimens based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Selection of antibiotic regimen will follow the ordered preference listed below. A lower-ranked regimen will only be prescribed if the patient or pharmacy record indicates a drug allergy or other contraindication to a higher-ranked regimen, or if the drug is not commercially available or appears on the FDA drug shortages list. The pharmacist shall assess reported drug allergies for validity by reviewing the patient's pharmacy record and documenting the reported reaction.

If the pharmacist has a recent patient creatinine level and current weight, the pharmacist may adjust the medication dose per the manufacturer package insert for patients with CrCl < 30.

A. First-line treatment
    a. Amoxicillin
        i. Contraindication: Penicillin allergy
        ii. Dosing: 500 mg PO twice daily x 10 days, or

b. Penicillin
    i. Contraindication: Penicillin allergy
    ii. Dosing
        1. Penicillin V, oral – 500mg PO twice daily x 10 days
        2. Penicillin G benzathine – 1.2million units IM, single dose, to be administered by the pharmacist.

B. Second-line treatment
    a. Cephalexin
        i. Contraindications
            1. Cephalosporin allergy
            2. Severe penicillin allergy
        ii. Dosing: 500 mg PO twice daily x 10 days
    b. Cefadroxil
        i. Contraindications
            1. Cephalosporin allergy
            2. Severe penicillin allergy
        ii. Dosing: 1g PO daily x 10 days

C. Third-line treatment *(Note: Potential resistance exists for both clindamycin and azithromycin. Clindamycin is the preferred third-line treatment.)*
    a. Clindamycin
        i. Contraindication: Clindamycin allergy
        ii. Dosing: 300 mg PO three times daily x 10 days
    b. Azithromycin
        i. Contraindication: Macrolide allergy
        ii. Dosing: 500 mg PO once daily x 5 days

D. Fourth-line treatment
    a. Clarithromycin
        i. Contraindication: Macrolide allergy
        ii. Dosing: 250 mg PO twice daily x 10 days

E. The pharmacist may recommend the following adjunctive therapy for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis, unless contraindicated:
    a. Acetaminophen PO according to OTC dosing recommendations; and
    b. Ibuprofen PO according to OTC dosing recommendations.

RECORDKEEPING

In any case where amoxicillin is not the selected regimen, the pharmacist shall document the rationale for selecting the antibiotic dispensed. Documentation may include medication sensitivity, cost, and shared clinical decision-making.

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for acute GAS pharyngitis pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;

- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antibiotic therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

COUNSELING

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on the following:

- If CLIA-waived test results are negative, counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (stay home for at least 24 hours after fever subsides, hygiene/infection control measures, drink plenty of fluids, treat symptoms as needed, etc.) or refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.
- If CLIA-waived test results are positive, counsel on CDC guidelines that a patient with a confirmed diagnosis of acute GAS pharyngitis should stay home from work or school until they are afebrile for at least 24 hours after starting antibiotic therapy;
- Medication counseling; and
- Signs and symptoms that warrant emergency medical care such as from a primary care provider or urgent/emergent treatment facility if symptoms worsen or do not improve within 48 hours.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

Acute Group A Streptococcal Pharyngitis Patient Form

PATIENT INFORMATION

Name		Date of Birth	Age
Address		Phone	Email
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

□ Yes □ No Are you 18 years of age or older?
□ Yes □ No Are you pregnant or breastfeeding?
□ Yes □ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
□ Yes □ No Do you have a history of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis?
□ Yes □ No Do you have a history of allergic reactions to antibiotics, such as penicillin, amoxycillin, cephalexin, clarithromycin, or clindamycin?
□ Yes □ No Do you have a pending test for your symptoms (COVID, strep, flu)?
□ Yes □ No Have you had a tonsillectomy in the previous 30 days?
□ Yes □ No Have you taken antibiotics in the last 30 days? If yes, why?
When did your symptoms start? □ More than four days ago. □ Fewer than four days ago
Do you have any of the following symptoms (check all that apply)? □ Fever □ Sore throat □ Pain swallowing □ Swollen/tender cervical lymph nodes □ Inflamed or swollen tonsils or uvula □ Other:

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
□ Yes □ No Acute altered mental status	Yes
Severe Symptoms of Respiratory Distress	Muffled voice; Drooling; Stridor; Respiratory distress; "Sniffing" or "tripod" positions; Fever and rigors; Severe unilateral sore throat; Bulging of the pharyngeal wall/floor or soft palate; Trismus; Crepitus; Stiff neck; or History of penetrating trauma to oropharynx.
Overt Viral Features	Conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula); and
- Reported symptom onset < 96 hours before time of presentation.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);

- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis;
- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- Patient has taken antibiotics for sore throat or upper respiratory infection in the last 30 days.
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Severe symptoms of respiratory distress, including:
    - Muffled voice;
    - Drooling;
    - Stridor;
    - Respiratory distress;
    - "Sniffing" or "tripod" positions;
    - Fever and rigors;
    - Severe unilateral sore throat;
    - Bulging of the pharyngeal wall/floor or soft palate;
    - Trismus;
    - Crepitus;
    - Stiff neck; or
    - History of penetrating trauma to oropharynx; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

□ Positive for acute GAS pharyngitis (continue)

□ Negative for acute GAS pharyngitis (refer to PCP as clinically appropriate + symptomatic treatment)

PATIENT ACTION

□ Yes □ No Acute GAS pharyngitis Diagnosed

□ Yes □ No Antibiotic Treatment Prescribed

□ Yes □ No Refer to PCP

Therapy Options (Refer to Drug Inclusions section of Protocol for drug order preference)		
Acute GAS Pharyngitis Adult **Treatment**		
Documentation of Rationale for Treatment Selection (if required):		
❑ Oral Amoxicillin	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days; or
❑ Oral Penicillin V	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
❑ IM Penicillin G benzathine	Dispense: ❑ 1.2million units IM, single dose No refills	To be administered by the pharmacist
❑ Oral Cephalexin	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
❑ Oral Cefadroxil	Dispense: ❑ 1g #10 No refills	Sig: Take 1 (one) (1g) by mouth daily for 10 days
❑ Oral Azithromycin	Dispense: ❑ 500mg #5 No refills	Sig: Take 1 (one) (500mg) by mouth daily for 5 days
❑ Oral Clindamycin	Dispense: ❑ 300mg #30 No refills	Sig: Take 1 (one) (300mg) by mouth three times daily for 10 days
❑ Oral Clarithromycin	Dispense: ❑ 250mg #20 No refills	Sig: Take 1 (one) (250mg) by mouth twice daily for 10 days

PHARMACIST PERFORMING ASSESSMENT AND/OR INITIATING TREATMENT

Printed Name	License Number

SIGNATURE DATE

VIRGINIA BOARD OF PHARMACY

Preventive Care

HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

Consistent with the manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PEP Patient Intake Form (pg. 2)
- Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-6)
- Utilize the standardized PEP Patient Informational Handout (pg. 7)
- Utilize the standardized PEP Provider Fax (pg. 8)

PHARMACIST EDUCATION AND TRAINING

- Prior to issuing a prescription to initiate treatment with, dispensing, or administering controlled substances for post-exposure prophylaxis under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.

*****Note: A pharmacy may create and use an electronic format for the PEP Patient Intake Form, PEP Assessment and Treatment Care Pathway, and PEP Patient Informational Handout, and PEP Provider Fax Notification if the information is identical to the forms included in this protocol.

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	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
8.	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
9.	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
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

1. Is the patient less than 18 years old?		Notes:
☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic	☐ No: Go to #2	
2. Was the patient a survivor of sexual assault?		Notes:
☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**	☐ No: Go to #3	
3. Is the patient known to be HIV-positive?		Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.
☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.	☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).	
4. What time did the exposure occur?		Notes:
☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.	☐ ≤72 hours ago: go to #5	
5. Was the exposure from a source person known to be HIV-positive?		
☐ Yes: Go to #6	☐ No: Go to #7	
6. 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:		Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.
Please check any/all that apply: ☐Blood ☐Semen ☐Vaginal secretions ☐Rectal secretions ☐Breast milk ☐Any body fluid that is visibly contaminated with blood If any boxes are checked, go to #9.	Please check any/all that apply (*Note: only applicable if not visibly contaminated with blood*): ☐Urine ☐Nasal Secretions ☐Saliva ☐Sweat ☐Tears ☐None of the above Go to #7	
7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?		Notes: This type of exposure puts the patient at a high risk for HIV acquisition
☐ Yes: Go to #9	☐ No: Go to #8	

8. 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?		Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.
☐ Yes: Please check all that apply and go to #9: ☐Was the source person known to be HIV-positive? ☐Were there cuts/openings/sores/ulcers on the oral mucosa? ☐Was blood present? ☐Has this happened more than once without PEP treatment? ☐None of the above	☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.	
9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?		Notes: Connection to care is critical for future recommended follow-up.
☐ Yes: Go to #10	☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.	
10. Does the patient have history of known Hepatitis B infection (latent or active)?		Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.
☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.	☐ No. Go to #11	
11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No Verify vaccine records or VIIS. Dates:_____		
☐ Yes: Go to #13	☐ No: Go to #12	
12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13. ☐Vaccine administered Lot:_____ Exp:_____ Signature:_____		
13. Does the patient have known chronic kidney disease or reduced renal function?		Notes: emtricitabine and tenofovir disoproxil fumarate requires renal dose adjustment when the CrCl <50 mL/min
☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.	☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.	

RECOMMENDED REGIMEN:

Medication	Age/Weight	Dose	Duration	Notes
emtricitabine 200mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic) PLUS raltegravir 400mg OR dolutegravir 50mg	≥ 18 years	Once daily No refills Twice daily No refills Once daily No refills	28 days	• Dosing adjustments with renal dysfunction if CrCl <60 ml/min. • Dolutegravir should not be used in pregnant women. • If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then the "alternate regimens" per CDC guidelines should be referenced and used. • Other FDA-approved regimens can be used if they become available. Formulation cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens. • Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such. • Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com • If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

COUNSELING POINTS (at minimum):

- Proper use of medication dosage, schedule, and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care

- The importance and requirement of follow up testing for HIV, renal function , hepatic function , hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____Date____/____/_____

This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Key Points

- You must start the medications within 72 hours of your exposure.
- Take every dose. If you miss a dose, take it as soon as you remember.
    - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking the medication without first asking your doctor or pharmacist.
- The most common side effects (if they do happen) are stomach upset. Taking the medication with food can help with stomach upset. Over-the- counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you. The pharmacy cannot do these lab tests.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
    - ☐ HIV antigen/antibody 4th generation
    - ☐ Hepatitis B surface antigen and surface antibody
    - ☐ Hepatitis C antibody
    - ☐ Treponema pallidum antibody
    - ☐ Comprehensive metabolic panel
4. If you think that 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.

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) has been initiated treatment for HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

_____

_____

This regimen was initiated on _____(Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Emtricitabine/tenofovir disoproxil fumarate needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Etricitabine/tenofovir disoproxil fumarate and raltegravir are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with emtricitabine/tenofovir disoproxil fumarate.
- Emtricitabine/tenofovir disoproxil fumarate is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

If you have further questions, please contact the pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for Influenza

Pursuant to § 54.1-3303.1, a pharmacist may initiate CLIA-waived point-of-care testing for Influenza and, when diagnostically confirmed, initiate the dispensing of an antiviral to treat the infection for persons 18 years of age or older.

A pharmacist may not initiate assessment or testing unless sufficient antiviral therapy is readily available to treat acute influenza infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

A pharmacist shall exercise clinical judgement in assessing patients pursuant to this Protocol outside of the standard influenza season (approximately October 1 – April 30). Resource: https://www.cdc.gov/flu/weekly/

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antiviral therapy under this Protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy. Additionally, the pharmacist shall maintain knowledge of the Centers for Disease Control and Prevention (CDC)'s current guidelines for the treatment of acute influenza. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

PATIENT INCLUSION CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antiviral therapy to treat acute influenza infection shall treat patients according to current CDC guidelines.

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis); and,
- Reported symptom onset < 48 hours before time of presentation.

PATIENT EXCLUSION CRITERIA

Any individual who meets **any** of the following criteria:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including

corticosteroids for greater than two (2) weeks, HIV/AIDS);
- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- A patient receiving hospice or home health services;
- A patient who has taken an antiviral in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

Pharmacists shall assess a patient based on the inclusion and exclusion criteria based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

FURTHER CONDITIONS

The pharmacist shall assess the patient's relevant medical and social history:
- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status

- Current Medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of flu-like signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's influenza status.

- If positive, the pharmacist may proceed to consideration for immediate antiviral therapy treatment.
- If negative, the pharmacist shall counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (stay home for at least 24 hours after fever subsides, drink plenty of fluids, treat symptoms as needed, and consider influenza immunization) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions.

DRUG INCLUSION CRITERIA

The pharmacist may immediately initiate antiviral therapy only in selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

A. Oral oseltamivir (Tamiflu)
    a. Contraindications
        i. Known hypersensitivity to oseltamivir or any component
        ii. Patients 18 years and older with CrCl < 10 ml/min. If the pharmacist is unable to obtain a current CrCl for a patient with a history of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.), then the patient should be excluded from receiving Tamiflu. For purposes of this Protocol, current CrCl means a lab value obtained within the past six months and documented by a physician's office, laboratory, or patient electronic health record, or reported by the patient and the pharmacist determines in their clinical judgment the patient report is accurate. The pharmacist shall document this information in the patient record.
    b. Dosing – all doses to be administered x 5 days
        i. Patients 18 years and older: 75 mg twice daily
        ii. Patients 18 years and older with renal impairment
            1. CrCl > 60 ml/min: no dosage adjustment necessary
            2. CrCl > 30 to 60 ml/min: 30mg twice daily
            3. CrCl > 10 to 30 ml/min: 30mg once daily

B. Oral baloxavir marboxil (Xofluza)
    a. Contraindications
        i. Known hypersensitivity to baloxavir or any component
        ii. Weight < 40 kg
    b. Dosing – all doses to be administered as a single dose
        i. Weight-based

1. 40 kg to < 80 kg: 40 mg
2. 80 kg and above: 80 mg

C. Inhaled zanamivir (Relenza Diskhaler)
   a. Contraindications
      i. Known hypersensitivity to zanamivir or any component
      ii. Underlying respiratory disease or asthma
   b. Dosing – all doses to be administered twice daily x 5 days
      i. 10 mg (two 5 mg inhalations)

If the patient qualifies for multiple therapies above, the pharmacist shall document the rationale for selecting the antiviral therapy dispensed. Documentation may include patient preference, cost, and shared clinical decision-making.

The pharmacy shall ensure that a pharmacist that has entered the Protocol shall monitor the patient for continuation or adjustment of therapy, including the following:

- As clinically appropriate, initiate telephone follow-up within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- If the patient is 65 years of age or older, telephone follow-up is mandatory within 72 hours of dispensing to assess the above patient status. If an initial follow-up does not result in direct patient contact, a second telephone follow-up attempt shall be made. Follow-up attempts must be documented by the pharmacist.
- Refer to a primary care provider or urgent/emergent treatment facility if any of the following are reported:
  - Significant deterioration in condition or new evidence of clinical instability;
  - Onset of symptoms inconsistent with influenza or indicative of serious complications of influenza; or
  - Medication adverse effects severe enough to warrant discontinuation.

RECORDKEEPING

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for influenza pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antiviral therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment,

testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

COUNSELING

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on the following:

- Influenza vaccination;
- Appropriate self-care, including symptom control, hygiene, and infection control measures;
- CDC guidelines that a patient with a confirmed diagnosis of influenza should stay home from work, school, or daycare until they are afebrile (100°F) for at least 24 hours without the use of a fever-reducing medication and at least 24 hours after starting antiviral therapy;
- Medication counseling; and
- Signs and symptoms that warrant emergency medical care.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

Influenza Patient Form

PATIENT INFORMATION

Name		Date of Birth	Age
Address		Phone	Email
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

□ Yes □ No Are you 18 years of age or older?
□ Yes □ No Are you pregnant or breastfeeding?
□ Yes □ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
□ Yes □ No Do you require supplemental oxygen therapy?
□ Yes □ No Have you taken an antiviral in the last 30 days?
□ Yes □ No Do you have a pending test for your flu-like symptoms (COVID, strep, flu)?
□ Yes □ No Have you tested positive for influenza in the previous four weeks?
When did your flu-like symptoms start? □ More than two days ago. □ 2 days ago, yesterday, or today.
Do you have any of the following symptoms (check all that apply)? □ Fever □ Nasal congestion □ Muscle/body aches □ Cough □ Sore Throat □ Other:
Do you have any of the following? □ History of allergic reactions to influenza treatment □ History of physiologic side effects from any previous influenza treatment
Have you received FluMist or a generic equivalent within the past two weeks? □ Yes □ No

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
□ Yes □ No Acute altered mental status	Yes

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis); and
- Reported symptom onset < 48 hours before time of presentation.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- Patient is receiving hospice or home health services;
  Patient has taken an antiviral in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or

- Any one of the following criteria:
  - Acute altered mental status;
  - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
  - Pulse >125 beats/min;
  - Respiratory rate >30 breaths/min;
  - Oxygen saturation (SpO2) < 90% via pulse oximetry; or
  - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

□ Positive for influenza (continue)

□ Negative for influenza (refer to PCP + symptomatic treatment)

PATIENT ACTION

□ Yes □ No Influenza Diagnosed

□ Yes □ No Antiviral Treatment Prescribed

□ Yes □ No Refer to PCP

Therapy Options		
Influenza Adult **Treatment**		
❑ Oral Oseltamivir (Tamiflu)	Dispense: ❑ 75mg #10; No refills ❑ Renal impairment CrCl > 30 to 60 ml/min: 30mg twice daily CrCl > 10 to 30 ml/min: 30mg once daily	Sig: Take 1 (one) (75mg) by mouth twice daily for 5 days
❑ Inhaled Zanamivir (Relenza Diskhaler)	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
❑ Oral Baloxavir Marboxil (Xofluza)	Dispense: ❑ 40mg x 1 ❑ 80mg x1 No refills	Take 1 tablet by mouth now

PHARMACIST PERFORMING ASSESSMENT AND/OR INITIATING TREATMENT

Printed Name	License Number

SIGNATURE DATE

Adopted: 9/9/2020
Effective Date: 12/22/2021
Revised: 11/28/2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Statewide Protocol to Lower Out-of-Pocket Expenses

For the purpose of lowering a patient's out-of-pocket health care costs, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following to persons 18 years of age or older:

- Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering drugs, devices, controlled paraphernalia, and other supplies and equipment under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use and follow any relevant evidence-based guidelines.

PATIENT INCLUSION CRITERIA

Patients eligible for drugs, devices, controlled paraphernalia, and other supplies and equipment under this protocol:

- An individual, 18 years of age or older, whose over-the-counter drug, device, controlled paraphernalia, and other supply or equipment is covered by the patient's health carrier and when the patient's out-of-pocket cost for the prescribed item is lower than the out-of-pocket cost to purchase the same drug over-the-counter;
- An individual, 18 years of age or older, whose over-the-counter drug would cost more out-of-pocket than a prescribed prescription-only drug that is a therapeutically equivalent drug product[1], as defined in § 54.1-3401, as the over-the-counter drug.

EXAMPLES OF INCLUDED DEVICES AND CONTROLLED PARAPHERNALIA

Examples of devices and controlled paraphernalia for which a pharmacist may issue a prescription to initiate treatment under the qualifying conditions of this protocol include:

- Diabetic blood sugar testing supplies,
- Injection supplies;
- Hypodermic needles and syringes;
- Nebulizers and associated supplies;
- Inhalation spacers;
- Peak flow meters;
- International Normalized Ratio (INR) testing supplies;
- Enteral nutrition supplies;
- Ostomy products and supplies

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Drug Control Act, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

[1]"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book.", § 54.1-3401.

Adopted: 9/9/2020
Revised: 9/26/2023, 12/8/2023
Effective Date: 12/8/2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Naloxone or Other Opioid Antagonist Statewide Protocol

Consistent with the naloxone manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- intranasal naloxone (nasal spray formulation or for administration by mucosal atomization device);
- intramuscular naloxone, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone;
- naloxone auto-injector; or,
- any other opioid antagonist formulation approved by the FDA for overdose reversal, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering naloxone or any other opioid antagonist formulation approved by the FDA for overdose reversal under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognizing signs of a possible overdose and proper administration of the drug.

PATIENT INCLUSION CRITERIA

Patients eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual, 18 years of age or older, experiencing or at risk of experiencing an opioid-related overdose, e.g., patient has a history of prior overdose, substance misuse, a morphine milligram equivalency of 120MME/day, or is currently prescribed an opioid with a concomitant benzodiazepine present;
- A family member, friend, or other person, 18 years of age or older, in a position to assist an individual who is experiencing or at risk of experiencing an opioid-related overdose.

PATIENT EXCLUSION CRITERIA

Patients NOT eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual less than 18 years of age;
- An individual receiving treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell, (iii) a patient in hospice care, (iv) a patient in palliative care, (v) a patient enrolled in a clinical trial as authorized by state or federal law. Refer patient to primary care provider to determine if naloxone appropriate.

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided a copy of the REVIVE! Pharmacy dispensing brochure and counsel the patient or the patient's agent on how to properly identify signs of a possible overdose and how to properly administer the naloxone or other opioid antagonist for overdose reversal.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

WHAT IS NALOXONE?

Naloxone is a medication designed to temporarily **block the effects of opioids**, and can reverse overdose.

- Naloxone only works if opioids are in the body, it has no effect on alcohol or other drugs
- It can take **1-3 minutes** to start working and may require more than one dose.
- Effects can **last 30-90 minutes**, this varies per person.
- Naloxone may cause an opioid dependent person to go into **withdrawal** (e.g. nausea, vomiting, agitation, muscle aches).

Naloxone Saves Lives.

To learn more about using naloxone attend a REVIVE! training event! These events are **free and available to anyone** wanting to learn how to save a life with naloxone.

A REVIVE! Opioid Overdose Response Kit is provided at each training free of charge and inlcudes:

- Latex-free gloves
- Rescue breathing face mask
- Instruction Card
- A training completion card
- And stickers to document time of dosing

ADDRESS

PO Box 1797
Richmond, VA 23218

WEB

dbhds.virginia.gov search "revive"

REVIVE!

HOW TO RECOGNIZE AND RESPOND TO AN OPIOID OVERDOSE EMERGENCY WITH NALOXONE

An opioid overdose can happen to anyone taking opioids — whether they are taking medications prescribed or using them recreationally. Opioids can cause a person's **breathing to slow down or stop** — this is considered an overdose.

Virginia Department of Behavioral Health & Developmental Services

McShin a Recovery Resource Foundation

One Care of Southwest Virginia, Inc.

SAARA of VIRGINIA

OPIOIDS

Opioids are a class of drugs that include prescription pain medications like:

- Hydrocodone
- Oxycodone
- Fentanyl
- Morphine
- Codeine
- Methadone
- Burprenorphine
- Tramadol

and also street drugs like heroin.

OVERDOSE

When a person consumes more opioids than their body can tolerate it can stop central nervous system functions such as breathing and heartbeat.

Someone may be overdosing if they are

- Unresponsive to yelling, pinching, or a sternum rub
- not breathing or having really slow/shallow breaths
- Having blue lips and/ or fingertips

REDUCE RISK

Some of the primary risk factors associated with overdose are:

- Mixing drugs
- Lowered Tolerance (haven't used opioids before or in a while)
- Using alone
- Age and Physical Health
- Mode of Transmission
- Previous non-fatal overdose

RESPOND

If you suspect someone has overdosed

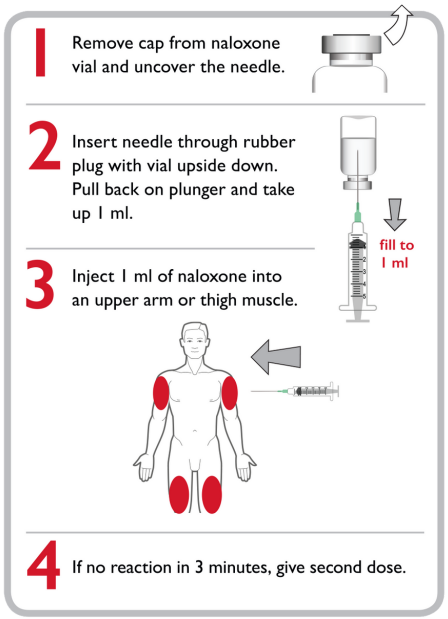
1. Check for responsiveness
2. Call 911
3. Give 2 Rescue Breaths
4. Give Naloxone
5. Begin Rescue Breathing

Naloxone expires, visit dbhds.virginia.gov to learn where you can get naloxone at no-cost.

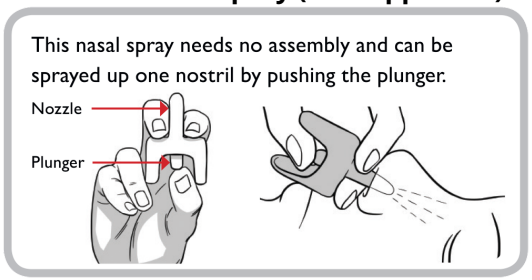
USING NALOXONE

Use Naloxone if you suspect someone is overdosing, even if you are unsure.

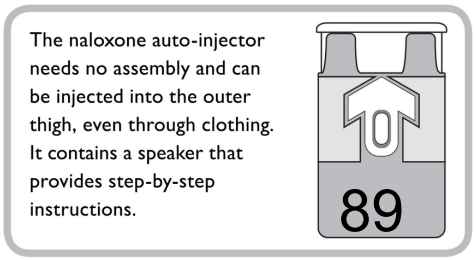
IM Injection (FDA Approved)



Narcan Nasal Spray (FDA Approved)



Auto-injector (FDA Approved)



Adopted: 9/9/2020
Effective Date: 1/3/2021
Revised: 11/28/2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Prenatal Vitamin Statewide Protocol

Consistent with the prenatal vitamin manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

- Prenatal vitamins for which a prescription is required.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering prenatal vitamins under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use and evidence-based guidelines.

PATIENT INCLUSION CRITERIA

Patients eligible for prenatal vitamins under this protocol:

- An individual, 18 years of age or older, who is considering pregnancy, attempting to become pregnant, or pregnant.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider and obstetrician/gynecologist (OB/GYN). If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Adopted: 9/9/2020
Effective Date: 1/3/2021
Revised: 11/28/2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Hormonal Contraceptive Statewide Protocol
(Excluding Emergency Contraception)

Consistent with the hormonal contraceptive manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Injectable or self-administered hormonal contraceptives provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering injectable or self-administered hormonal contraceptive under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed an Accreditation Council for Pharmacy Education (ACPE)-accredited educational training program related to the prescribing of contraceptives by a pharmacist.

PATIENT INCLUSION CRITERIA

Patients eligible for injectable or self-administered hormonal contraceptives approved by the FDA under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire** and who the pharmacist has determined is eligible for a hormonal contraceptive, consistent with the most current version of the Centers for Disease Control and Prevention *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use*, i.e., the prescribed drug is assessed at a "1" or "2" for all conditions applicable to the patient.

*Note: A pharmacy may create and use an electronic routine hormonal contraceptive self-screening questionnaire if the collection of patient information and assessment process is identical to the Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

To determine patient eligibility, the pharmacist shall:

1. Obtain from each new patient and, at a minimum of every twelve months for each returning patient, a completed *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire**; and,
2. Utilize and follow the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives* or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate* to perform the patient assessment.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT be eligible for a hormonal contraceptive as indicated by the *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use* and the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptive*s or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate*, as applicable, shall be referred to a healthcare practitioner and may not receive a hormonal contraceptive under this statewide protocol. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

FURTHER CONDITIONS

1. For each new patient requesting a contraceptive service a participating pharmacist must provide the patient with a visit summary.
2. A pharmacist shall not:
    a. Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit. Such evidence may be obtained by the response on the *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire* regarding the date of the patient's last women's health clinical visit.
    b. Prescribe in instances that the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptive*s or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate*, as applicable, requires referral to a provider.

DRUG INCLUSION CRITERIA

The following drug formulations approved by the FDA to prevent pregnancy are included in this statewide protocol:

- injectable depot medroxyprogesterone acetate;
- transdermal patches;
- vaginal rings; and,
- contraceptives intended to be taken orally.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER; COUNSELING

1. If the pharmacist initiates treatment with or dispenses or administers a hormonal contraceptive, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider and obstetrician/gynecologist (OB/GYN), the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located; and,

2. Additionally, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

VIRGINIA ROUTINE HORMONAL CONTRACEPTIVE SELF-SCREENING QUESTIONNAIRE

Name: _____ Today's Date: _____ Weight: _____

Date of Birth: _____ Age: _____ Healthcare Provider's Name: _____

Healthcare Provider's Telephone, Fax, or Email:_____

What was the date of your last women's health clinical visit? _____

Any Allergies to Medications? *Yes / No* If yes, list them here: _____

Pregnancy Screen:

1.	Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, *AND* have you had no menstrual period since the delivery?	Yes □ No□
2.	Have you had a baby in the last 4 weeks?	Yes □ No□
3.	Did you have a miscarriage or abortion in the last 7 days?	___/___/___
4.	Did your last menstrual period start within the past 7 days?	Yes □ No □
5.	Have you abstained from sexual intercourse since your last menstrual period or delivery?	Yes □ No □
6.	Have you been using a reliable contraceptive method consistently and correctly?	Yes □ No □
If you answered NO to ALL of the questions above, you may stop here and consult with the pharmacist. If you answered YES to at least one of the questions above, please proceed with completing this form.		

Additional Information:

7.	Do you think you might be pregnant now?	Yes □ No□
8.	Have you used emergency contraception within the last 5 days?	Yes □ No□
9.	What was the first day of your last menstrual period?	___/___/___
10.	Have you ever been told by a medical professional not to take hormones?	Yes □ No □
11.	Have you ever taken birth control pills, or used a birth control patch, ring, or injection?	Yes □ No □
12.	Did you ever experience a bad reaction to using hormonal birth control?	Yes □ No □
13.	- If yes, what kind of reaction occurred?	
14.	Have you previously had contraceptives prescribed to you by a pharmacist?	Yes □ No □
15.	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes □ No □
16.	- If yes, which one do you use? (List here)	
17.	Do you have a preferred method of birth control that you would like to use? (check box) ☐ A pill that you take daily ☐ A patch that you change weekly ☐ A vaginal ring that you change monthly ☐ An injection that you receive every 3 months	
Medical History		
Smoking:		
18.	Do you smoke cigarettes or vape nicotine?	Yes □ No □
19.	-If yes, number or equivalent number of cigarettes per day either smoked or vaped.	_____ /day

Postpartum (nonbreastfeeding women)/Breastfeeding:

20.	Have you given birth within 21 days? If yes, how long ago?	Yes □ No □
21.	Are you currently breastfeeding?	Yes □ No □
Diabetes:		
22.	Do you have diabetes?	Yes □ No □
Headaches:		
23.	Do you get migraine headaches?	Yes □ No □

Adopted by Virginia Board of Pharmacy: 9/9/2020
Effective Date: 1/3/2021

24.	- If yes, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes □ No □
Hypertension, History of high blood pressure during pregnancy:		
25.	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes □ No □
Deep venous thrombosis (DVT)/Pulmonary embolism (PE), Ischemic heart disease, Known thrombogenic mutations, Multiple risk factors for atherosclerotic cardiovascular disease, Peripartum cardiomyopathy, Stroke, Valvular heart disease:		
26.	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes □ No □
27.	Have you ever had a blood clot?	Yes □ No □
28.	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes □ No □
29.	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □ No □
History of bariatric surgery:		
30.	Have you had bariatric surgery or stomach reduction surgery?	Yes □ No □
Breast disease:		
31.	Do you have or have you ever had breast cancer?	Yes □ No □
Cirrhosis, Gallbladder disease, History of cholestasis, Liver tumors, Viral hepatitis:		
32.	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes □ No □
Rheumatoid arthritis, Systemic lupus erythematosus:		
33.	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes □ No □
Epilepsy, HIV, Tuberculosis, Drug Interactions (Antiretrovirals, Anticonvulsant, Antimicrobial therapy):		
34.	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes □ No □
35.	- If yes, list them here:	
Other information:		
36.	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes □ No □
37.	- If yes, list them here:	
38.	Will you be immobile for a long period? (e.g., flying on a long airplane trip, etc.)	Yes □ No □

Internal use only

☐ Verified DOB with valid photo ID BP Reading _____/_____

☐ Drug Prescribed:_____

Sig:_____

Pharmacist Name:_____

Pharmacy Name and Address:_____

Pharmacy Phone:_____

☐Patient Referred

Reason(s):_____

Notes:_____

_____

_____

Adopted by Virginia Board of Pharmacy: 9/9/2020
Effective Date: 1/3/2021

Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives

1) Pregnancy Screen
Review Pregnancy Screen section of Virginia Routine Hormonal Contraceptive Self-screening Questionnaire
If YES to at least one question and is free of pregnancy symptoms, proceed to next step.
If NO to All questions, pregnancy cannot be ruled out – Refer.

Possible Pregnancy → Refer; provide info per protocol if no PCP

Patient is not pregnant

2) Health and History Screen
Evaluate responses on Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire using CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use
1 or 2 (green boxes) = Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes)= Hormonal contraception is contraindicated – Refer.

Contraindicating Conditions/Medications → Refer; provide info per protocol if no PCP

No Contraindicating Conditions/Medications

3) Blood Pressure Screen
Is blood pressure < 140/90?
Note: Pharmacist may choose to take a second reading if initial is high.

BP > 140/90 → Refer; provide info per protocol if no PCP

BP < 140/90

4) Evaluate past use, preference, and current use of birth control.

Not currently on birth control

5a) Choose Contraception
Initiate contraception for new therapy based on patient preferences, adherence, and history.
Issue prescription for up to 12 months for dispensing at patient's pharmacy of choice (quantity based on professional judgement and patient preference).

Patient currently on birth control

5b) Choose Contraception
Continue current form of pills, patch, or ring, if no change necessary. – Or-
Alter therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate.

6) Discuss Initiation Strategy for New Treatment/Change in Treatment (as applicable)
a) Counseling – Regular or Quick Start- Instruct patient she can begin today; use backup method for 7 days.
b) Counseling – Discuss the management and expectations of side effects (bleeding irregularity, etc.)
c) Counseling - Discuss adherence and expectations for follow-up visits.

7a) Inquire of Healthcare Providers, Counsel, Notify Providers
a) If prescribe, notify primary care provider and OB/GYN; counsel patient to seek preventative care per protocol.
b) If no primary care provider, counsel on benefits of relationship and provide information per protocol.

Adopted 9/9/2020; Effective 1/3/2021

Virginia Algorithm for Pharmacists to Prescribe & Administer Depot Medroxyprogesterone Acetate

1) Pregnancy Screen
Review Pregnancy Screen section of Virginia Routine Hormonal Contraceptive Self-screening Questionnaire
If YES to at least one question and is free of pregnancy symptoms, proceed to next step.
If NO to All questions, pregnancy cannot be ruled out – Refer.

Possible Pregnancy → Refer; provide info per protocol if no PCP

Patient is not pregnant

2) Health and History Screen
Evaluate responses on Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire using CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use
1 or 2 (green boxes) = Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes) = Hormonal contraception is contraindicated – Refer.

Contraindicating Conditions/Medications → Refer; provide info per protocol if no PCP

No Contraindicating Conditions/Medications

3) Blood Pressure Screen
Is blood pressure < 140/90?
Note: Pharmacist may choose to take a second reading if initial is high.

BP > 140/90 → Refer; provide info per protocol if no PCP

BP < 140/90

4) Discuss DMPA therapy with patient
a) Address any unexplained vaginal bleeding that worries patient. Refer, when necessary.
b) Counseling- Discuss management and expectations of side effects (bleeding irregularity, etc.)
c) Counseling – Discuss plans for follow-up visits, particularly for q3 month administration DMPA; Stress importance of returning for next injection 11-13 weeks of previous injection. Provide patient with specific calendar date range for next injection.
d) Counseling – Caution with use of DMPA > 2 years (due to loss of bone mineral density). For therapy > 2 years, consultation with primary healthcare provider or OB/GYN is indicated.

First dose of DMPA

q 3 month dose of DMPA

5a) Issue prescription and administer DMPA
Pharmacist shall issue a prescription for depot medroxyprogesterone and administer the medication. Monitor patient for 20 minutes for adverse reaction.
Note: Instruct patient that if this injection is not within 7 days of start of period, then abstain or use backup method for 7 days.

5b) Ongoing administration of DMPA
Pharmacist shall confirm that date of last injection was within 11 weeks.
- If > 13 weeks, then pharmacist must rule out pregnancy (refer to Pregnancy Screening section on *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire*), and instruct patient to abstain or use backup method for 7 days.
- If between 11-13 weeks ago, administer the medication.

7a) Inquire of Healthcare Providers, Counsel, Notify Providers
a) If prescribe, notify primary care provider and OB/GYN; counsel patient to seek preventative care per protocol.
b) If no primary care provider, counsel on benefits of relationship and provide information per protocol.

VIRGINIA BOARD OF PHARMACY

TUBERCULIN SKIN TESTING ONE-STEP PROTOCOL

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration, and interpretation of the Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing, administration, and interpretation of TST under this protocol, the pharmacist(s) must successfully complete the following training:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection[2] or from a comparable provider approved by the Virginia Board of Pharmacy

Records documenting completion of required training shall be maintained by the pharmacist for a minimum of six years following the last patient encounter pursuant to this protocol or subsequent iterations for which the training is required. The training records may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either onsite or offsite. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Prior to initiating the dispensing, administration, and interpretation of TST under this protocol, the pharmacist(s) must understand and follow procedures as specified by:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing
- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations[3]: Sections 1 and 2

[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm.**

[2] CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf

[3] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations

- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019[4]
- High Burden TB Country List, Virginia Department of Health[5]

INCLUSION CRITERIA

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration, and interpretation of TSTs to adults aged ≥ 18 years who:

- Are at increased risk for latent or active tuberculosis disease
- Need TST documented for school attendance, occupational requirements, insurance purposes, or other administrative purposes

EXCLUSION CRITERIA

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month[6] (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a documented positive TST
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)
- History of documented previous Bacilli Calmette-Guerin (BCG) vaccine

CONSIDERATIONS

- Individuals from high-burden TB countries may have received the BCG vaccination and not remember, this should be considered when administering the TST.

(NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration

[4] Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[5] High Burden TB Country List, Virginia Department of Health. Available at: https://www.vdh.virginia.gov/tuberculosis/screening-testing/

[6] Fact Sheets: Tuberculin Skin Testing. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.
- Individuals who are contacts of a confirmed positive TB case may seek testing from a pharmacist. If a pharmacist becomes aware of this during the risk assessment, notification shall be made to the local health department. TST may still be performed.

MEDICATIONS

This protocol authorizes pharmacists to administer TST antigen, also known as purified protein derivative (PPD), read, and interpret the TST. The TST is one of two standard methods for determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

Product	Mfr. / Dist.	NDCs*
Tubersol	Sanofi Pasteur	1mL (10 tests) = 49281-752-21 5mL (50 tests) = 49281-752-22
Aplisol	Parkdale	1 mL (10 tests) = 42023-104-05 5mL (50 tests) = 42023-104-05

**or any other FDA-approved tuberculin skin test antigen*

PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct a TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined in this protocol and in the American Thoracic Society (ATC)/CDC Guideline.[1] A risk assessment should be conducted by the pharmacist prior to initiation of the TST. The form in Appendix A can be used to complete the risk assessment. This assessment should not be self-administered by the client. The Report of Tuberculosis Screening in Appendix B must be completed at the conclusion of the screening. The Report (Appendix B) may be provided to the patient and may be subsequently provided to an employer, if necessary, and authorized by the patient. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix C for detailed procedures for placing the TST).

PROCEDURES FOR MONITORING AND FOLLOW UP

The skin test reaction should be read between 48 and 72 hours after administration. Schedule an appointment for the reading at the time the TST is administered. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations (NTCA/NTSC, 2021) [3] (Appendix D). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), patients must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

COUNSELING REQUIREMENTS

Individuals receiving TST will receive counseling regarding:

- Need to return in 48-72 hours for interpretation of the TST
- If mild itchiness occurs, avoid scratching the site. Do not use creams or other treatments to treat the itchiness.
- Redness may develop. This is a normal reaction, avoid using creams or other treatments.
- Result of the TST
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

DOCUMENTATION

Pharmacists will document via prescription or medical record each person who receives a TST under this protocol including:

1. Documentation for the dispensing of prescription medication; and documentation that the individual receiving the TST was provided with the required counseling and referral information pursuant to this protocol.
2. Documentation of the completion of the risk assessment, date and time of test placement, date and time of test reading, results and interpretation must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of the test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as a requirement of employment. The Report of TB Screening is included in Appendix B. The individual should sign a release of information indicating the individual's consent that this information can be shared (refer to the Patient Authorization section in Appendix A).
4. Certain laws or regulations may preclude a pharmacist from signing documentation for an individual to certify the individual has been examined and is free of tuberculosis. This should be ascertained prior to administration of the TST. The individual may have to be referred back to their primary care provider to obtain necessary certification.

NOTIFICATION AND REFERRAL

Prior to screening the patient for TB, the patient must complete and sign the Patient Authorization section of Appendix A authorizing the pharmacist to notify the primary health care provider or local health department of a positive TST result. If the patient refuses such authorization, the pharmacist shall not screen the patient for TB and shall refer the patient to a primary health care provider for evaluation. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist who administers PPD for a TST shall notify the patient's primary health care provider that the pharmacist has administered a TST and inform the provider of the test results within three (3) business days, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider andprovide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in

which the patient is located.
Note: A pharmacy may create and use an electronic format of this protocol if the questions and process are identical to the Board-adopted protocol.

VIRGINIA BOARD OF PHARMACY TUBERCULOSIS RISK ASSESSMENT FORM
(For Pharmacist Use When Screening Patient; Not intended to be a Self-Screening Document)

Name: _____ Today's Date: _____ Weight: _____
Date of Birth: _____ Age: _____ Healthcare Provider's Name: _____
Healthcare Provider's Telephone, Fax, or Email:_____
Any Allergies to Medications? *Yes / No* If yes, list here: _____

Are you required to have a Tuberculosis (TB) Risk Assessment or Tuberculin Skin Test (TST) for your job, school, or other mandatory reason? Yes □ No□
If yes, specify reason? _____

If YES, ensure pharmacists may legally sign document certifying assessment or TST results for intended purpose. If pharmacist may not legally certify, refer patient to PCP.
If NO, proceed with completing form.

Patient Authorization:
I hereby authorize the pharmacist to perform the TB Risk Assessment and administer the TST, if warranted. I agree that the results of this test may be shared with other health care providers. I acknowledge that I have received the Notice of Privacy Practices. I understand that: this information will be used by health care providers for care and not for statistical purposes only; this information will be kept confidential; medical records must be kept at a minimum of six years following the last patient encounter except for (i) records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative, or (ii) records that are required by contractual obligation or federal law to be maintained for a longer period of time.

I agree to return to the pharmacy located at _____
to have the results of the test read by the pharmacist on this date_____.

I further authorize the pharmacist to notify the following of a positive TB Skin Test (choose one):

☐Primary Care Physician:_____ _____
(First & Last Name) (Tel. #)
☐ Local Free Clinic ☐ Local Federally-Qualified Healthcare Center

*Patient Printed Name:*_____ *Date:*_____
*Patient Signature:*_____ *Date:*_____

If patient does not agree to Patient Authorization section, refer patient to PCP.

Screening for TB Symptoms:

1.	Do you have coughing that has lasted for more than 3 weeks?	Yes □ No□
2.	Are you coughing up blood or mucous?	Yes □ No□
3.	Do you have a fever? Temperature reading:_____	Yes □ No□
4.	Have you experienced unintentional weight loss?	Yes □ No □
5.	Do you have a loss of appetite? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
6.	Are you experiencing night sweats? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
7.	Do you have fatigue? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
If patient answered YES to at least one of the questions above (taking 5, 6, and 7 in context), stop here and refer patient to PCP. If patient answered NO to all of the questions above, proceed with completing this form.		

Screening for TB History:

8.	Have you ever been treated for TB Disease/Latent Tuberculosis Infection (LTBI)?	Yes □ No□

9.	Have you ever had a documented prior positive test for TB infection? If yes, date of positive test (if known):_____ Type of Test: ☐ TST/IGRA ☐ TST Reading:_____mm If yes to prior positive test, did you have a chest radiograph performed after the positive test? CXR date (if known):_____ Results: ☐ Normal ☐ Abnormal If chest radiograph was normal after positive test, did you receive LTBI treatment?	Yes □ No□ Yes □ No□ Yes □ No□
If YES to prior positive TB test, those seeking testing for administrative purposes must have documentation of the past prior positive TB test otherwise testing will still be required for work clearance. If YES to prior positive TB test, and NO subsequent chest radiograph performed, refer patient to PCP. If YES to prior positive TB test and YES to subsequent NORMAL chest radiograph, no repeat TB testing is indicated if asymptomatic; refer for LTBI treatment if previously untreated. If NO prior positive TB test, proceed with completing this form.		
Screening for TB Infection Risk		
10.	Have you had close contact to someone with known or suspected active TB disease at any time? Name of source case:_____	Yes □ No□
If YES, report to local health department. TST may still be performed. If NO, proceed with completing this form.		
Screening for High Burden TB Countries:		
11.	Were you born in a country outside of the United States? If yes, which country? _____	Yes □ No□
12.	Have you traveled or resided in a country outside of the United States for 3 months or longer? If yes, which country? _____	Yes □ No□
13.	Have you traveled or resided in a country outside of the United States for the purpose of receiving medical treatment? If yes, which country? _____	Yes □ No□
Refer to current VDH High Burden TB Countries list. If YES and born in or traveled to/resided in country on list ≥ 3 months, refer to BCG vaccination status. If BCG vaccinated, refer for IGRA. For others, TST may still be performed. If NO or country did not appear on list, proceed with completing this form.		
Screening for BCG		
14.	Were you ever administered the BCG vaccination?	Yes □ No□
If YES, refer. If NO, proceed with completing form.		
Assessing Other Risks for Acquiring LTBI		
15.	Do you reside or work in a high TB risk congregate setting (e.g., correctional facility, nursing home, and long-term care facilities for elderly, mentally ill, or persons living with AIDS)?	Yes □ No □
16.	Are you a healthcare worker who serves high-risk clients? ***NOTE: Stop and refer patient to local health department if screening is part of an ongoing contact investigation within the facility approved by the local health department.***	Yes □ No □
17.	Have you experienced homelessness within the past two years?	Yes □ No □
18.	Do you inject drugs for recreational use or use crack cocaine?	Yes □ No □
19.	Do you have a regular health care provider? Have you received medical care within the last two years? ***If NO to both questions, patient is considered medically underserved.***	Yes □ No □ Yes □ No □
If YES to any of the questions (#15-18) or if the patient is medically underserved, and screening is NOT part of an ongoing contact investigation within a facility approved by the local health department, a TST is indicated. If NO to questions #15-18 and patient is not medically underserved, proceed with completing form.		
Assessing Risk for Developing TB Disease if Infected		
20.	Have you been diagnosed with HIV infection?	Yes □ No □

21.	Are you at risk for HIV infection? ***If YES, recommend an HIV test. Administer TST even if patient refuses HIV test or consider referral for IGRA testing.***	Yes □ No □
22.	Were you recently infected with Mycobacterium tuberculosis?	Yes □ No □
23.	Do you have any of the following medical conditions: - Low body weight due to chronic malabsorption syndromes? - Lung disease silicosis caused by breathing in tiny bits of silica? - Diabetes? - End stage renal disease or on hemodialysis? - Head or neck cancer? - Leukemia? - Lymphoma? - Hematologic or reticuloendothelial disease?	 Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □
24.	Have you ever had any of the following procedures: - Gastrectomy? - Intestinal bypass? - Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)?	 Yes □ No □ Yes □ No □ Yes □ No □
25.	Do you receive treatment with TNF-alpha antagonists (e.g., infliximab, etanercept), steroids (equivalent of prednisone ≥ 15mg/day for ≥ 1 month) or other immunosuppressive medication?	Yes □ No□
If YES to any of the questions in this section, TST test is indicated. If YES to HIV positive questions or on immunosuppressive therapy, consider referal for IGRA testing.		
Note: Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment.		

Report of Tuberculosis Screening

Name: _____ Date of Birth: _____ Date: _____

TO WHOM IT MAY CONCERN: The above individual has been evaluated by (PRINT OR TYPE):
Name of Pharmacist: _____
Name of Pharmacy: _____ Tel. #:_____
Pharmacy Address: _____
TB Screening and/or Testing Conclusions

I. No Symptoms or Risks Identified on TB Risk Assessment

☐ A tuberculin skin test (TST) is not indicated at this time due to the absence of symptoms suggestive of active TB, no risk factors identified for infection or for developing active TB if infected, and no known recent contact with active TB. Health care workers employed in a low risk facility according to CDC "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" do not need annual testing.

☐ The individual has a history of TB infection. Follow-up chest x-ray is not indicated at this time due to the absence of symptoms suggestive of active TB.

If one of these two statements applies, select the appropriate statement and skip to section IV and select statement "A".
If neither statement applies, go to section II.
If in a health care setting that requires a test for TB infection but no symptoms are present, go to Section III.

II. Symptoms Consistent with Potential Tuberculosis are Present

Call the local health department to refer the person for further TB evaluation immediately. This notification is necessary even when the individual prefers to pursue an evaluation privately. Advise of isolation precautions. Proceed to section IV and select statement "B". If there are no symptoms consistent with TB, go to section III.

III. Testing for TB Infection via Tuberculin Skin Test (record both tests if a 2-step TST was required)

#1 TST Lot: _____ Date Administered: _____ Time: _____Site: _____
Pharmacist Name: _____
Date read: _____ Time: _____Results: _____mm Interpretation: Negative ☐ Positive ☐
Pharmacist Name: _____

#2 TST Lot: _____ Date Administered: _____ Time: _____ Site: _____
Pharmacist Name: _____
Date read: _____ Time:_____Results: _____mm Interpretation: Negative ☐ Positive ☐
Pharmacist Name: _____

If test(s) above are negative, proceed to section IV and select statement "A".
If test(s) above are positive, proceed to section IV and select statement "B".

IV. TB Screening/Testing Conclusion

☐ A. Based on the TB Screening and/or TST, the individual listed above does not demonstrate a risk of having tuberculosis in a communicable form.

☐ B. Active tuberculosis cannot be ruled out in the individual listed above. The individual was counseled and referred to (check all that apply):

☐Primary Care Provider (Name): _____ (Tel.) _____
☐ Local Health Department (Name):_____ (Tel.) _____
☐ Provided Contact Information for Primary Health Care Providers

This individual should be treated by a PCP for:

☐ Evaluation for Active TB Disease Based on Symptoms *(pharmacist must immediately call local health department);*
☐ Prior Positive Test with No Subsequent Normal Chest Radiograph;
☐ Prior Positive Test with Normal Chest Radiograph, but LTBI Previously Untreated;
☐ IGRA since Individual Born in High Burden TB Country;
☐ IGRA since Individual has Received BCG;
☐ IGRA since Individual is Immunocompromised or on Immunosuppressive Therapy;
☐ Positive TST Result.

Appendix F. Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

Date _____ *Trainer (QC by)* _____ *Trainee (TST placed by)* _____

Scoring: ✓ *or Y = Yes* *X or N = No* *NA = Not Applicable*

1. Preliminary

_____ Uses appropriate hand hygiene methods before starting.
_____ Screens patient for contraindications (severe adverse reactions to previous TST).*
_____ Uses well-lit area.

2. Syringe† filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen§

_____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.¶
_____ Checks label and expiration date on vial.
_____ Marks opening date on multidose vial.
_____ Fills immediately after vial removed from refrigeration.
_____ Cleans vial stopper with antiseptic swab.
_____ Twists needle onto syringe to ensure tight fit.
_____ Removes needle guard.
_____ Inserts needle into the vial.
_____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.
_____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
_____ Removes needle from vial.
_____ Returns antigen vial to the refrigerator immediately after filling.

3. TST administration site selected and cleaned

_____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**
_____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.
_____ Cleans the site with antiseptic swab using circular motion from center to outside.
_____ Allows site to dry thoroughly before administering antigen.

4. Needle inserted properly to administer antigen

_____ Rests arm on firm, well-lit surface.
_____ Stretches skin slightly.††
_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ Advances needle until entire bevel is under the first layer of skin.
_____ Releases stretched skin.
_____ Injects entire dose slowly.
_____ Forms wheal, as liquid is injected.
_____ Removes needle without pressing area.
_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____mm).
_____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
_____ Discards used gauze or cotton ball according to local standard precautions.
_____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
_____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
_____ Uses appropriate hand hygiene methods after placing TST.

5. Explanation to the client regarding care instructions for the injection site

_____ The wheal (bump) is normal and will remain about 10 minutes.
_____ Do not touch wheal; avoid scratching.
_____ Avoid pressure or bandage on injection site.
_____ Rare local discomfort and irritation does not require treatment.
_____ May wash with soap and water (without pressure) after 1 hour.
_____ No lotions or liquids on site, except for light washing, as above.
_____ Keep appointment for reading.

* Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

† Use a ¼–½-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

§ Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95.

¶ Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid–containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:662–4.

** If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site.
SOURCE: National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

†† Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

Appendix F. (*Continued*) Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

Date _____ **Trainer (QC by)** _____ **Trainee (TST placed by)** _____

Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable

1. Preliminary

_____ Uses appropriate hand hygiene methods before starting.
_____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
_____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
_____ Uses well-lit area.
_____ Inspects for the site of the injection.

2. Palpate — finding margin ridges (if any)

_____ Palpates with arm bent at elbow at a 90° angle.
_____ Lightly sweeps 2-inch diameter from injection site in four directions.
_____ Uses zigzag featherlike touch.
_____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

If induration is present, continue with these steps†:

3. Placing marks

_____ Holds palm over injection site.
_____ Cleanse site with antiseptic swab using circular motion from center to outside.
_____ Uses fingertips to find margins of the induration.
_____ Marks the induration by placing small dots on both sides of the induration.
_____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.
_____ Marks dots transverse (perpendicular) to long axis of forearm.

4. Placing and reading ruler

_____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
_____ Uses appropriate hand hygiene methods after reading TST result.

5. Documenting results

_____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
_____ Correctly records results in mm; only a single measured induration in mm should be recorded.
Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.
† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).
§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

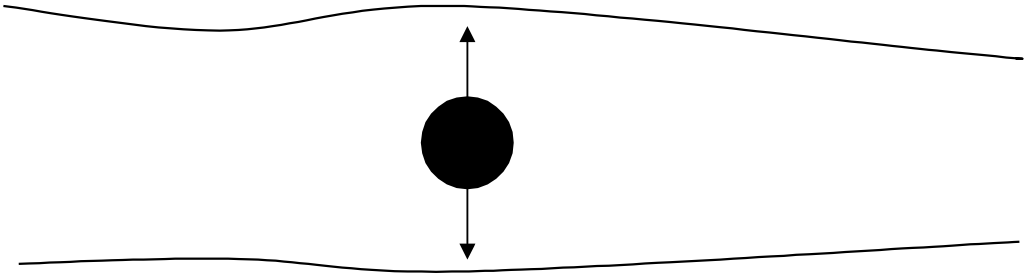
Classification of the Tuberculin Skin Test Reaction[1]

≥5 mm Induration	≥10 mm Induration	≥15 mm Induration
Considered positive in the following persons: ● Persons living with the human immunodeficiency virus (HIV) ● Recent contacts of a person with Tuberculosis (TB) disease ● Persons with a chest radiography (CXR) findings suggestive of previous TB disease ● Patients with organ transplants ● Persons who are immunosuppressed for other reasons (e.g., prolonged therapy with corticosteroids equivalent of ≥15 mg per day of prednisone for for 1 month or longer or those taking tumor necrosis factor-alpha [TNF-alpha] antagonists)	Considered positive in the following persons: ● Persons born in countries where TB disease is common including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB ● Persons with substance use disorders ● Mycobacteriology laboratory personnel ● Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities ● Persons with certain medical conditions that place them at high risk for TB, such as silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions ● Persons <90% of ideal body weight ● Children aged <5 years ● Infants, children, and adolescents exposed to adults in high-risk categories	Considered positive in any person, inducing persons with no known risk factors for TB.

*All tests should be interpreted based on patient risk and test characteristics.

A negative TST result does not exclude LTBI or active TB disease.

[1] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations, Appendix 1: Interpretation of Test Results.(NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6182608/2021-LTBI-Testing-Treatment-Publication-Registration



Measure TSTs Transversely

CDC LTBI: A Guide for Primary Health Care Providers

https://www.cdc.gov/tb/publications/ltbi/pdf/LTBIbooklet508.pdf

VIRGINIA BOARD OF PHARMACY

TUBERCULIN SKIN TESTING TWO-STEP PROTOCOL:
FOR INITIAL TESTING IN ADULTS WHO MAY BE UNDERGOING ANNUAL TESTING

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration, and interpretation of the Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control. The two-step testing will help in reducing the likelihood that a boosted reaction to a subsequent TST will be misinterpreted as a recent infection.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing, administration, and interpretation of a TST under this protocol, the pharmacist(s) must successfully complete the following training:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection[2] or from a comparable provider approved by the Virginia Board of Pharmacy

Records documenting completion of required training shall be maintained by the pharmacist for a minimum of six years following the last patient encounter pursuant to this protocol or subsequent iterations for which the training is required. The training records may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either onsite or offsite. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Prior to initiating the dispensing, administration, and interpretation of a TST under this protocol, the pharmacist(s) must understand and follow procedures as specified by:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing

[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm.**

[2] CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf

- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations[3]: Sections 1 and 2
- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019[4]
- High Burden TB Country List, Virginia Department of Health[5]

INCLUSION CRITERIA

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration, and interpretation of TSTs to adults aged ≥ 18 years who are receiving initial TB skin testing and may continue to receive an annual TST for employment purposes. The 2020 CDC Guidelines for Screening, Testing and Treatment of Healthcare Personnel no longer include a recommendation for serial screening for the majority of healthcare personnel after the initial screening, unless they fall into a particular high risk group (e.g., pulmonologists) or there is an exposure or on-going transmission at the healthcare facility[6].

EXCLUSTION CRITERIA

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to a TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month[7] (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a positive TST

[3]Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations (NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration

[4] Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[5] High Burden TB Country List, Virginia Department of Health. Available at: https://www.vdh.virginia.gov/tuberculosis/screening-testing/

[6] Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[7] Fact Sheets: Tuberculin Skin Testing. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

- History of documented previous Bacilli Calmette-Guerin (BCG) vaccine

CONSIDERATIONS

- Individuals from high-burden TB countries may have received the BCG vaccine and not remember, this should be considered when administering the TST.
- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.
- Individuals who are contacts of a confirmed positive TB case may seek testing from a pharmacist. If a pharmacist becomes aware of this during the risk assessment, notification shall be made to the local health department. TST may still be performed.

MEDICATIONS

This protocol authorizes pharmacists to administer tuberculin skin test antigen, also known as purified protein derivative (PPD), read, and interpret the TST. TST is one of two standard methods for determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

Product	Mfr. / Dist.	NDCs*
Tubersol	Sanofi Pasteur	1mL (10 tests) = 49281-752-21 5mL (50 tests) = 49281-752-22
Aplisol	Parkdale	1 mL (10 tests) = 42023-104-05 5mL (50 tests) = 42023-104-05

**or any other FDA-approved tuberculin skin test antigen*

PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct a TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined in this protocol and in the American Thoracic Society (ATS)/CDC Guideline.[1] In addition, the need for periodic retesting and the presence of individual risk factors for occupational exposures will be used to determine the need for two-step testing. A risk assessment should be conducted by the pharmacist prior to initiation of the TST. The form in Appendix A can be used to complete the risk assessment. This assessment should not be self-

administered by the client. The Report of Tuberculosis Screening in Appendix B must be completed at the conclusion of the screening. The Report (Appendix B) may be provided to the patient and may be subsequently provided to an employer, if necessary, and authorized by the patient. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix C for detailed procedures for placing the TST).

PROCEDURES FOR MONITORING AND FOLLOW UP

The skin test reaction should be read between 48 and 72 hours after administration. Schedule an appointment for the reading at the time the TST is administered. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in ATS/CDC Guideline[1] (Appendix D). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), patients must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

An initial positive reaction is considered a TB infection and a second TST is not required. The patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. An initial negative reaction requires a retest 1-3 weeks after the initial TST. Upon retesting, a negative reaction suggests the patient does not have a TB infection, in which case a TST can be repeated annually, if required. However, a positive reaction after retesting is considered a boosted reaction due to a TB infection that occurred a long time ago. In this case, the patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. A referral is required for this follow-up and so that treatment considerations can be made if latent TB infection is diagnosed (see Appendix E)[2].

COUNSELING REQUIREMENTS

Individuals receiving TST will receive counseling regarding:

- Need to return in 48-72 hours for interpretation of the TST
- If mild itchiness occurs, avoid scratching the site. Do not use creams or other treatments to treat the itchiness.
- Redness may develop. This is a normal reaction, avoid using creams or other treatments.
- Result of the TST
- Need for a second TST in 1-3 weeks if the initial result is negative
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

DOCUMENTATION

Pharmacists will document via prescription or medical record each person who receives a TST under this protocol including:

1. Documentation for the dispensing of prescription medication; and documentation that the individual receiving the TST was provided with the required education and referral information pursuant to this protocol.
2. Documentation of the completion of the risk assessment, date and time of test placement, date and time of test reading, results and interpretation must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of the test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as a requirement of employment. The Report of TB Screening is included in Appendix B. The individual should sign a release of information indicating their consent that this information can be shared (refer to the Patient Authorization section in Appendix A).
4. Certain laws or regulations may preclude a pharmacist from signing documentation for an individual to certify the individual has been examined and is free of tuberculosis. This should be ascertained prior to administration of the TST. The individual may have to be referred back to their primary care provider to obtain necessary certification.

NOTIFICATION AND REFERRAL

Prior to screening the patient for TB, the patient must complete and sign the Patient Authorization section of Appendix A authorizing the pharmacist to notify the primary health care provider or local health department of a positive TST result. If the patient refuses such authorization, the pharmacist shall not screen the patient for TB and shall refer the patient to a primary health care provider for evaluation. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist who administers PPD for a TST shall notify the patient's primary health care provider that the pharmacist has administered a TST and inform the provider of the test results within three (3) business days, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Note: A pharmacy may create and use an electronic format of this protocol if the questions and process are identical to the Board-adopted protocol.

VIRGINIA BOARD OF PHARMACY TUBERCULOSIS RISK ASSESSMENT FORM
(For Pharmacist Use When Screening Patient; Not intended to be a Self-Screening Document)

Name: _____ Today's Date: _____ Weight: _____
Date of Birth: _____ Age: _____ Healthcare Provider's Name: _____
Healthcare Provider's Telephone, Fax, or Email:_____
Any Allergies to Medications? *Yes / No* If yes, list here: _____

Are you required to have a Tuberculosis (TB) Risk Assessment or Tuberculin Skin Test (TST) for your job, school, or other mandatory reason? Yes □ No□
If yes, specify reason? _____

If YES, ensure pharmacists may legally sign document certifying assessment or TST results for intended purpose. If pharmacist may not legally certify, refer patient to PCP.
If NO, proceed with completing form.

Patient Authorization:
I hereby authorize the pharmacist to perform the TB Risk Assessment and administer the TST, if warranted. I agree that the results of this test may be shared with other health care providers. I acknowledge that I have received the Notice of Privacy Practices. I understand that: this information will be used by health care providers for care and not for statistical purposes only; this information will be kept confidential; medical records must be kept at a minimum of six years following the last patient encounter except for (i) records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative, or (ii) records that are required by contractual obligation or federal law to be maintained for a longer period of time.

I agree to return to the pharmacy located at _____
to have the results of the test read by the pharmacist on this date_____.

I further authorize the pharmacist to notify the following of a positive TB Skin Test (choose one):

☐Primary Care Physician:_____ _____
(First & Last Name) (Tel. #)
☐ Local Free Clinic ☐ Local Federally-Qualified Healthcare Center

*Patient Printed Name:*_____ *Date:*_____
*Patient Signature:*_____ *Date:*_____

If patient does not agree to Patient Authorization section, refer patient to PCP.

Screening for TB Symptoms:

1.	Do you have coughing that has lasted for more than 3 weeks?	Yes □ No□
2.	Are you coughing up blood or mucous?	Yes □ No□
3.	Do you have a fever? Temperature reading:_____	Yes □ No□
4.	Have you experienced unintentional weight loss?	Yes □ No □
5.	Do you have a loss of appetite? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
6.	Are you experiencing night sweats? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
7.	Do you have fatigue? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
If patient answered YES to at least one of the questions above (taking 5, 6, and 7 in context), stop here and refer patient to PCP. If patient answered NO to all of the questions above, proceed with completing this form.		

Screening for TB History:

8.	Have you ever been treated for TB Disease/Latent Tuberculosis Infection (LTBI)?	Yes □ No□

9.	Have you ever had a documented prior positive test for TB infection? If yes, date of positive test (if known):_____ Type of Test: ☐ TST/IGRA ☐ TST Reading:_____mm If yes to prior positive test, did you have a chest radiograph performed after the positive test? CXR date (if known):_____ Results: ☐ Normal ☐ Abnormal If chest radiograph was normal after positive test, did you receive LTBI treatment?	Yes □ No□ Yes □ No□ Yes □ No□
If YES to prior positive TB test, those seeking testing for administrative purposes must have documentation of the past prior positive TB test otherwise testing will still be required for work clearance. If YES to prior positive TB test, and NO subsequent chest radiograph performed, refer patient to PCP. If YES to prior positive TB test and YES to subsequent NORMAL chest radiograph, no repeat TB testing is indicated if asymptomatic; refer for LTBI treatment if previously untreated. If NO prior positive TB test, proceed with completing this form.		
Screening for TB Infection Risk		
10.	Have you had close contact to someone with known or suspected active TB disease at any time? Name of source case:_____	Yes □ No□
If YES, report to local health department. TST may still be performed. If NO, proceed with completing this form.		
Screening for High Burden TB Countries:		
11.	Were you born in a country outside of the United States? If yes, which country? _____	Yes □ No□
12.	Have you traveled or resided in a country outside of the United States for 3 months or longer? If yes, which country? _____	Yes □ No□
13.	Have you traveled or resided in a country outside of the United States for the purpose of receiving medical treatment? If yes, which country? _____	Yes □ No□
Refer to current VDH High Burden TB Countries list. If YES and born in or traveled to/resided in country on list ≥ 3 months, refer to BCG vaccination status. If BCG vaccinated, refer for IGRA. For others, TST may still be performed. If NO or country did not appear on list, proceed with completing this form.		
Screening for BCG		
14.	Were you ever administered the BCG vaccination?	Yes □ No□
If YES, refer. If NO, proceed with completing form.		
Assessing Other Risks for Acquiring LTBI		
15.	Do you reside or work in a high TB risk congregate setting (e.g., correctional facility, nursing home, and long-term care facilities for elderly, mentally ill, or persons living with AIDS)?	Yes □ No □
16.	Are you a healthcare worker who serves high-risk clients? ***NOTE: Stop and refer patient to local health department if screening is part of an ongoing contact investigation within the facility approved by the local health department.***	Yes □ No □
17.	Have you experienced homelessness within the past two years?	Yes □ No □
18.	Do you inject drugs for recreational use or use crack cocaine?	Yes □ No □
19.	Do you have a regular health care provider? Have you received medical care within the last two years? ***If NO to both questions, patient is considered medically underserved.***	Yes □ No □ Yes □ No □
If YES to any of the questions (#15-18) or if the patient is medically underserved, and screening is NOT part of an ongoing contact investigation within a facility approved by the local health department, a TST is indicated. If NO to questions #15-18 and patient is not medically underserved, proceed with completing form.		
Assessing Risk for Developing TB Disease if Infected		
20.	Have you been diagnosed with HIV infection?	Yes □ No □

21.	Are you at risk for HIV infection? ***If YES, recommend an HIV test. Administer TST even if patient refuses HIV test or consider referral for IGRA testing.***	Yes □ No □
22.	Were you recently infected with Mycobacterium tuberculosis?	Yes □ No □
23.	Do you have any of the following medical conditions: - Low body weight due to chronic malabsorption syndromes? - Lung disease silicosis caused by breathing in tiny bits of silica? - Diabetes? - End stage renal disease or on hemodialysis? - Head or neck cancer? - Leukemia? - Lymphoma? - Hematologic or reticuloendothelial disease?	 Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □
24.	Have you ever had any of the following procedures: - Gastrectomy? - Intestinal bypass? - Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)?	 Yes □ No □ Yes □ No □ Yes □ No □
25.	Do you receive treatment with TNF-alpha antagonists (e.g., infliximab, etanercept), steroids (equivalent of prednisone ≥ 15mg/day for ≥ 1 month) or other immunosuppressive medication?	Yes □ No□
If YES to any of the questions in this section, TST test is indicated. If YES to HIV positive questions or on immunosuppressive therapy, consider referal for IGRA testing.		
Note: Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment.		

Report of Tuberculosis Screening

Name: _____ Date of Birth: _____ Date: _____

TO WHOM IT MAY CONCERN: The above individual has been evaluated by (PRINT OR TYPE):
Name of Pharmacist: _____
Name of Pharmacy: _____ Tel. #:_____
Pharmacy Address: _____
TB Screening and/or Testing Conclusions

I. No Symptoms or Risks Identified on TB Risk Assessment

☐ A tuberculin skin test (TST) is not indicated at this time due to the absence of symptoms suggestive of active TB, no risk factors identified for infection or for developing active TB if infected, and no known recent contact with active TB. Health care workers employed in a low risk facility according to CDC "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" do not need annual testing.

☐ The individual has a history of TB infection. Follow-up chest x-ray is not indicated at this time due to the absence of symptoms suggestive of active TB.

If one of these two statements applies, select the appropriate statement and skip to section IV and select statement "A".
If neither statement applies, go to section II.
If in a health care setting that requires a test for TB infection but no symptoms are present, go to Section III.

II. Symptoms Consistent with Potential Tuberculosis are Present

Call the local health department to refer the person for further TB evaluation immediately. This notification is necessary even when the individual prefers to pursue an evaluation privately. Advise of isolation precautions. Proceed to section IV and select statement "B". If there are no symptoms consistent with TB, go to section III.

III. Testing for TB Infection via Tuberculin Skin Test (record both tests if a 2-step TST was required)

#1 TST Lot: _____ Date Administered: _____ Time: _____Site: _____
Pharmacist Name: _____
Date read: _____ Time: _____Results: _____mm Interpretation: Negative ☐ Positive ☐
Pharmacist Name: _____

#2 TST Lot: _____ Date Administered: _____ Time: _____ Site: _____
Pharmacist Name: _____
Date read: _____ Time:_____Results: _____mm Interpretation: Negative ☐ Positive ☐
Pharmacist Name: _____

If test(s) above are negative, proceed to section IV and select statement "A".
If test(s) above are positive, proceed to section IV and select statement "B".

IV. TB Screening/Testing Conclusion

☐ A. Based on the TB Screening and/or TST, the individual listed above does not demonstrate a risk of having tuberculosis in a communicable form.

☐ B. Active tuberculosis cannot be ruled out in the individual listed above. The individual was counseled and referred to (check all that apply):

☐Primary Care Provider (Name): _____ (Tel.) _____
☐ Local Health Department (Name):_____ (Tel.) _____
☐ Provided Contact Information for Primary Health Care Providers

This individual should be treated by a PCP for:

☐ Evaluation for Active TB Disease Based on Symptoms *(pharmacist must immediately call local health department);*
☐ Prior Positive Test with No Subsequent Normal Chest Radiograph;
☐ Prior Positive Test with Normal Chest Radiograph, but LTBI Previously Untreated;
☐ IGRA since Individual Born in High Burden TB Country;
☐ IGRA since Individual has Received BCG;
☐ IGRA since Individual is Immunocompromised or on Immunosuppressive Therapy;
☐ Positive TST Result.

Appendix F. Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

Date _____ *Trainer (QC by)* _____ *Trainee (TST placed by)* _____

Scoring: ✓ *or Y = Yes* *X or N = No* *NA = Not Applicable*

1. Preliminary

_____ Uses appropriate hand hygiene methods before starting.
_____ Screens patient for contraindications (severe adverse reactions to previous TST).*
_____ Uses well-lit area.

2. Syringe† filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen§

_____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.¶
_____ Checks label and expiration date on vial.
_____ Marks opening date on multidose vial.
_____ Fills immediately after vial removed from refrigeration.
_____ Cleans vial stopper with antiseptic swab.
_____ Twists needle onto syringe to ensure tight fit.
_____ Removes needle guard.
_____ Inserts needle into the vial.
_____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.
_____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
_____ Removes needle from vial.
_____ Returns antigen vial to the refrigerator immediately after filling.

3. TST administration site selected and cleaned

_____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**
_____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.
_____ Cleans the site with antiseptic swab using circular motion from center to outside.
_____ Allows site to dry thoroughly before administering antigen.

4. Needle inserted properly to administer antigen

_____ Rests arm on firm, well-lit surface.
_____ Stretches skin slightly.††
_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ Advances needle until entire bevel is under the first layer of skin.
_____ Releases stretched skin.
_____ Injects entire dose slowly.
_____ Forms wheal, as liquid is injected.
_____ Removes needle without pressing area.
_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____mm).
_____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
_____ Discards used gauze or cotton ball according to local standard precautions.
_____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
_____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
_____ Uses appropriate hand hygiene methods after placing TST.

5. Explanation to the client regarding care instructions for the injection site

_____ The wheal (bump) is normal and will remain about 10 minutes.
_____ Do not touch wheal; avoid scratching.
_____ Avoid pressure or bandage on injection site.
_____ Rare local discomfort and irritation does not require treatment.
_____ May wash with soap and water (without pressure) after 1 hour.
_____ No lotions or liquids on site, except for light washing, as above.
_____ Keep appointment for reading.

* Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

† Use a ¼–½-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

§ Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95.

¶ Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid–containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:662–4.

** If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site.
SOURCE: National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

†† Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

Appendix F. (*Continued*) Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

Date _____ **Trainer (QC by)** _____ **Trainee (TST placed by)** _____

Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable

1. Preliminary

_____ Uses appropriate hand hygiene methods before starting.
_____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
_____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
_____ Uses well-lit area.
_____ Inspects for the site of the injection.

2. Palpate — finding margin ridges (if any)

_____ Palpates with arm bent at elbow at a 90° angle.
_____ Lightly sweeps 2-inch diameter from injection site in four directions.
_____ Uses zigzag featherlike touch.
_____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

If induration is present, continue with these steps†:

3. Placing marks

_____ Holds palm over injection site.
_____ Cleanse site with antiseptic swab using circular motion from center to outside.
_____ Uses fingertips to find margins of the induration.
_____ Marks the induration by placing small dots on both sides of the induration.
_____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.
_____ Marks dots transverse (perpendicular) to long axis of forearm.

4. Placing and reading ruler

_____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
_____ Uses appropriate hand hygiene methods after reading TST result.

5. Documenting results

_____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
_____ Correctly records results in mm; only a single measured induration in mm should be recorded.
Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.
† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).
§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

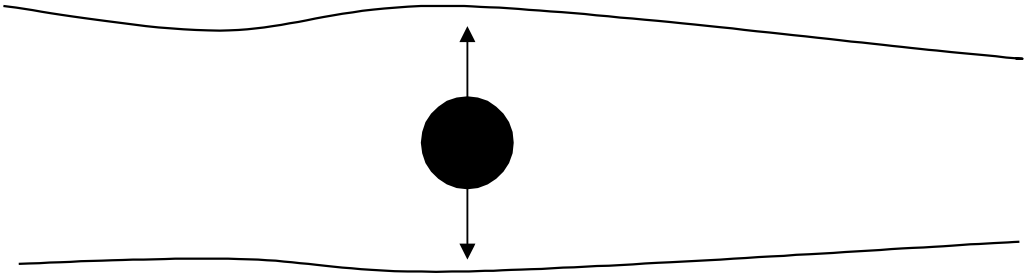
Classification of the Tuberculin Skin Test Reaction[1]

≥5 mm Induration	≥10 mm Induration	≥15 mm Induration
Considered positive in the following persons: ● Persons living with the human immunodeficiency virus (HIV) ● Recent contacts of a person with Tuberculosis (TB) disease ● Persons with a chest radiography (CXR) findings suggestive of previous TB disease ● Patients with organ transplants ● Persons who are immunosuppressed for other reasons (e.g., prolonged therapy with corticosteroids equivalent of ≥15 mg per day of prednisone for for 1 month or longer or those taking tumor necrosis factor-alpha [TNF-alpha] antagonists)	Considered positive in the following persons: ● Persons born in countries where TB disease is common including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB ● Persons with substance use disorders ● Mycobacteriology laboratory personnel ● Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities ● Persons with certain medical conditions that place them at high risk for TB, such as silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions ● Persons <90% of ideal body weight ● Children aged <5 years ● Infants, children, and adolescents exposed to adults in high-risk categories	Considered positive in any person, inducing persons with no known risk factors for TB.

*All tests should be interpreted based on patient risk and test characteristics.

A negative TST result does not exclude LTBI or active TB disease.

[1] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations, Appendix 1: Interpretation of Test Results.(NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration



Measure TSTs Transversely

CDC LTBI: A Guide for Primary Health Care Providers

https://www.cdc.gov/tb/publications/ltbi/pdf/LTBIbooklet508.pdf

Figure 1: The TST Booster Phenomenon

As the years pass, the person's ability to react to tuberculin lessens. Occurs mainly in previously infected older adults whose ability to react to tuberculin has decreased over time. These people should still be considered for LTBI treatment after ruling out TB disease, particularly if they have risk factors for progression to disease.

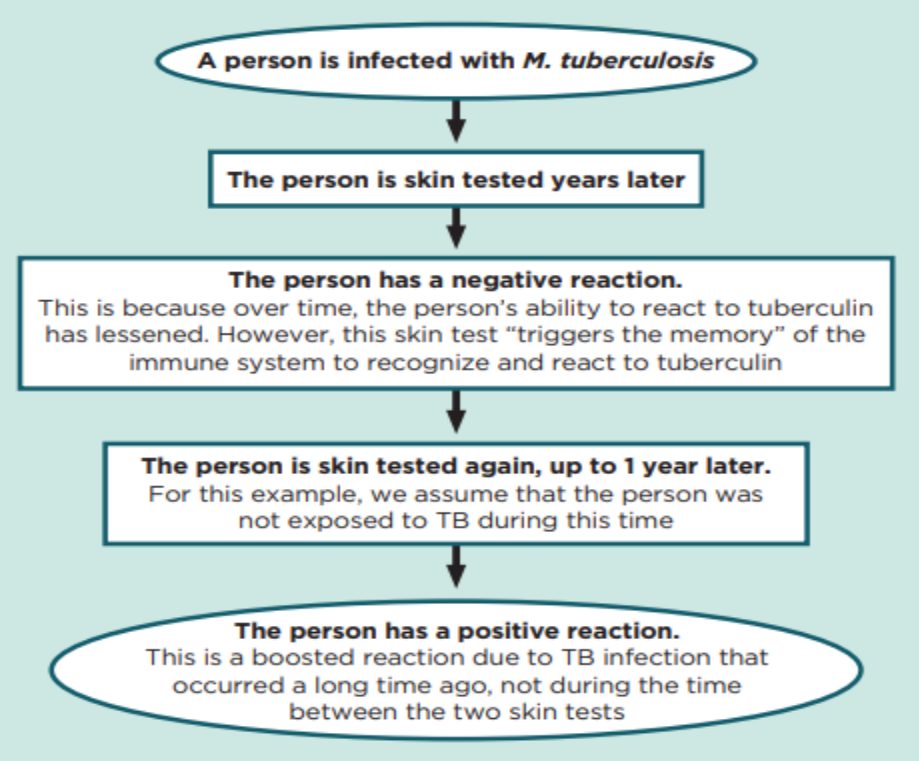
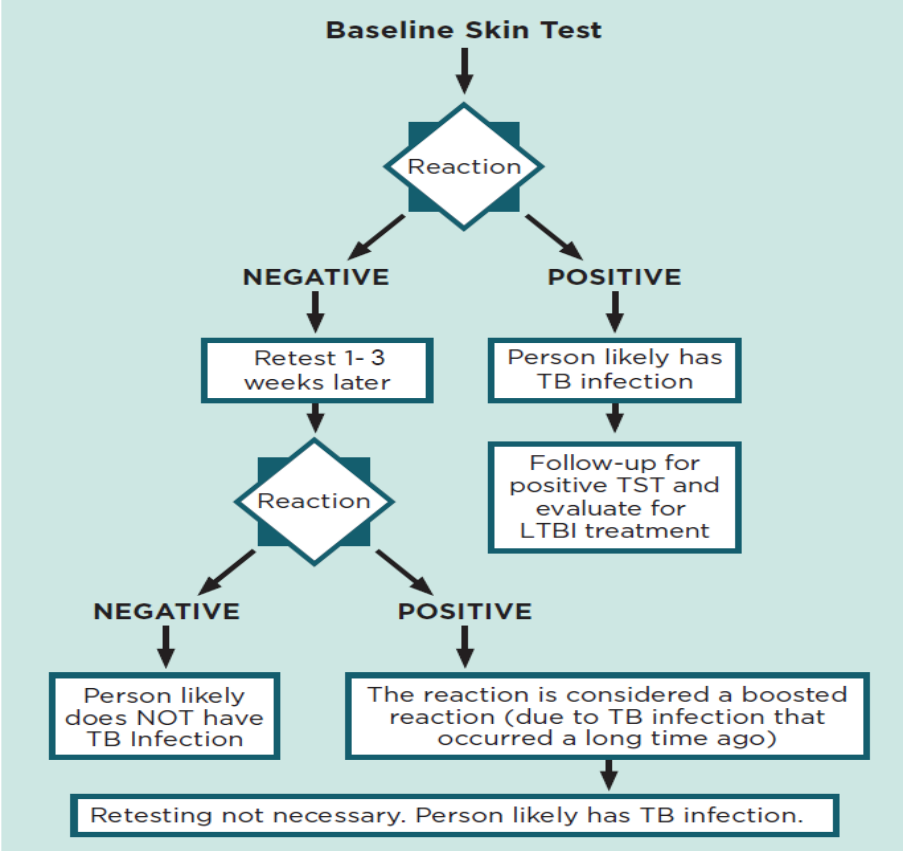


Figure 2: Two-Step TST Testing

Two-step testing is a strategy used to reduce the likelihood that a boosted reaction will be misinterpreted as a recent infection (Figure 2). Two-step testing should be used for the initial skin testing of persons who will be retested periodically. If the reaction to the first TST is classified as negative, a second TST should be repeated 1 to 3 weeks later. A positive reaction to the second TST likely represents a boosted reaction. Based on this second test result, the person should be classified as previously infected. This would not be considered a skin test conversion or a new TB infection; however, the patient may still be a candidate for LTBI treatment. If the second skin test result is also negative, the person should be classified as having a negative baseline TST result. **If either the first or second test result is positive, the individual should be referred for follow-up and evaluation for LTBI treatment.**


Baseline Skin Test
Reaction
NEGATIVE
POSITIVE
Retest 1- 3 weeks later
Person likely has TB infection
Follow-up for positive TST and evaluate for LTBI treatment
Reaction
NEGATIVE
POSITIVE
Person likely does NOT have TB Infection
The reaction is considered a boosted reaction (due to TB infection that occurred a long time ago)
Retesting not necessary. Person likely has TB infection.

Adopted: October 6, 2022
Effective: February 21, 2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Statewide Protocol for Tobacco Cessation

Consistent with Virginia Code § 54.1-3303.1, a pharmacist may initiate treatment with U.S Food and Drug Administration-approved Nicotine Replacement Therapy ("NRT") and other tobacco cessation therapies ("Non-NRT"), including controlled substances as defined in the Drug Control Act (Va. Code § 54.1-3400 et seq.), together with providing appropriate patient counseling.

PHARMACIST INITIATION OF TREATMENT

A licensed pharmacist may prescribe an individual 18 years of age or older NRT and Non-NRT for tobacco cessation.

PHARMACIST EDUCATION AND TRAINING

Pharmacists initiating treatment for tobacco cessation shall receive appropriate training to conduct the activity in a safe and effective manner. This includes a minimum of two hours of documented continuing education provided by the Accreditation Council for Pharmacy Education ("ACPE") related to pharmacists prescribing tobacco cessation products.

OBTAINING HISTORY

The pharmacist shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of tobacco cessation therapy.

RECORDKEEPING

The pharmacist shall maintain records in accordance with 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Tobacco Cessation Self-Screening Patient Intake Form

CONFIDENTIAL- Protected Health Information

Date_____/___/____ Date of Birth_____/___/_____ Age_____

Legal Name_____ Preferred Name _____

Sex Assigned at Birth (circle) M / **F** Gender Identification (circle) M / F / Other

Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____

Street Address_____

Phone ( ) _____ Email Address _____

Primary Care Provider _____ Phone ( ) _____ Fax ( ) _____

Do you have health insurance? Yes/ No Insurance Provider Name _____

Any allergies to medications? Yes/ No If yes, please list _____

Any allergies to foods (ex. menthol/soy)? Yes/ No If yes, please list _____

List of medicine(s) you take: _____

_____

Do you consent to the pharmacy notifying your primary care provider should medication be initiated? Yes/ No

Do you have a preferred tobacco cessation product you would like to use?_____

Have you tried quitting smoking in the past? If so, please describe _____

What best describes how you have tried to stop smoking in the past?

- ☐ "Cold turkey"
- ☐ Tapering or slowly reducing the number of cigarettes you smoke a day
- ☐ Medicine
  - o Nicotine replacement (like patches, gum, inhalers, lozenges, etc.)
  - o Prescription medications (ex. bupropion [Zyban®, Wellbutrin®], varenicline [Chantix®])
- ☐ Other _____

Health and History Screen - Background Information:

1.	Are you under 18 years old?	□Yes□ No
2.	Are you pregnant, nursing, or planning on getting pregnant or nursing in the next 6 months?	□Yes□ No□ Not sure
3.	Are you currently using and trying to quit non-cigarette products (ex. Chewing tobacco, vaping, e-cigarettes, Juul)?	□Yes□ No

Medical History:

4.	Have you ever had a heart attack, irregular heartbeat or angina, or chest pains in the past two weeks?	□ Yes □ No □ Not sure
5.	Do you have stomach ulcers?	□ Yes □ No □ Not sure
6.	Do you wear dentures or have TMJ (temporomandibular joint disease)?	□ Yes □ No □ Not sure
7.	Do you have a chronic nasal disorder (ex. nasal polyps, sinusitis, rhinitis)?	□ Yes □ No □ Not sure
8.	Do you have asthma or another chronic lung disorder (ex. COPD, emphysema, chronic bronchitis)?	□ Yes □ No □ Not sure

Tobacco History:

9.	Do you smoke between 0-4 cigarettes per day OR less than 1 can or pouch per week of snuff or chew?	□Yes□ No
10	Do you smoke between 5-10 cigarettes per day OR 1-2 cans or pouches per week of snuff or chew OR 3-6mg/ml e-liquid?	□Yes□ No
11	Do you smoke 11+ cigarettes per day OR 2 cans or pouches per week of snuff or chew OR 6-12+mg/ml e-liquid?	□Yes□ No

Tobacco Cessation Self-Screening Patient Intake Form
CONFIDENTIAL- Protected Health Information

Blood Pressure Reading _____/_____ mmHg *(Note: Must be taken by a pharmacist)*

Stop here if patient and pharmacist are considering nicotine replacement therapy or blood pressure is ≥ 160/100 mmHg.

If patient and pharmacist are considering non-nicotine replacement therapy (ex. varenicline or bupropion) and blood pressure is < 160/l00mmHg continue to answer the questions below.

Medical History Continued:

12.	Have you ever had an eating disorder such as anorexia or bulimia?	□Yes□ No□ Not sure
13.	Have you ever had a seizure, convulsion, significant head trauma, brain surgery, history of stroke, or a diagnosis of epilepsy?	□Yes□ No□ Not sure
14.	Have you ever been diagnosed with chronic kidney disease?	□Yes□ No□ Not sure
15.	Have you ever been diagnosed with liver disease?	□Yes□ No□ Not sure
16.	Have you been diagnosed with or treated for a mental health illness in the past 2 years? (ex. depression, anxiety, bipolar disorder, schizophrenia)?	□Yes□ No□ Not sure

Medication History:

17.	Do you take a monoamine oxidase inhibitor (MAOI) antidepressant? (ex. selegiline [Emsam®, Zelapar®], Phenelzine [Nardil®], Isocarboxazid [Marplan®], Tranylcypromine [Parnate®], Rasagiline [Azilect®])	□ Yes □ No □ Not sure
18.	Do you take linezolid?	□ Yes □ No □ Not sure
19.	Do you use alcohol or have you recently stopped taking sedatives? (ex. Benzodiazepines)	□ Yes □ No □ Not sure

The Patient Health Questionnaire 2 (PHQ 2):

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not At All	Several Days	More Than Half the Days	Nearly Every Day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3

Suicide Screening:

Over the last 2 weeks, how often have you had thoughts that you would be better off dead, or have you hurt yourself or had thoughts of hurting yourself in some way?	0	1	2	3

Patient Signature_____Date_____

Tobacco Cessation Assessment and Treatment Care Pathway

STEP 1: Health and History Screen Part 1 Review Tobacco Cessation Patient Questionnaire (Questions 1 -2)	No, continue to step 2	Yes/Not sure= If patient wants NRT, counsel per NRT dosing worksheet. If patient consents, initiate NRT and refer to Virginia Quit Line. 1- 800-QUIT-NOW
STEP 2: Health and History Screen Part 2 Review Tobacco Cessation Patient Questionnaire (Question 3)	Smoking Cigarettes, continue to step 3	Smokeless tobacco, continue to step 3 and consider varenicline
STEP 3: Blood Pressure Screen Take and document patient's current blood pressure. (Note: RPh may choose to take a second reading if initial is high)	BP< 160/100, continue to step 4	BP ≥ 160/100, continue to step 4 but inform PCP of reading if drug initiated.
STEP 4: Medical History Nicotine Replacement Therapy Questions (Questions 4-5)	No, to question 4 and 5. Continue to step 5	Yes, to question 4 and/or 5, refer to PCP and Virginia Quit Line. 1-800-QUIT-NOW
STEP 5: Medical History & Tobacco History Nicotine Replacement Therapy Questions (Questions 6-11)	If patient wants NRT, initiate per NRT dosing guideline for low, medium, or high nicotine use (questions 9-11) & take questions 6-8 into consideration. Question 6= if yes, avoid nicotine gum; Question 7 = if yes, avoid nicotine nasal spray; Question 8 = if yes, avoid nicotine inhaler.	For smokeless tobacco or if patient wants bupropion or varenicline, continue to step 6.
STEP 6: Medical History Bupropion and varenicline screening Questions 12-16	Yes to any question 12-16, consider NRT. Continue to step 7.	
	a) If yes to any question 12-16, avoid bupropion. If patient still wants bupropion, refer to PCP and Virginia Quit Line. 1- 800-QUIT-NOW	
	b) If yes to any question from 14-16, avoid varenicline. If patient still wants varenicline, refer to PCP & Virginia Quit Line. 1- 800-QUIT-NOW	
	c) If yes to question 12 and/or 13, but no to questions 14-16 AND wants varenicline, skip to step 8.	
	No to questions 12-16, continue to step 7.	
Step 7: Medication History Questions 17-19	No to questions 17-19, review depression screening in step 8.	
	Yes to any question from 17-19, avoid bupropion. If patient still wants bupropion, refer to PCP & Virginia Quit Line. 1- 800-QUIT-NOW	
	Yes to any question from 17-19 and patient wants varenicline, continue to depression screening in step 8.	
STEP 8: The Patient Health Questionnaire 2 (PHQ 2) Depression Screening	Score < 3 on PHQ2. Review Suicide Screening in step 9.	Score ≥ 3 on PHQ 2, avoid bupropion and varenicline. Refer to PCP for treatment and Virginia Quit Line. 1- 800-QUIT-NOW NRT can be offered.
STEP 9: Suicide Screening	Score of 0 on suicide screening. May prescribe bupropion or varenicline per dosing guideline and refer to Virginia Quit Line. 1- 800-QUIT-NOW	Score of ≥1 on suicide screening, **immediate** referral to PCP by calling PCP office & notifying of positive suicide screening. After hours, refer to suicide hotline 1-800-273-8255.

Dosing Guidelines

Nicotine Replacement Therapy (NRT) Dosing:

	High Nicotine Use	Medium Nicotine Use	Low Nicotine Use
•Initiate therapy based on maximum use of nicotine/day at therapy initiation. •Combination Nicotine Replacement Therapy is strongly recommended. Monotherapy may also be appropriate. •Therapy choice should be based on time to first use, quantity, patient preference and comorbidities, data from past attempts, and desired quit date. •**NRT use in women who are pregnant or breastfeeding**: the patient should be educated on the risks or smoking or vaping versus the unknown risks of NRT. If the patient consents to NRT, then intermittent delivery formulations (gum, lozenge or inhaler) are believed to be safer than continuous delivery (avoid use of Transdermal Dermal patch). If the patient is pregnant, educate on importance of PCP/OBGyn for further prenatal care.	11+ cigarettes per day OR ≥ 2 cans or pouches per week of snuff or chew OR 6-12+mg/ml e-liquid	5-10 cigarettes per day OR 1 to 2 cans or pouches per week of snuff or chew OR 3-6mg/mL e-liquid	0-4 cigarettes per day OR less than 1 can or pouch per week of snuff or chew
	Per Product Label: •Nicotine Patch 21mg/24hrs for 8 weeks. Then, •Nicotine Patch 14mg/24hrs for 2 weeks. Then, •Nicotine Patch 7mg/24hrs for 2 weeks. **AND/OR any of the following as needed** NRT products •Nicotine Gum 4mg every hour as needed for cravings. (Max 20 pieces/day) x 12 weeks. OR •Nicotine lozenge 4mg every hour as needed for cravings. (Max 15/day) x 12 weeks. OR •Nicotine Oral Inhaler Puff 6-16 cartridges per day as needed for cravings x12 weeks. OR •Nicotine Nasal Inhaler 1-2 doses/hour; 8-40 doses per day as needed for cravings x 12 weeks.	Per Product Label: •Nicotine Patch 14mg/24hrs for 8 **weeks**. Then, •Nicotine Patch 7mg/24hrs for 4 Weeks. **AND/OR any of the following as needed** NRT products •Nicotine Gum 2mg every hour as needed for cravings. (Max 20 pieces/day) x 12 weeks. OR •Nicotine lozenge 2mg every hour as needed for cravings. (Max 15/day) x 12 weeks. OR •Nicotine Oral Inhaler Puff 6-16 cartridges per day as needed for cravings x12 weeks. OR •Nicotine Nasal Inhaler 1-2 doses/hour; 8-40 doses per day as needed for cravings x 12 weeks.	Per Product Label: •Nicotine Gum 2mg every hour as needed for cravings. (Max 20 pieces/day) x 12 weeks. OR •Nicotine lozenge 2mg every hour as needed for cravings. (Max 15/day) x 12 weeks. OR •Nicotine Oral Inhaler Puff 6-8 cartridges per day as needed for cravings *x* 12 weeks. OR •Nicotine Nasal Inhaler 1-2 doses/hour; 8-20 doses per day as needed for cravings x 12 weeks.
Additional Pearls	• **Nicotine Patches:** Adjustment may be required during initial treatment (move to higher dose if experiencing withdrawal symptoms; lower dose if side effects are experienced). • **Nicotine Inhaler**: If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation. *Discontinuation of therapy:* After initial treatment, gradually reduce daily dose over 6 to 12 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly. • **Nasal Spray**: Adjust dose as needed based on patient response; do not exceed more than 5 doses (10 sprays) per hour [maximum: 40 mg/day (80 sprays)] or 3 months of treatment. If using nicotine nasal spray alone without nicotine patches, for best results, use at least the recommended minimum of 8 doses per day (less is likely to be effective). Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation. *Discontinuation of therapy:* Discontinue over 4 to 6 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.		

Dosing Guidelines

Non-Nicotine Replacement Therapy Dosing:

Prescribing Bupropion

- 150mg SR daily for 3 days then 150mg SR twice daily for 8 weeks or longer. Quit day after day 7.
- Consider combining with Nicotine patch or Nicotine lozenge or Nicotine gum for increased efficacy.
- For patients who do not tolerate titration to the full dose, consider continuing 150mg once daily as the lower dose has shown efficacy.

Prescribing Varenicline

- 0.5mg daily for 3 days then 0.5mg twice daily for 4 days then 1mg twice daily for 12 to 24 weeks. Quit day after day 7 or alternatively quit date up to 35 days after initiation of varenicline.
- Generally not used in combination with other smoking cessation medications as first line therapy.
- Advise patient to limit alcohol use while taking varenicline until known if it affects patient's ability to tolerate alcohol.

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for Suspected Acute Uncomplicated Lower Urinary Tract Infection in Women

Pursuant to § 54.1-3303.1, a pharmacist may initiate CLIA-waived point-of-care testing for acute uncomplicated lower urinary tract infections (UTI) in women and, when diagnostically confirmed, initiate the dispensing of antibiotics to treat the infection for persons 18 years of age or older.

A pharmacist may not initiate assessment or testing unless sufficient antibiotics are readily available to treat acute UTI infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antibiotic therapies under this Protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy. Additionally, the pharmacist shall maintain knowledge of the current Infectious Disease Society of America (IDSA)'s Guidelines for the treatment of Uncomplicated Cystitis and Pyelonephritis (UTI) and the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin for the Treatment of Urinary Tract Infections in Nonpregnant Women. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures and destruction of biohazard materials.

In addition, a pharmacist shall ensure that a private restroom is available for collecting the patient specimen and appropriate procedures are in place to prevent contamination of the specimen and ensure proper cleaning of the restroom.

Informed consent shall include ensuring that the patient understands that this Protocol does not include treating yeast infection, detecting drugs of abuse, detecting pregnancy, produce a urine culture, etc.

PATIENT INCLUSION CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotic therapy to treat UTI shall treat patients according to current IDSA guidelines.

Pharmacists shall assess a patient based on the inclusion and exclusion criteria below based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

Any patient who presents to the pharmacy and meets **all** of the following criteria:

- Female patient ≥18 years of age but <65 years, and able to give informed consent;
- Prior history of UTI(s);
- One or more of the following symptoms: dysuria, increased frequency, and/or urgency; and
- Positive urine dipstick for nitrites or leukocytes via a CLIA-waived point-of-care detection test kit.

PATIENT EXCLUSION CRITERIA

Any patient who meets **any** of the following criteria:

- Male;
- Pregnant or breastfeeding;
- Post-menopausal;
- Vaginitis symptoms (e.g., vaginal discharge or itching);
- Symptom onset >7 days prior;
- Immunocompromised state (e.g., hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS);
- Renal transplantation;
- Renal dysfunction (based on individual's report or pharmacy records);
- Diabetes mellitus;
- History of any urologic surgery, including but not limited to ureteral implantation, cystectomy, or urinary diversion;
- History of Clostridioides difficile (formerly Clostridium difficile) a.k.a. c.diff;
- Abnormal urinary tract function or structure (e.g., indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents);
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Antibiotic therapy prescribed within the previous 30 days;
- Inpatient or hospital stay within the previous 30 days;
- History of recurrent UTIs (>3 per year)
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit;
- Has or reports symptoms suggestive of pyelonephritis including:
    - Presence of fever (≥100.4 F; taken orally);
    - Nausea and vomiting; or
    - Flank pain; or
- A patient receiving hospice or home health services.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

Pharmacists shall assess a patient based on the inclusion and exclusion criteria based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Patients who do not qualify for antibiotic dispensing following testing will be referred for additional evaluation when the pharmacist has high suspicion of a false-negative result, determines that the patient is at high risk for complications, or otherwise considers additional care to be in the best interest of the patient.

FURTHER CONDITIONS

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential: pregnancy and breastfeeding status
- Current medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's UTI status.

- If positive, the pharmacist may proceed to consideration for antibiotic therapy treatment.
- If negative, the pharmacist shall counsel the patient on the risk of a false-negative test result and on appropriate self-care (get plenty of rest, drink plenty of fluids, treat symptoms as needed, etc.) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions:

- Allergic reaction, hypersensitivity, or contraindication to a treatment listed in this Protocol
- Renal insufficiency (nitrofurantoin monohydrate/macrocrystals and phenazopyridine)
- Previous UTI treatment failure
- History of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.)

DRUG INCLUSION CRITERIA

The pharmacist may initiate antibiotic therapy only in selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and

screening.

Selection of an antibiotic regimen will follow the ordered preference from the list below. If the patient is currently receiving another antibiotic, the pharmacist shall not change the dosage of the patient's current medication. The pharmacist shall assess reported drug allergies for validity by reviewing the patient's pharmacy record and documenting the reported reaction. The choice between the antibiotic medication regimens should be individualized and based on patient allergy, contraindications/precautions, adherence history, local community resistance patterns, cost, and availability.

If prior authorization is needed for prescription insurance coverage, the Pharmacist may seek prior authorization or consider use of an alterative antibiotic therapy in the Protocol, if not contraindicated, and shall counsel the patient about cost options.

A. First-line Treatment
    a. Cephalexin
        i. Dosing: 500mg PO BID for 5 days
    b. Cefdinir
        i. Dosing: 300mg PO BID for 5 days
    c. Nitrofurantoin monohydrate/macrocrystals *(for Cephalexin allergy)*
        i. Dosing: 100 mg PO BID for 5 days
B. Alternative Treatment
    a. Fosfomycin trometamol
        i. Dosing: 3 gm PO single dose
C. This Protocol also authorizes pharmacists to initiate the dispensing of the following medication for the treatment of UTI related dysuria: Phenazopyridine 100-200 mg PO three times daily (TID) after meals for up to 2 days when used concomitantly with an antibiotic agent.

RECORDKEEPING

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for UTI pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antibiotic therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to

comply with other state and federal laws.

COUNSELING

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on all the following:

- Instructions on when to seek medical attention, including:
  - Symptoms that do not resolve or worsen after 48 hours;
  - Development of a fever (temperature ≥100.4 F, taken orally); or
  - Flank pain;
- Medication counseling;
- Counseling on the importance of adherence to an antibiotic regimen and completion of the entire course; and
- Counseling regarding prevention of UTIs, including signs and symptoms that warrant emergency medical care.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

Acute Uncomplicated Lower Urinary Tract Infection, Women
Patient Form

PATIENT INFORMATION

Name		Date of Birth	□ Male □ Female
Email			Phone
Address			
City	State	Zip	
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

□ Yes □ No Are you 18-64 years of age?
□ Yes □ No Do you have a history of urinary tract infections? If yes, explain how many and over what time period:
□ Yes □ No Are you pregnant or breastfeeding?
□ Yes □ No Are you pre-menopausal?
□ Yes □ No Are you diabetic?
□ Yes □ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
□ Yes □ No Have you ever been diagnosed with c.diff (Clostridioides difficile, formerly Clostridium difficile)?
□ Yes □ No Do you have a history of renal transplant, dysfunction, urologic surgery (ureteral implantation, cystectomy, urinary diversion), or abnormal urinary tract function or structure (indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents)?
□ Yes □ No Do you have a history of allergic reactions to antibiotics, such as penicillin, amoxicillin, cephalexin, clarithromycin, or clindamycin?
□ Yes □ No Are you receiving hospice or home health services?
□ Yes □ No Do you have a pending test for your symptoms?

□ Yes □ No Have you been prescribed antibiotics in the previous 30 days?
□ Yes □ No Have you had an inpatient or hospital stay in the previous 30 days?
When did your symptoms start? □ More than seven days ago. □ Fewer than seven days ago
Do you have any of the following symptoms (check all that apply)? □ Pain when urinating □ Increased urinary frequency or urgency □ Vaginal discharge or itching □ Nausea/vomiting □ Flank pain □ Other:

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (dual criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria, or pyelonephritis possibility in combination with nausea/vomiting or flank pain)
□ Yes □ No Acute altered mental status	Yes

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Female patient ≥18 years of age but <65 years, and able to give informed consent;
- Prior history of UTI(s);
- One or more of the following symptoms: dysuria, increased frequency, and/or urgency; and
- Positive urine dipstick for nitrites or leukocytes via a CLIA-waived point-of-care detection test kit.

Refer to PCP and exclude from testing if:

- Male;
- Pregnant or breastfeeding;
- Post-menopausal;
- Vaginitis symptoms (e.g., vaginal discharge or itching);
- Symptom onset >7 days prior;
- Immunocompromised state (e.g., hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS);
- Renal transplantation;
- Renal dysfunction (based on individual's report or pharmacy records);
- Diabetes mellitus;
- History of any urologic surgery, including but not limited to ureteral implantation, cystectomy, or urinary diversion;
- History of Clostridioides difficile (formerly Clostridium difficile) a.k.a. c.diff;
- Abnormal urinary tract function or structure (e.g., indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents);
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Antibiotic therapy prescribed within the previous 30 days;

- Inpatient or hospital stay within the previous 30 days;
- History of recurrent UTIs (>3 per year)
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit;
- Has or reports symptoms suggestive of pyelonephritis including:
    - Presence of fever (≥100.4 F; taken orally);
    - Nausea and vomiting; or
- Flank pain; or
- A patient receiving hospice or home health services.

CLIA-WAIVED POC TEST RESULT

□ Positive urine dipstick for nitrites or leukocytes indicating UTI

□ Negative for UTI

PATIENT ACTION

□ Yes □ No UTI Diagnosed

□ Yes □ No Antibiotic Treatment Prescribed

□ Yes □ No Refer to PCP

Therapy Options		
□ UTI Antibiotic Treatment Prescribed as Marked Below □ No Treatment – Referred to PCP		
Documentation of Rationale for Treatment Selection (if required):		
First-line Treatment		
❑ Cephalexin	Dispense: ❑ 500mg #10 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 5 days.
❑ Cefdinir	Dispense: ❑ 300mg #10 No refills	Sig: Take 1 (one) (300mg) by mouth twice daily for 5 days.

❑ Oral Nitrofurantoin monohydrate/macrocrystals *(for cephalexin allergy)*	Dispense: ❑ 100mg #10 No refills	Sig: Take 1 (one) (100mg) by mouth twice daily for 5 days.
Alternative Antibiotic Therapy		
❑ Oral Fosfomycin trometamol	Dispense: ❑ 3 gm, single dose No refills	Sig: Dissolve one packet (3 grams) in 4 ounces of water and drink as one dose.
For Dysuria		
❑ Phenazopyridine	Dispense: ❑ 100mg #6 ❑ 200mg #6 No refills	Sig: Take 1 tablet by mouth three times daily after meals for up to 2 days.

PHARMACIST PERFORMING ASSESSMENT AND INITIATING THERAPY OPTION

Printed Name	License Number

SIGNATURE

DATE

Adopted: 9/24/2021
Revised: 9/26/2023
Effective: 9/26/2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer vaccines, including vaccines for COVID-19, to persons 18 years of age or older. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering vaccine or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

Pharmacist shall review applicable medical history prior to administering vaccine to ensure vaccine administration is appropriate for patient's medical condition(s), e.g., pregnancy, immunocompromised state. Patients eligible for vaccine under this protocol:

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC inclusive of additional information for COVID-19 vaccination;

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual, 18 years of age or older, preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
Patients NOT eligible for vaccine under this protocol:

- An individual less than 18 years of age;
- An individual for whom a vaccine is not recommended by the CDC such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

VIRGINIA BOARD OF PHARMACY

Vaccine Statewide Protocol for Persons Ages Three (3) through Seventeen (17)

(Does not include influenza or COVID-19 vaccines)

Except for influenza and COVID-19 vaccines, consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) and the third enactment clause of HB1323, a pharmacist may issue a prescription to initiate treatment with or administer a vaccine to a person age three (3) through seventeen (17) recommended at his or her age, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such vaccine. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine. Please note that this protocol does not authorize the administration of influenza or COVID-19 vaccines to persons ages three through seventeen. COVID-19 vaccines may be administered to this age group pursuant to the PREP Act until such authority expires. Influenza vaccines may be administered to this age group pursuant to the PREP Act until such authority expires or §54.1-3408 (W).

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with a patient, dispensing, or administering vaccines or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

The pharmacist shall review applicable medical history prior to administering a vaccine to ensure the vaccine administration is appropriate for the patient's medical condition(s)

(e.g., pregnancy or immunocompromised state). The following patients are eligible for vaccines under this protocol:

- An individual ages 3 through 17 whose immunization history is incomplete or unknown and for whom a vaccine (other than influenza or COVID-19) is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule published by the CDC, and
- An individual ages 3 through 17 preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine (other than influenza or COVID-19) is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
The following patients are NOT eligible for vaccines under this protocol:

- An individual less than 3 years of age or older than 17 years of age;
- An individual for whom a vaccine is not recommended by the CDC for reasons such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. The pharmacist shall also provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.