CONTINUATION OF THERAPY

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe any non-controlled medication to extend a patient's prescription therapy to avoid interruption of treatment.

PRESCRIBING PARAMETERS:

- Quantity sufficient for the circumstances
- Maximum quantity: May not exceed a 60-day supply
- Maximum frequency: No more than two extensions in a rolling 12-month period per medication

COUGH AND COLD SYMPTOM MANAGEMENT – BENZONATATE

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe benzonatate.

PRESCRIBING PARAMETERS:

• Maximum: Not to exceed a 7-day supply

COUGH AND COLD SYMPTOM MANAGEMENT – INTRANASAL CORTICOSTEROIDS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe prescription and OTC intranasal corticosteroids.

COUGH AND COLD SYMPTOM MANAGEMENT - PSEUDOEPHEDRINE

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe pseudoephedrine.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- INCLUSION CRITERIA: Age 18 and older, verified by positive ID
- EXCLUSION/REFERRAL CRITERIA: Age < 18

PRESCRIBING PARAMETERS:

- Pharmacist must review PDMP prior to issuing prescription, and retain documentation of review
- Maximum quantity: 3.6g or a 60 count quantity per prescription, whichever is less
- Maximum frequency: 3 prescriptions in a rolling 12-month period

COUGH AND COLD SYMPTOM MANAGEMENT – SHORT ACTING B-AGONISTS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe prescription and OTC short acting beta agonists, with or without a spacer, to treat cough symptoms.

PRESCRIBING PARAMETERS:

• Maximum: Not to exceed 1 inhaler with or without a spacer or 1 box of nebulizer ampules, per rolling 12-month period

CONDITIONS

VULVOVAGINAL CANDIDIASIS (VVC)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe a single course of treatment for non-complicated vulvovaginal candidiasis (VVC).

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Vulvovaginal Candidiasis / Yeast Infection Intake Form (pg. 2)
- Utilize the standardized Vulvovaginal Candidiasis Assessment and Treatment Care Pathway (pg. 3-6)

Vulvovaginal Candidiasis (Yeast Infection) Self-Screening Intake Form (CONFIDENTIAL-Protected Health Information)

	/	Date of Birth/	
-	ame	Preferred Name	
	igned at Birth (circle) M / F ed Pronouns (circle) She/Her/Hers, He/Him/His, Th	Gender Identification (cir	
	Address		
Phone		Email Address	
	care Provider Name	Phone () Fax ()
	have health insurance? Yes / No	Insurance Provider Name	
	ergies to medications? Yes / No	If yes, please list	
1.	Has a provider ever diagnosed you with a yeast inf		□ Yes □ No □ Not sure
т.	If so, how recently?		
	How many have you experienced within the last ye	ear?	-
	How many have you experienced within your lifeti		
	Have you ever experienced a difficult to treat yeas		□ Yes □ No □ Not sure
	What treatments (if any) have you tried for past ar		
	Please list them here:	•	
2.	Symptom review:		
	- Soreness, burning, or itchy vaginal area		□ Yes □ No
	- Abnormal discharge (color, smell, consistency, et	c.)	□ Yes □ No
	- Pain with urination		□ Yes □ No
	- Fever		□ Yes □ No
	- Pain in the lower abdomen and/or back		🗆 Yes 🗆 No
3.	- Other symptoms:		🗆 Yes 🗆 No
5.	Have you ever been sexually active? If so, how recently?		
4.	Have you ever been tested for OR diagnosed with a	a sexually transmitted infection?	□ Yes □ No □ Not sure
	If yes, when?		
5.	When was the first day of your last menstrual period	od?	Date:
6.	Are you currently pregnant?		\Box Yes \Box No \Box Not sure
7.	Are you using any of the following contraceptive d	evices?	
	1. Vaginal sponge		🗆 Yes 🗆 No
	2. Diaphragm		🗆 Yes 🗆 No
	3. Intrauterine device (IUD)		🗆 Yes 🗆 No
8.	Have you used antibiotics in the last month?		□ Yes □ No □ Not sure
9.	Has a provider ever diagnosed you with an autoim	mune disease?	□ Yes □ No □ Not sure
	If yes, list them here:		
10.	Do you have diabetes?		□ Yes □ No □ Not sure
11.	Have you ever been diagnosed with a heart rhythm	n condition (or QT prolongation)?	□ Yes □ No □ Not sure
	If yes, list them here:		
12.	Do you have any other medical problems?		□ Yes □ No □ Not sure
	If yes, list them here:		
13.	Are you currently taking any medications, supplem	nents, and/or vitamins?	□ Yes □ No □ Not sure
	If yes, list them here:		

Standardized Assessment and Treatment Care Pathway Vulvovaginal Candidiasis (VVC)

1) Vulvovaginal Candidiasis (VVC) and Sexually Transmitted Infection (STI) Screen (Form Qs: #1-5)

- a. Reoccurrence: If 4 or more episodes within 12 months or recurrent symptoms within 2 months → Refer
- b. Symptoms inconsistent with VVC: Pain with urination, fever, pain in the lower abdomen and/or back, symptoms consistent with STI, or any other inconsistencies. If YES to any of these symptoms → Refer

2) Pregnancy Screen (Form Qs: #5-6)

- a. 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?
- b. Have you had a baby in the last 4 weeks?
- c. Did you have a miscarriage or abortion in the last 7 days?
- d. Did your last menstrual period start within the past 7 days?
- e. Have you abstained from sexual intercourse since your last menstrual period or delivery?
- f. Have you been using a reliable contraceptive method consistently and correctly?

If YES to AT LEAST ONE of these questions and is free of pregnancy symptoms, proceed to next step.

If NO to ALL of these questions, pregnancy cannot be ruled out ightarrow Refer

3) Medication and Disease State Screen (Form Qs: #7-13)

- a. Are you using the following contraceptive devices: vaginal sponge, diaphragm, IUD \rightarrow Refer
- b. Do you have diabetes or other immunosuppressed conditions? \rightarrow Refer
- c. Are you taking corticosteroids or immunosuppressive medications, including antineoplastics? -> Refer

4) Assess and Initiate Antifungal Therapy:

All therapies are equally effective in treating uncomplicated VVC. Choice of therapy should be based on patient safety, preference, availability, and cost.

All therapy is limited to one course of treatment.

- a. *Oral therapy*. If indicated, the pharmacist shall issue a prescription for fluconazole and counsel on side effects and follow-up.
 - Fluconazole 150mg tablet, #1
- b. *Topical therapy*. If indicated, the pharmacist shall discuss the most appropriate option with the patient, issue a prescription, and counsel on side effects and follow-up of any one of the following treatments:
 - Clotrimazole (various strengths/formulations)
 - Miconazole (various strengths/formulations)
 - Tioconazole (various strengths/formulations)

5) Complete Patient Encounter

Advise: Patient should seek medical advice from a care provider if symptoms do not resolve in 7-14 days. *Encourage:* Routine health screenings, STI prevention, etc. *Document*: All required elements

Standardized Assessment and Treatment Care Pathway Vulvovaginal Candidiasis (VVC)

Medication options/considerations:

- Fluconazole¹:
 - *Dose and directions*: 150mg Tablet, quantity #1; Take one tablet by mouth one time. If symptoms do not resolve after 1 week, contact your primary care provider.
 - Warnings/Precautions: Potential patient harm is associated with known side effects of taking fluconazole. It is well tolerated, but may cause symptoms such as nausea, vomiting, dizziness, and headache. More rare side effects may include:
 - Prolonged QT interval which could lead to Torsades de Pointes. This is rarely a concern unless a patient is taking multiple QT prolonging drugs, has a preexisting heart condition, or known prolonged QT interval.
 - Hepatic toxicity (i.e. hepatitis, cholestasis, fulminant hepatic failure, etc.). Monitor liver function tests of patients with known impaired hepatic function
 - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other azoles
 - Skin reactions: Monitor for rash development
 - o Metabolism: Inhibits CYP2C19 (strong), CYP2C9 (moderate), CYP3A4 (moderate)
 - Contraindications for fluconazole use: (consider other therapy)
 - Prolonged QT interval
 - Multiple QT prolonging drugs
 - Impaired hepatic function
 - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other azoles
 - Other interacting medications

- Clotrimazole²:

- Dose and directions:
 - Cream: If symptoms do not resolve after 1 week, contact your primary care provider.
 - 1%: One applicatorful inserted intravaginally at night daily for 7 days.
 - 2%: One applicatorful inserted intravaginally at night daily for 3 days.
 - 10%: One applicatorful to be inserted intravaginally at night as a single dose.
- *Warnings/Precautions*: It is well tolerated, but may cause symptoms such as irritation and burning.
- Drug Interactions:
 - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination*)
 - Sirolimus: may increase the serum concentration of Sirolimus (*Risk C: Monitor therapy*)
 - Tacrolimus (systemic): may increase the serum concentration of Tacrolimus (Systemic) (*Risk C: Monitor therapy*)
- Contraindications for clotrimazole use: (consider other therapy)
 - Progesterone
 - Sirolimus
 - Tacrolimus (systemic)
 - Other interacting medications

Standardized Assessment and Treatment Care Pathway Vulvovaginal Candidiasis (VVC)

- Miconazole³:

- Dose and directions:
 - Suppository Capsule: If symptoms do not resolve after 1 week, contact your primary care provider.
 - 100mg: one capsule inserted intravaginally at night daily for 7 days.
 - 200mg: one capsule inserted intravaginally at night daily for 3 days.
 - 1,200mg: one capsule to be inserted intravaginally at night as a single dose.
 - Cream: If symptoms do not resolve after 1 week, contact your primary care provider.
 - 2%: One applicatorful inserted intravaginally at night daily for 7 days.
 - 4%: One applicatorful inserted intravaginally at night daily for 3 days.
- *Warnings/Precautions*: It is well tolerated, but may cause symptoms such as irritation and burning.
- Drug Interactions:
 - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination*)
 - Vitamin K Antagonists (i.e. warfarin): may increase the serum concentration of Vitamin K Antagonists (*Risk D: Consider therapy modification*)
 - Sulfonylureas: may inhibit the metabolism of oral sulfonylureas
- o Contraindications for miconazole use: (consider other therapy)
 - Progesterone
 - Vitamin K Antagonists (i.e. warfarin)
 - Sulfonylureas
 - Other interacting medications

- Tioconazole⁴:

- Dose and directions:
 - Ointment: If symptoms do not resolve after 1 week, contact your primary care provider.
 - 6.5%: One applicatorful to be inserted intravaginally at night as a single dose.
- *Warnings/Precautions*: It is well tolerated, but may cause symptoms such as irritation and burning.
- Drug Interactions:
 - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination*)
- Contraindications for tioconazole use: (consider other therapy)
 - Progesterone
 - Other interacting medications

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- 4. Tioconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Updated November 22, 2019. Accessed February 15, 2020.
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Vulvovaginal Candidiasis (VVC) Prescription

Optional -May be used by pharmacy if desired

Patient Name:	Date of birth:	
Address:		
City/State/Zip Code:	Phone number:	
□ Verified DOB with valid photo	ID	
Rx .		
Drug:		
Sig:		
Quantity:		
Refills: 0		
DAW:		
ritten Date:		
escriber Name:	Prescriber Signature:	
	Pharmacy Phone:	
armacy Address:		
	Pharmacy Phone:	
armacy Address:	Pharmacy Phone:	
armacy Address: Patient Referred	Pharmacy Phone:	
armacy Address: Patient Referred	Pharmacy Phone:	
armacy Address: Patient Referred	Pharmacy Phone:	
armacy Address: Patient Referred	Pharmacy Phone:	
armacy Address: Patient Referred	Pharmacy Phone:	
armacy Address: Patient Referred	Pharmacy Phone:	

PREVENTATIVE CARE - CONDOMS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe male and female condoms.

PREVENTATIVE CARE - EMERGENCY CONTRACEPTION

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe prescription and OTC emergency contraception, not including abortifacients.

PREVENTIVE CARE

TOBACCO CESSATION – NRT (Nicotine Replacement Therapy) and Non-NRT

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe individual or multiple Nicotine Replacement Therapy (NRT) OTC and Rx for tobacco cessation.
- Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe non-NRT medications for tobacco cessation.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Tobacco Cessation Patient Intake Form (pg. 2-4)
- Utilize the standardized Tobacco Cessation Assessment and Treatment Care Pathway (pg. 5-6)

PHARMACIST TRAINING/EDUCATION:

• Minimum 2 hours of documented ACPE CE related to pharmacist prescribing of tobacco cessation products

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					
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					
Any allergies to foods (ex. menthol/soy)? Yes / No	If yes, please list					
List of medicine(s) you take:						
Do you have a preferred tobacco cessation product you	u 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.)
 - 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	Yes No Not sure
	months?	
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 fewer than 10 cigarettes a day?	🗆 Yes 🗆 No
----	--	------------

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 $\geq 160/100$ mmHg.



If patient and pharmacist are considering non-nicotine replacement therapy (ex. varenicline or bupropion) and blood pressure is < 160/100mmHg continue to answer the questions below.

Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Medical History Continued:

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

Medication History:

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

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

Patient Signature_____

Date_____

Tobacco	Cessation Assessme	ent & 1	reatmen	t Care Path	way	
STEP 1: Health and History Screen Part Review Tobacco Cessation Patient Questionnaire (Questions 1 -2)	1 No = No Contraindicatin Conditions. Continue to step 2	ng	Yes/Not sure Conditions.	e = Contraindicat	ing Refer	Refer to PCP and/or Oregon Quit Line 1- 800-QUIT-NOW
STEP 2: Health and History Screen Part Review Tobacco Cessation Patient Questionnaire (Question 3)	2 Smoking Cigarettes. Continue to step 3		Yes to quest	ion 3 Refer	1-800	er to Oregon Quit Line D-QUIT-NOW to receive ounseling and NRT
STEP 3: Blood Pressure Screen Take and document patient's current b may choose to take a second reading if	lood pressure. (Note: RPh	BP < 160/ Continue		BP <u>></u> 160/100	Refer	Refer to PCP AND Oregon Quit Line 1-800-QUIT-NOW
STEP 4: Medical History Nicotine Replacement Therapy Questions (Questions 4-5)	No, to question 4 and 5. Continue to step 5		Yes, to ques 4 and/or 5	tion	Refer	Refer to PCP AND Oregon Quit Line 1-800-QUIT-NOW
STEP 5: Medical HistoryNicotine Replacement Therapy Questions (Questions 6-8)Question 6 = if Yes, avoid using nicotine gumQuestion 7 = if Yes, avoid using nicotine nasal sprayQuestion 8 = if Yes, avoid using nicotine inhaler			ants NRT, pre			s bupropion or ntinue to step 6.
	-	If Yes to	o smoking </td <td></td> <td>rt with n</td> <td>re) icotine patch 14mg/day tine patch 21mg/day</td>		rt with n	re) icotine patch 14mg/day tine patch 21mg/day
STEP 6: Medical History Bupropion and varenicline screening Questions 10-14	Consider NRT* if yes to any a) If yes to any question → If patient still wan b) If yes to any questions for If patient still wan If patient answered no to co 11, AND wants varenicline	e avoid bu ots buprop rom 12-14 ots varenic questions questions	propion. pion, refer. ↓→ avoid var cline, refer. 10 – 14, cont 12-14, but ye	tinue to step 7. es to question 10	Refer Refer) and/or	Refer to PCP AND Oregon Quit Line 1-800-QUIT-NOW
STEP 7: Medication History Questions 15-17 on questionnaire.	screening step 8.	17 → Avo Refer if pa If patient	id bupropior atient still wa	n. ants bupropion. icline, continue t	Refer	Refer to PCP if patient wants bupropion; NRT* can be considered
STEP 8: The Patient Health Questionnaire 2 (PHQ 2): Depression Screening	Score < 3 on PHQ2. Review Suicide Screening in step 9.	n Avoid b				Refer to PCP; NRT* can be considered
STEP 9: Suicide Screening	Score of 0 on suicide screening. May prescribe bupropion o varenicline.		1 on suicide iate referral	-	positive deteri hours,	office to notify them of e suicide screening and mine next steps. After refer to suicide hotline 1-800-273-8255
Prescribing Bupr	opion:			Prescribing Va	areniclin	e:
150mg SR daily for 3 days then 150mg longer. Quit day after day 7.	SR twice daily for 8 weeks o	r 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			r day 7 or alternatively	
Consider combining with Nicotine patc Nicotine gum for increased efficacy.*	-	quit date up to 35 days after initiation of varenicline. Generally not used in combination with other smoking cessation medications as first line therapy.				
for patients who do not tolerate titration to the full dose, consider continuing 150mg once daily as the lower dose has shown efficacy.			r			

Tobacco Cessation Assessment & Treatment Care Pathway

*Nicotine Replacement Dosing:

	Dose
Long Acting NRT	
Nicotine Patches	 Patients smoking >10 cigarettes/day: begin with 21mg/day for 6 weeks, followed by 14mg/day for 2 weeks, finish with 7mg/day for 2 weeks Patients smoking ≤ 10 cigarettes/day: begin with 14mg/day for 6 weeks, followed by 7mg/day for 2 weeks Note: Adjustment may be required during initial treatment (move to higher dose if experiencing withdrawal symptoms; lower dose if side effects are experienced).
Acute NRT	
Nicotine Gum	 Chew 1 piece of gum when urge to smoke occurs. If strong or frequent cravings are present after 1 piece of gum, may use a second piece within the hour (do not continuously use one piece after the other). Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended. Use according to the following 12-week dosing schedule: Weeks 1 to 6: Chew 1 piece of gum every 1 to 2 hours (maximum: 24 pieces/day); if using nicotine gum alone without nicotine patches, to increase chances of quitting, chew at least 9 pieces/day during the first 6 weeks Weeks 7 to 9: Chew 1 piece of gum every 2 to 4 hours (maximum: 24 pieces/day)
Nicotine Lozenges	 • Weeks 10 to 12: Chew 1 piece of gum every 4 to 8 hours (maximum: 24 pieces/day) • 1 lozenge when urge to smoke occurs; do not use more than 1 lozenge at a time • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: • Weeks 1 to 6: 1 lozenge every 1 to 2 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day); if using nicotine lozenges alone without nicotine patches, to increase chances of quitting, use at least 9 lozenges/day during the first 6 weeks • Weeks 7 to 9: 1 lozenge every 2 to 4 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day) • Weeks 10 to 12: 1 lozenge every 4 to 8 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day)
Nicotine Inhaler	 Initial treatment: 6 to 16 cartridges/day for up to 12 weeks; maximum: 16 cartridges/day 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: 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.
Nicotine Nasal Spray	 Initial: 1 to 2 doses/hour (each dose [2 sprays, one in each nostril] contains 1 mg of nicotine) 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. <i>Discontinuation of therapy:</i> Discontinue over 4 to 6 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.

Oregon licensed pharmacist must adhere to Prescribing Parameters, when issuing any prescription for tobacco cessation.

PRESCRIBING PARAMETERS:

- 1st prescription up to 30 days
- Maximum duration = 12 weeks
- Maximum frequency = 2x in a rolling 12-month period

TREATMENT CARE PLAN:

• Documented follow-up: within 7-21 days, phone consultation permitted

Tobacco Cessation Prescription

Optional-May be used by pharmacy if desired

	Date of birth:
Address:	
City/State/Zip Code:	Phone number:
BP Reading:/ mmHg '	it Line (1-800-QUIT-NOW or www.quitnow.net/oregon) *must be taken by a RPh
Note: RPh must refer patient if blood	pressure <u>></u> 160/100
Rx	
Written Date:	
	Prescriber Signature:
	Prescriber Signature: Pharmacy Phone:
Prescriber Name:	Prescriber Signature:
Prescriber Name: Pharmacy Address:	Prescriber Signature: Pharmacy Phone:
Prescriber Name: Pharmacy Address:	Prescriber Signature: Pharmacy Phone:

PREVENTIVE CARE

TRAVEL MEDICATIONS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe pre-travel medications.
 - Malaria prophylaxis
 - Traveler's diarrhea
 - o Acute mountain sickness
 - Motion sickness

> STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Travel Medications Patient Intake Form (pg. 2-3)
- Utilize the standardized Travel Medications Assessment and Treatment Care Pathway (pg. 4-10)

PHARMACIST TRAINING/EDUCATION:

- APhA Pharmacy-Based Immunization Delivery certificate (or equivalent); and
- Minimum of 4 hour comprehensive training program related to pharmacy-based travel medicine services intended for the pharmacist (one-time requirement); and
- A minimum of 1 hour of travel medication continuing education (CE), every 24 months.

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

PATIENT INFORMATION				
Date/		Date of Birth]/	Age
Legal Name		Preferred Name		
		Gender Identification (circle) M / F / Other		
Preferred Pronouns (circle) She/Her/Hers, He/Him/His,	They/Them/T	heir, Ze/Hir/Hirs, Oth	ner	
Street Address				
Phone ()	Email Addı	ress		
Healthcare Provider Name	_ Phone (ress	_ Fax ()
Do you have health insurance? Yes / No	Insurance	Provider Name		
Any allergies to medications? Yes / No	lf yes, plea	yes, please list		
TRAVEL SPECIFICS				
Purpose of Trip:				
Activities:				
Departure Date: Return Date:				
Countries <u>AND</u> Cities to be Visited (In Order of V	/isits)	Arrival Date	Depa	arture Date

Have you traveled outside the United States before?

Yes
No

If yes, where and when?

1.	Will you be ONLY using airplane as your mode of transportation If no, explain:	□ Yes □ No □ Not sure
2.	Will you be ONLY visiting major cities? If no, explain:	□ Yes □ No □ Not sure
3.	Will you be ONLY staying in hotels? If no, explain:	□ Yes □ No □ Not sure
4.	Will you be visiting friends and family?	□ Yes □ No □ Not sure
5.	Will you be ascending to high altitudes? (> 7,000 ft or 2,300 meters) in the mountains	□ Yes □ No □ Not sure
6.	Will you be working in the medical or dental field with exposure to blood or bodily fluids?	□ Yes □ No □ Not sure

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

ALLERGIES

□ No known drug allergies □ No known food allergies

Drug Allergies: _____

Food Allergies: _____

VACCINE MEDICAL INFORMATION

Please complete the table below (please bring your vaccination record to the pre-travel consult)

Vaccinations	Yes – (En	ter vaccination	date below)	No	Not Sure
COVID					
(Manufacturer):	Dose 1:	2:			
Hepatitis A	Dose 1:	2:			
Hepatitis B	Dose 1:	2:	3:		
Influenza					
Japanese Encephalitis					
Meningococcal	Dose 1:	2:			
Meningitis					
MMR (Measles, Mumps,	Dose 1:	2:			
Rubella)					
Pneumonia	PPSV23:	PCV13:			
Polio (Adult Booster)					
Rabies					
Shingles					
Tetanus (Tdap/Td/DTaP/DT)					
Typhoid (Oral / Shot)					
Varicella					
Yellow Fever					
Other:					
Other:					

MEDICAL HISTORY

List your current prescription medications and medical conditions treated (include birth control pills and anti-depressants): Current Medical Conditions:

Current Prescription Medications:_____

Regularly used Non-Prescription Medications (over the counter, herbal, homeopathic, vitamins, and supplements including those purchased at health-food stores):

7.	Are you currently using steroids?	□ Yes □ No □ Not sure
8.	Are you currently receiving radiation therapy?	□ Yes □ No □ Not sure
9.	Are you currently receiving immunosuppressive therapy?	□ Yes □ No □ Not sure
10.	Are you pregnant or are you planning to become pregnant within the next year?	□ Yes □ No □ Not sure
11.	Are you currently breast-feeding?	Yes No Not sure

QUESTIONS/CONCERNS

Please list additional questions or concerns that you might have regarding your travel:

Signature:_____

_Date:_____

STEP 1: Assess routine and travel vaccinations

STEP 2: Choose and issue prescription for appropriate prophylaxis medication, in adherence to the CDC's 2020 Yellow Book: Health Information for International Travel (06/11/2019) and this protocol, to include documented screening for contraindications (see pgs. 6-7).

STEP 3: Prescribe medications and administer vaccinations.

STEP 4: Provide a written individualized care plan to each patient.

1. Malaria Prophylaxis

a. Patient assessment

- i. Review detailed itinerary
- ii. Identify zones of resistance
- iii. Review recommendations by the CDC
- iv. Discuss planned activities
- v. Assess risk of acquiring malaria and body weight (kg)

b. Prophylaxis

- i. Discuss insect precautions and review signs/symptoms of malaria with patient
- ii. Screen for contraindications
- iii. Assess travel areas for resistance:

1. Non-chloroquine resistant zone

- a. Chloroquine (Aralen®)
 - Adult dosing: Chloroquine 500 mg
 - Begin 1-2 weeks prior to travel-1 tablet weekly
 - Taken once weekly during trip and for 4 weeks after leaving Pediatric dosing:

8.3 mg/kg (maximum is adult dose)

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during trip and for 4 weeks after leaving

OR

b. Hydroxychloroquine (Plaquenil®)

Adult Dosing: Hydroxychloroquine 400 mg

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during trip and for 4 weeks after leaving <u>Pediatric Dosing:</u>

6.5 mg/kg (maximum is adult dose)

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during trip and for 4 weeks after leaving

2. Chloroquine-resistant zone

a. Atovaquone/Proguanil (Malarone®)

Adult Dosing: Atovaquone/Proguanil 250mg/100mg

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 7 days after leaving

Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg

5–8 kg: 1/2 pediatric tablet daily

9–10 kg: 3/4 pediatric tablet daily

- 11–20 kg: 1 pediatric tablet daily
- 21-30 kg: 2 pediatric tablets daily
- 31-40 kg: 3 pediatric tablets daily

> 40 kg: 1 adult tablet daily

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 7 days after leaving

OR

- b. Doxycycline (Vibramycin®) (≥8 years) Adult Dosing:
 - Begin 1 tablet daily 1-2 days prior to travel
 - Taken daily during trip and 4 weeks after leaving

Pediatric Dosing:

≥8 years old: 2.2 mg/kg (maximum is adult dose) daily

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

OR

c. Mefloquine (Lariam®)

Adult Dosing: Mefloquine 250mg

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during and for 4 weeks after leaving

Pediatric Dosing:

- ≤9 kg: 5 mg/kg
- 10-19 kg: ¼ tablet weekly
- 20-30 kg: ½ tablet weekly
- 31-45 kg: ¾ tablet weekly
- > 45 kg: 1 tablet weekly
 - Begin 1-2 weeks prior to travel-1 tablet weekly
 - Taken once weekly during and for 4 weeks after leaving

3. Mefloquine-Resistant zone

- a. Doxycycline (Vibramycin®) (≥8 years)
 - Adult dosing: Doxycycline 100 mg
 - Begin 1 tablet daily 1-2 days prior to travel
 - Taken daily during trip and 4 weeks after leaving

Pediatric dosing:

≥8 years old: 2.2 mg/kg (maximum is adult dose) daily

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

OR

b. Atovaquone/Proguanil (Malarone®) <u>Adult dosing:</u> Atovaquone/Proguanil 250mg/100mg <u>Pediatric Dosing:</u> Atovaquone/Proguanil 62.5mg/25mg

5–8 kg: 1/2 pediatric tablet daily

9-10 kg: 3/4 pediatric tablet daily

- 11–20 kg: 1 pediatric tablet daily
- 21-30 kg: 2 pediatric tablets daily
- 31-40 kg: 3 pediatric tablets daily
- > 40 kg: 1 adult tablet daily
 - Begin 1 tablet daily 1-2 days prior to travel

• Taken daily during trip and 7 days after leaving

2. <u>Traveler's diarrhea (TD)</u>

- a. Patient assessment
 - i. Review detailed itinerary and identify travel areas of increased risk
 - ii. Assess patient's risk of acquiring traveler's diarrhea and body weight (kg)
 - iii. Screen for contraindications
 - iv. Consult CDC guidelines for list of high-risk factors for TD
- b. Prophylaxis education
 - i. Discuss dietary counseling, avoidance of high-risk foods, food and beverage selection and sanitary practices, oral rehydration
 - ii. Educate patient on how to recognize symptoms and severity of traveler's diarrhea
 - 1. **Mild:** diarrhea that is tolerable, not distressing, and does not interfere with planned activities
 - 2. Moderate: diarrhea that is distressing or interferes with planned activities
 - 3. **Severe:** dysentery (bloody stools) and diarrhea that is incapacitating or completely prevents planned activities
 - iii. Pharmacotherapy prophylaxis

Pepto-Bismol®: Two 262-mg tablets or 2 fluid oz (60 mL) QID for up to 3 weeks **Note:** Avoid in patients <12 years old, patients taking doxycycline for malaria prophylaxis, anticoagulants, allergic to aspirin, probenecid, methotrexate

c. Treatment (Note: while Yellow Book includes ciprofloxacin, this protocol only permits azithromycin)

- i. First line for mild TD and adjunctive treatment for moderate TD
 - 1. Loperamide (OTC- Imodium[®] AD) Adult Dosing: Loperamide 2 mg
 - Take 4 mg at onset of diarrhea, followed by additional 2 mg after each loose stool (Max of 16 mg per day)
 - Pediatric Dosing:
 - 22 to 26 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 4 mg per day)
 - 27 to 43 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 6 mg per day)
- ii. Antibiotic treatment (for moderate or severe TD)
 - 1. Consult CDC guidelines for resistance rates to antibiotics
 - 2. Empiric treatment for moderate TD and severe TD (age <18 requires a prescription form PCP)
 - a. Azithromycin 500mg
 - 1 tablet daily for 1-3 days
 - 1 course/14 days, Max 2 courses for trips >14 days

OR

b. *Azithromycin 1000mg:* Single dose of one tablet (if symptoms are not resolved after 24 hours, continue daily dosing for up to 3 days)

3. Acute Mountain Sickness

- a. Patient assessment/Education
 - i. Review detailed itinerary and identify travel areas of increased risk
 - ii. Assess patients' risk of acquiring Acute Mountain Sickness (AMS) and body weight (kg)
 - iii. Review signs/symptoms of AMS, discuss safe ascent rates and tips for acclimating to higher altitudes (alcohol abstinence, limited activity)
 - iv. Screen for contraindications
 - 1. AcetaZOLAMIDE
 - a. Hypersensitivity to acetazolamide or sulfonamides
- b. Prophylaxis
 - i. Consult CDC guidelines for list of risk factors for AMS. If risk factors are present and warrant prophylaxis:
 - 1. AcetaZOLAMIDE (Diamox[®])
 - Adult Dosing: Acetazolamide 125 mg
 - Take 1 tablet twice daily starting 24 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return

Pediatric Dosing:

2.5 mg/kg/dose every 12 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return. (Maximum of 125 mg/dose)

4. Motion Sickness

- a. Patient assessment
 - i. Review detailed itinerary and identify travel areas of increased risk
 - ii. Assess patients' risk of acquiring motion sickness and body weight (kg)
 - iii. Review signs/symptoms of motion sickness, discuss tips for reducing motion sickness: being aware of triggers, reducing sensory input
 - iv. Screen for contraindications
- b. Prophylaxis
 - i. Consult CDC guidelines for list of risk factors for Motion sickness. If risk factors present and warrant pharmacologic prevention:
 - ii. Adults
 - First-line: Scopolamine transdermal patches (Age <18 Requires prescription from PCP)
 Apply 1 patch (1.5 mg) to hairless area behind ear at least 4 hours prior to exposure; replace every 3 days as needed

AND/OR

2. Second-line:

- a. *Promethazine 25mg Tablets:* Take one tablet by mouth 30 60 minutes prior to exposure and then every 12 hours as needed
- b. *Promethazine 25mg Suppositories:* Unwrap and insert one suppository into the rectum 30-60 minutes prior to exposure and then every 12 hours as needed
- *Meclizine 12.5-25mg* (OTC/Rx): Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

iii. Pediatrics

- 1. First-line:
 - a. 7-12 years old
 - DimenhyDRINATE (OTC Dramamine[®]) 1-1.5mg/kg/dose: Take one dose 1 hour before travel and every 6 hours during the trip. (Maximum 25 per dose)
 - DiphenhydrAMINE (OTC Benadryl[®]) 0.5-1mg/kg/dose: Take one dose 1 hour before travel and every 6 hours during the trip. (Maximum 25 mg per dose)
 - b. \geq 12 years old
 - *Meclizine 12.5-25mg* (OTC/Rx): Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

Screen for Contraindications:

Malaria Prophylaxis

- 1. Chloroquine
 - c. Age < 7 years old
 - d. Hypersensitivity to chloroquine, 4-aminoquinolone compounds, or any component of the formulation
 - e. Presence of retinal or visual field changes of any etiology
- 2. Hydroxychloroquine
 - a. Age < 7 years old
 - b. Hypersensitivity to hydroxychloroquine, 4 aminoquinoline derivatives, or any component of the formulation
- 3. Atovaquone/proguanil
 - a. Age < 7 years old
 - b. Weight < 5 kg
 - c. Hypersensitivity to atovaquone, proguanil or any component of the formulation
 - d. Prophylactic use in severe renal impairment (CrCl < 30 mL/min)
- 4. Doxycycline
 - a. Age < 8 years old
 - b. Hypersensitivity to doxycycline, other tetracyclines
 - c. Use in infants and children < 8 years old
 - d. During second or third trimester of pregnancy
 - e. Breast-feeding
- 5. Mefloquine
 - a. Age < 7 years old
 - b. Hypersensitivity to mefloquine, related compounds (i.e. quinine and quinidine)
 - c. Prophylactic use in patients with history of seizures or psychiatric disorder (including active or recent history of depression, generalized anxiety disorder, psychosis, schizophrenia, or other major psychiatric disorders)

Traveler's Diarrhea

- 1. Loperamide
 - a. Age < 7 years old
 - b. Hypersensitivity to loperamide or any component of the formulation
 - c. Abdominal pain without diarrhea
 - d. Acute dysentery
 - e. Acute ulcerative colitis
 - f. Bacterial enterocolitis (caused by Salmonella, Shigella, Campylobacter)
 - g. Pseudomembranous colitis associated with broad-spectrum antibiotic use
 - h. OTC—do not use if stool is bloody of black
- 2. Azithromycin
 - a. Age < 18 years old will require a prescription from a PCP
 - b. Hypersensitivity to azithromycin, erythromycin or other macrolide antibiotics
 - c. History of cholestatic jaundice/hepatic dysfunction associated with prior azithromycin use

Acute Mountain Sickness

- 1. AcetaZOLAMIDE
 - a. Age < 7 years old
 - b. Marked hepatic disease or insufficiency
 - c. Decreased sodium and/or potassium levels
 - d. Adrenocortical insufficiency
 - e. Cirrhosis
 - f. Hyperchloremic acidosis
 - g. Severe renal dysfunction or disease

h. Long term use in congestive angle-closure glaucoma

Motion Sickness

- 1. Scopolamine
 - a. Age < 18 years old will require a prescription from a PCP
 - b. Hypersensitivity to scopolamine
 - c. Glaucoma or predisposition to narrow-angle glaucoma
 - d. Paralytic ileus
 - e. Prostatic hypertrophy
 - f. Pyloric obstruction
 - g. Tachycardia secondary to cardiac insufficiency or thyrotoxicosis
- 2. Promethazine
 - a. Age < 7 years old
 - b. Hypersensitivity to promethazine or other phenothiazines (i.e. prochlorperazine, chlorproMAZINE, fluPHENAZine, perphenazine, etc)
 - c. Treatment of lower respiratory tract symptoms
 - d. Asthma
- 3. Meclizine
 - a. Age < 12 years old
 - b. Hypersensitivity to meclizine
- 4. DimenhyDRINATE
 - a. Age < 7 years old
 - b. Hypersensitivity to dimenhyDRINATE or any component of the formulation
 - c. Neonates
- 5. DiphenhydrAMINE
 - a. Age < 7 years old
 - b. Hypersensitivity to diphenhydrAMINE or other structurally related antihistamines or any component of the formulation
 - c. Neonates or premature infants
 - d. Breast feeding

PREVENTIVE CARE

HIV POST-EXPOSURE PROPHYLAXIS (PEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe post-exposure prophylaxis (PEP) drug regimen.

> STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PEP Patient Intake Form (pg. 2)
- Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-5)
- Utilize the standardized PEP Patient Informational Handout (pg. 7)
- Utilize the standardized PEP Provider Fax (pg. 8)

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

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

	(CONFIDENTIAL-Protect	cted Health Information)			
Date	//	Date of Birth/	/ Age		
	Name	Preferred Name			
Sex A	ssigned at Birth (circle) M / F	Gender Identification (c	ircle) M / F / Other		
Prefe	rred Pronouns (circle) She/Her/Hers, He/Him/His, The	ey/Them/Their, Ze/Hir/Hirs, Other			
Stree	t Address				
Phon	e ()	Email Address Fax			
	hcare Provider Name	Phone () Fax	<()		
	ou have health insurance? Yes / No	Insurance Provider Name			
Any a	Ilergies to medications? Yes / No	If yes, please list			
Back	round Information:				
1.	Do you think you were exposed to Human Immunode	eficiency 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 contac	t or a sexual assault?	Yes No Not sure		
5.	Was the exposure through contact with any of the fo	llowing body fluids? Select any/all	Yes No Not sure		
	that apply:				
	Blood Tissue fluids Semen Vaginal secretions Saliva Tears Sweat Other				
	(please specify):				
6.	Did you have vaginal or anal sexual intercourse witho	out a condom?	Yes No Not sure		
7.	Did you have oral sex without a condom with visible	blood in or on the genitals or	🗆 Yes 🗆 No 🗆 Not sure		
	mouth of your partner?				
8.					
	genitals or oral cavity of your partner?				
9.	Were you exposed to body fluids via injury to the skin	n, a needle, or another instrument	□ Yes □ No □ Not sure		
	or object that broke the skin?				
10.	Did you come into contact with blood, semen, vagina	al secretions, or other body fluids of	□ Yes □ No □ Not sure		
	one of the following individuals?				
	persons with known HIV infection				
	nen who have sex with men with unknown HIV star	tus			
	□persons who inject drugs				
	□sex workers				
11.	Did you have another encounter that is not included	above that could have exposed	Yes 🗆 No 🗆 Not sure		
	you to high risk body fluids? Please specify:				
Medi	cal History:				
12.	Have you ever been diagnosed with Human Immuno	deficiency Virus (HIV)?	□ Yes □ No □ Not sure		

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:	□ Yes □ No □ Not sure
	If no, would you like a vaccine today? Yes/No	
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___

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

Name:	Date of Birth://Today's	Date://
 Is the patient less than 13 years of 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 Was the patient a survivor of sexu 	□ No: Go to #2	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-port Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.	sitive? No: Go to #4. Conduct 4 th generation HIV fingerstick test if available (optional).	Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.
 4. What time did the exposure occur □ >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	Notes:
5. Was the exposure from a source p	erson known to be HIV-positive?	
□ Yes: Go to #6	🗆 No: Go to #7	
 6. Was there exposure of the patient membrane, or non-intact skin, or particular fluids: 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. 	Solution of the above Solution of the above	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.
	ertive anal/vaginal intercourse without a	Notes: This type of exposure
condom with a partner of known of Ves: Go to #9	Dr unknown HIV status?	puts the patient at a high risk for HIV acquisition

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

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	_	No: Use clinical judgement. Risk of	
□Was the source person known to be		acquiring HIV is low.	
□Were there cuts/openings/sores/uld	cers on the oral mucosa?	Consider referral. If	
Was blood present?	with out DED treatment?	clinical determination is to	
\Box Has this happened more than once \Box None of the above	without PEP treatment?	prescribe PEP then	
		continue to #9.	
9. Does the patient have an establish			Notes: Connection to care is
up? –OR- Can the pharmacist direc	-	racted provider or	critical for future
public health department for appr	· ·		recommended follow-up.
□ Yes: Go to #10	□ No: Do not prescribe PEP.		
	local primary care provider (P department (ED), urgent care		
	disease specialist, or public h		
10. Does the patient have history of kr		•	Notes: Tenofovir disoproxil
☐ Yes: Do not prescribe PEP. Refer	□ No. Go to #11		fumarate treats HBV,
patient to local primary care			therefore once stopped
provider (PCP), emergency			and/or completed, the
		patient could experience an	
		acute Hepatitis B flare.	
public health dept.			
11. Has the patient received the full H		∃Yes □No	
Verify vaccine records or Alert-IIS. Dates:			
Yes: Go to #13	□ No: Go to #12		
12. Review the risks of hepatitis B exact		tient. Offer	
vaccine if appropriate and go to #1	.3.		
□Vaccine administered	apaturo		
Lot: Exp: Signature: 13. Does the patient have known chronic kidney disease or reduced renal function?			Notes: Truvada [®] requires
	□ No: PEP prescription recor		renal dose adjustment when
patient to local primary care	below for recommended regi		the CrCl <50 mL/min
provider (PCP), emergency	counseling points. Patient mu		
department (ED), urgent care,	referred to appropriate provi		
infectious disease specialist, or	prescription of PEP for requir	-	
public health dept.	follow-up testing. Pharmacist	must notify both	
	the provider and patient.		

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

Truvada®	Notes:	
(emtricitabine 200	•	There may be other FDA-approved regimens available for treatment of PEP.
mg/tenofovir disoproxil		Truvada [®] plus Isentress [®] is the only regimen permitted for pharmacist prescribing
fumurate 300 mg) one		at this time.
tablet by mouth daily	•	Although labeling is for 28 day supply, 30 days is recommended for prescribing due
for 30 days		to the products being available only in 30-day packaging and high cost of the
DI LIC		medications which could provide a barrier to availability and care. If able, 28-day
PLUS		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 [®] (raltegravir		Isentress [®] are preferred medications during pregnancy. If the patient is pregnant,
400 mg) one tablet by		please report their demographics to the Antiretroviral Pregnancy Registry:
mouth twice daily for		http://www.apregistry.com
30 days	•	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:

- Truvada[®]:
 - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.
 - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
- Isentress[®]:
 - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
 - If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress[®].
- Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.
- Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

*Oregon licensed pharmacists are mandatory reporters of child abuse, per <u>ORS Chapter 419B</u>. Reports shall be made to Oregon Department of Human Services @ **1-855-503-SAFE (7233)**.

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____/___/_____

PEP Prescription

Optional-May be used by pharmacy if desired

Address: City/State/Zip Code: Verified DOB with valid photo ID Note: RPh must refer patient if exposure occurred >	Phone number:
Verified DOB with valid photo ID	Phone number:
Note: RPh must refer patient if exposure occurred >	
······································	72 hours prior to initiation of medication
Rx	
 Drug: emtricitabine 200 mg/tenofovir disop Sig: Take one tablet by mouth once daily in Quantity: #30 Refills: none 	
AN	ID
 Drug: raltegravir 400mg (Isentress) Sig: Take one tablet by mouth twice daily in Quantity: #60 Refills: none 	n combination with Truvada for 30 days.
Written Date:	
Prescriber Name:	Prescriber Signature:
Pharmacy Address:	Pharmacy Phone:
-0 <i>r</i> -	
 Patient Referred Hepatitis B Vaccination administered: Lot: Expiration Date: Dose: 	of 2 or 3 (circle one)
Notes:	

Patient Information Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:
Pharmacy Address:
Pharmacy Phone Number:

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 the medications and directions you have been prescribed, 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.

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

- Truvada (emtricitabine/tenofovir disoproxil) 200 mg/300 mg take 1 tablet by mouth daily for 30 days, AND
- Isentress (raltegravir) 400 mg take 1 tablet by mouth twice daily for 30 days

Key Points

- 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 either medication without first asking your doctor or pharmacist.
- Truvada and Isentress don't have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress 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.

Provider Notification Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:		
Pharmacy Address:		
Pharmacy Phone:	Pharmacy Fax:	
Dear Provider	(name), ()	(FAX)
Your patient	(name)/ (DOB) has l	been prescribed HIV Post-
Exposure Prophylaxis (PEP) at	Pharmacy.	

This regimen consists of:

- Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets one tab by mouth daily for 30 days AND
- Isentress (raltegravir) 400mg tablets one tab by mouth twice daily for 30 days.

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:

- Truvada needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Truvada and Isentress 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 Truvada.
- Truvada 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 prescribing 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 <u>cdc.gov/hiv/basics/pep.html</u>.

PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe pre-exposure prophylaxis (PrEP) drug regimen.

> 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.4-8)
- Utilize the standardized PrEP Provider Fax (pg.10)

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

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

(CONFIDENTIAL-Protected Health Information)

Do you have health insurance? Yes / No Insu	Gender Identification hem/Their, Ze/Hir/Hirs, Other ail Address ne () F urance Provider Name	(circle) M	/ F / Other
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/T Street Address	hem/Their, Ze/Hir/Hirs, Other_ ail Address ne () F urance Provider Name		
Street Address Emiliary Phone () Emiliary Healthcare Provider Name Photo Do you have health insurance? Yes / No Insurance	ail Address F ne () F urance Provider Name		
Phone () Email Healthcare Provider Name Pho Do you have health insurance? Yes / No Insurance	irance Provider Name	ax ()	
Do you have health insurance? Yes / No Insu	irance Provider Name	ax ()	
Do you have health insurance? Yes / No Insu	irance Provider Name	ax ()	
Any anergies to medications: res / No II y	es, please list		
 Background Information: These questions are highly confidered for you and what Human Immunodeficiency Virus (HIV) and Severecommended. Do you answer yes to any of the following? u yes 	ually Transmitted Infection (ST		
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 ti	me you ha	ad sex without a
condom.		•	
% of the time			
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 vagina 	l sex		
 Insertive- you have a penis and you use it for vaginal s 	ex		
5. Do you have anal sex?			
Receptive- someone uses their penis to perform anal s	sex on you		
 Insertive- you use your penis to perform anal sex on set 	omeone 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 methampheta	mine 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:	🗆 yes 🗆 no
 If no, would you like a Hepatitis B immunization today? □ 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)?	🗆 yes 🗆 no
 Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen) 	
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	🗆 yes 🗆 no
them here:	

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

(CONFIDENTIAL-Protected Health Information)

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.	🗆 Yes 🗆 No
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.	
2. I understand that I must complete STI screening at least every 6 months while on	🗆 Yes 🗆 No
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.	
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses.	🗆 Yes 🗆 No
Missing doses increases the risk of getting HIV.	

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: _____

(CONFIDENTIAL- Protected Health Information)

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	 Condomless sex greatly increases risk of HIV and STIs.
% of the time // last sex without	• For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP).
a condom	 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	Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV.
methamphetamine use	 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. •

•

(CONFIDENTIAL- Protected Health Information)

Testing:

The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

			Needs
<u>Test Name</u>	Date of Test	<u>Result</u>	<u>referral</u>
 HIV ag/ab (4th gen) test: 	//	_	e 🗆 Yes
Reactive and indeterminate tes	ts are an automatic refe	erral to county health or the patient's health	care provider for
confirmatory testing. NOTE: HIV	/ test must be performe	ed within the 14 days prior to prescribing and	d dispensing.
• Syphilis/Treponemal antibody:	//	_ 🗆 <i>reactive</i> 🗆 <i>indeterminate</i> 🗆 negativ	e 🗆 Yes
Reactive treponemal antibody t	esting will result in an a	automatic referral to county health or the pa	tient's primary
care provider for follow-up and	confirmatory testing.		
• Hepatitis B surface antigen:	//	<i>positive</i> \Box negative	□ Yes
Positive surface antigen indicat	es either acute or chron	ic Hepatitis B and PrEP should be referred to	county health
or a specialist physician.			
Gonorrhea/Chlamydia:	//		□ Yes
Urinalysis result:	Pharyngeal test re	sult: Rectal test result:	
🗆 reactive 🛛 indeterminate	🗆 reactive 🗆 indet	erminate 🛛 reactive 🗆 indeterminate	
negative	negative	negative	
All reactive or indeterminate ch	lamydia and/or gonorri	hea results will result in an automatic referra	ıl to county
health or the patient's healthca	re provider for evaluati	on and treatment.	
• Renal function (CrCl):	//	mL/min 🛛 CrCl > 60 mL/mi	n 🗆 Yes
SCrmg/dL		□ CrCl 30-60 mL/n	nin
		□ CrCl < 30 mL/mi	n
CrCl > 60mL/min: Kidney function	adequate for PrEP; CrCl	30-60mL/min: Only Descovy indicated; CrCl	<30 mL/min:
referral for evaluation/follow-up. I	NOTE: Concurrent NSAIL	D use would favor Descovy.	
 Signs/symptoms of STI not 		Present	□ Yes
otherwise specified:	//		
• Condomless sex in past two		□ Yes	□ Yes
weeks	//		
2. Is HIV ab/ag 4 th gen test comp	lata? avec/no	n-reactive 🛛 yes/reactive or indeterm	inate 🗆 no
 If ves and non-reactive: Procee 	-		inate 🗆 no
$\overline{}$ II ves allu llullieaulive. FIULee	u lu uucsliuii #J		

- 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 are complete? ges go no

- If yes, RPH may prescribe PrEP and next labs due in 90 days. Proceed to next section: Medical History.
- If no, RPH 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.

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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.

County Health Department Directory:

https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

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
 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.
 Presence of Hepatitis B infection Needs Referral: □ yes □ no 	 Truvada and Descovy 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 	 Truvada is approved for patients with a CrCl >60mL/min. Consider Descovy 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 <i>Needs Referral:</i> □ <i>yes</i> □ 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 Descovy over Truvada. 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 <u>OAR 855-019-0280</u>.
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. Truvada 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 prescribe in accordance with this RPH 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 prescribe and dispense PrEP in accordance with this RPH protocol. Proceed to next sections: Regimen Selection and Prescription.

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Regimen Selection:

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

*generic versions are acceptable in all cases if available.

PrEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:	
Address:		
City/State/Zip Code:	Phone number:	
	oust refer patient if HIV test reactive or indeterminate	
-	ovir disoproxil fumarate) 200/300mg tablets uth daily for 90 days, #90, 0 refills	
	-or-	
	ovir alafenamide) 200/25mg tablets uth daily for 90 days, #90, 0 refills	
Expiration Date: (This prescription	expires 90 days from the written date)	
Prescriber Name:	expires 90 days from the written date)	
Prescriber Name:	expires 90 days from the written date) Prescriber Signature:	
Prescriber Name: Pharmacy Address: Patient Referred Hepatitis B Vaccination administe	expires 90 days from the written date) Prescriber Signature: Pharmacy Phone: -or- ered: Dose: of 2 or 3 (circle one)	
Prescriber Name: Pharmacy Address: Patient Referred Hepatitis B Vaccination administer Lot: Expiration Date: _	expires 90 days from the written date) Prescriber Signature: Pharmacy Phone: -or- ered: Dose: of 2 or 3 (circle one)	

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) ł	has been
prescribed HIV Pre-Exposure Prop	ohylaxis (PrEP) by				,	RPH. This regimen
was filled on/// // (Date)	(Date) and follow-up H	IV testing is	recomme	nded in appi	roximate	ly 90 days
This regimen consists of the follo Truvada (emtricitabine/tend 200/300mg tablets • Take one tablet by r		200/2	25mg table			fenamide) ily for 90 days
Your patient has been tested for	and/or indicated the follow	wing:				
Test Name	Date of Test	<u>Result</u>				Needs referral
 HIV ag/ab (4th gen): 	//	□ reactive	🗆 indeter	r <i>minate</i> 🗆 ne	egative	□ Yes
• Syphilis/Treponemal antibody:	//	□ reactive	🗆 indeter	r <i>minate</i> 🗆 ne	egative	□ Yes
Hepatitis B surface antigen:	//	positive	🗆 negati	ve		□ Yes
Gonorrhea/Chlamydia:	//					□ Yes
Urinalysis result:	Pharyngeal test result:		Rectal te	st result:		
\square reactive \square indeterminate	□ reactive □ indeterminate	2	🗆 reactive	e 🗆 indeterr	ninate	
negative	negative		🗆 negativ	'e		
Renal function (CrCl):	//		mL/min			□ Yes
CrCl >60mL/min	CrCl 30mL/min - 60mL/n	nin	□ CrCl <3	0mL/min		
 Signs/symptoms of STI not 		present				□ Yes
otherwise specified:	//					
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:

- 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.

Pharmacy monitoring of HIV PrEP:

- The pharmacy prescribing 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.

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 <u>CDC website</u>.

DEVICES AND SUPPLIES

PRESCRIPTIVE AUTHORITY - OREGON PHARMACIST

AUTHORITY and PURPOSE: Per <u>ORS 689.645</u>, a pharmacist may prescribe and dispense an FDAapproved drug or device, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis

➢ Following all elements outlined in <u>OAR 855-020-0110</u>, a pharmacist licensed and located in Oregon may prescribe the following devices and supplies:

- Diabetic blood sugar testing supplies;
- Injection supplies;
- Nebulizers and associated supplies;
- Inhalation spacers;
- Peak flow meters;
- International Normalized Ratio (INR) testing supplies;
- Enteral nutrition supplies;
- Ostomy products and supplies; and
- Non-invasive blood pressure monitors

v. 06/2021

SAMPLE Visit Summary

11---

Conect Patient N	ame:		DOB:
Chief	Subjective Data	Objective Data	History of Present Illness
Complaint			
	□Allergies		
	□Past Medical History		
	□Social History		
	Medications	Post-diagnostic? □Yes □No	
	<u>Adherence</u>	Diagnosis:	
	□Past 90 day use	Therapy Initiation	
		Extension of Therapy	
	<u>Safety</u>		
	□ Relevant Medications	🗆 Other	

Assess Per Drug Therapy Management Protocol □ Attached □ Inclusion Criteria Met Exclusion Criteria Met □ Referral Criteria Met

Resource(s) Used

(e.g. Protocol, Guideline(s), Other Evidence Based Source, etc. (Note: this information shall be referenced in the established Drug Therapy Management Protocol) _____

Plan and Implement

	Name	
Treatment Goals	Address	Date
□ Monitoring Parameters OR □ Referral Reason	R×#	Refills
	RPh Signature Address	NPI/DEA #
Ollow-up (Monitor and Evaluate):		Date:

□ Provider Referral: _

□ Notification Sent

Prescribing RPh Printed Name

RPh Signature

Date

Sample Template: Please feel free to customize this document, however you must retain all elements required per OAR 855-020-0110.

Subjective Data	
Objective Data	
History of Present Illness	
Assessment	
Care Plan	

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