CONDITIONS

VULVOVAGINAL CANDIDIASIS (VVC)

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 855-020-0110, 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

Name_____ Preferred pronouns: _____ Date of Birth_____ Age_____
Health Care Provider's Name_____
Do you have health insurance? *Yes / No* Name of Insurance Provider_____
Any allergies to Medications? *Yes / No* If yes, list them here _____

1.	Has a provider ever diagnosed you with a yeast infection? If so, how recently? _____ How many have you experienced within the last year? _____ How many have you experienced within your lifetime? _____ Have you ever experienced a difficult to treat yeast infection or had treatment not work? What treatments (if any) have you tried for past and/or current yeast infections? Please list them here: _____ _____	□ Yes □ No □ Not sure □ Yes □ No □ Not sure
2.	Symptom review: - Soreness, burning, or itchy vaginal area - Abnormal discharge (color, smell, consistency, etc…) - Pain with urination - Fever - Pain in the lower abdomen and/or back - Other symptoms: _____	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
3.	Have you ever been sexually active? If so, how recently? : _____	□ Yes □ No
4.	Have you ever been tested for OR diagnosed with a sexually transmitted infection? If yes, when? : _____	□ Yes □ No □ Not sure
5.	When was the first day of your last menstrual period?	Date: _____
6.	Are you currently pregnant?	□ Yes □ No □ Not sure
7.	Are you using any of the following contraceptive devices? 1. Vaginal sponge 2. Diaphragm 3. Intrauterine device (IUD)	 □ Yes □ No □ Yes □ No □ Yes □ No
8.	Have you used antibiotics in the last month?	□ Yes □ No □ Not sure
9.	Has a provider ever diagnosed you with an autoimmune disease? If yes, list them here: _____ _____	□ Yes □ No □ Not sure
10.	Do you have diabetes?	□ Yes □ No □ Not sure
11.	Have you ever been diagnosed with a heart rhythm condition (or QT prolongation)? If yes, list them here: _____ _____	□ Yes □ No □ Not sure
12.	Do you have any other medical problems? If yes, list them here: _____ _____	□ Yes □ No □ Not sure
13.	Are you currently taking any medications, supplements, and/or vitamins? If yes, list them here: _____ _____ _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

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 → **Refer**

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

a. Are you using the following contraceptive devices: vaginal sponge, diaphragm, IUD → **Refer**
b. Do you have diabetes or other immunosuppressed conditions? → **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

Medication options/considerations:

- ***Fluconazole***[1]:
    - *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 Torsade's 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
    - *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

- ***Clotrimazole***[2]*:*
    - *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

- ***Miconazole***[3]*:*
    - *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
    - *Contraindications for miconazole use: (consider other therapy)*
        - Progesterone
        - Vitamin K Antagonists (i.e. warfarin)
        - Sulfonylureas
        - Other interacting medications
- ***Tioconazole***[4]*:*
    - *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

References:

1. Fluconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Updated February 12, 2020. Accessed February 14, 2020.
2. Clotrimazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Updated February 14, 2020. Accessed February 15, 2020.
3. Miconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Updated February 17, 2020. Accessed February 17, 2020.
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.
5. Peter G. Pappas, Carol A. Kauffman, David R. Andes, Cornelius J. Clancy, Kieren A. Marr, Luis Ostrosky-Zeichner, Annette C. Reboli, Mindy G. Schuster, Jose A. Vazquez, Thomas J. Walsh, Theoklis E. Zaoutis, Jack D. Sobel, Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America, *Clinical Infectious Diseases*, Volume 62, Issue 4, 15 February 2016, Pages e1–e50, https://doi.org/10.1093/cid/civ933

Assessment notes/Clinical decision-making rationale:

_____
_____
_____
_____
_____

Plan:

- ☐ Patient referred

  OR

- ☐ Prescription written

Optional Prescription template-May be used by pharmacy if desired

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

Rx

Drug:

Sig:

Quantity:

Refills: 0

DAW: ____

Written Date: _____

Prescriber Name: _____

Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

PREVENTIVE CARE

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

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 855-020-0110, 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 OAR 855-020-0110, 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

Name_____Date of Birth_____Age____ *Today's Date* _____
Today's BP_____/_____mmHg
Do you have health insurance? *Yes / No* Name of insurance provider _____
PCP/Health Care Provider's Name_____
List of medicine you take _____
_____
_____
Any allergies to medicines? Yes / No If yes, list them here _____
Any food allergies (ex. menthol/soy) _____
_____
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_____

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 heart beat 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

Stop here if patient and pharmacist are considering nicotine replacement therapy.

KEEP GOING

If patient and pharmacist are considering non-nicotine replacement therapy (ex. varenicline or bupropion) continue to answer the questions below.

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 of stroke, or a diagnosis of epilepsy?	□ Yes □ No □ Not sure
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? (ex. depression, anxiety, bipolar disorder, schizophrenia)?	□ Yes □ No □ Not sure

Medication History:

15.	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
16.	Do you take linezolid?	□ Yes □ No □ Not sure
17.	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 thoughts of hurting yourself in some way?	**0**	**1**	**2**	**3**

Patient Signature_____Date_____

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
- ☐ Referred patient to Oregon Quit Line (1-800-QUIT-NOW or www.quitnow.net/oregon)
- ☐ BP Reading: ____/____ *must be taken by a RPh

Note: RPh must refer patient if blood pressure ≥ 160/100

Rx

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:

_____

Tobacco Cessation Assessment & Treatment Care Pathway

1) Health and History Screen Part 1 Review Tobacco Cessation Patient Questionnaire (Questions 1 -2)	No = No Contraindicating Conditions. Continue to step 2	Yes/Not sure = Contraindicating Conditions. → Refer	Refer to PCP and/or Oregon Quit Line 1-800-QUIT-NOW
2) Health and History Screen Part 2 Review Tobacco Cessation Patient Questionnaire (Question 3)	Smoking Cigarettes. Continue to step 3	Yes to question 3 → Refer	Refer to Oregon Quit Line 1-800-QUIT-NOW to receive counseling and NRT
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 → Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW
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	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW

5) Medical History Nicotine Replacement Therapy Questions (Questions 6-8) Question 6 = if Yes, avoid using nicotine gum Question 7 = if Yes, avoid using nicotine nasal spray Question 8 = if Yes, avoid using nicotine inhaler	If patient wants NRT, prescribe NRT*	If patient wants bupropion or varenicline, continue to step 6.

Prescribing NRT*(pg.2):	• Combination NRT is preferred (Nicotine patch + Acute NRT) • Acute NRT = Nicotine gum, Nicotine lozenge, Nicotine nasal spray, Nicotine inhaler	**Tobacco History (Question 9 on questionnaire)** If Yes to smoking < 10 cigs/day, start with nicotine patch 14mg/day If No to smoking > 10 cigs/day start with nicotine patch 21mg/day

6) Medical History Bupropion and varenicline screening Questions 10-14	Consider NRT* if yes to any question from 10-14		
	a) If yes to any question → avoid bupropion. If patient still wants bupropion, refer. → Refer		Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW
	b) If yes to any questions from 12-14→ avoid varenicline. If patient still wants varenicline, refer. → Refer		
	If patient answered no to questions 10 – 14, continue to step 7. If patient answered no to questions 12-14, but yes to question 10 and/or 11, AND wants varenicline (but not bupropion), skip to step 8		

7) Medication History Questions 15-17 on questionnaire.	If patient answered no to questions 15-17, review depression screening step 8.	If patient answered yes to any question from 15-17 → Avoid bupropion. → Refer - Refer if patient still wants bupropion. - If patient wants varenicline, continue to depression screening step 8.	Refer to PCP if patient wants bupropion; NRT* can be considered

8) The Patient Health Questionnaire 2 (PHQ 2): Depression Screening	Score < 3 on PHQ2. Review Suicide Screening in step 9.	Score ≥ 3 on PHQ. → Refer Avoid bupropion and varenicline, refer to PCP for treatment. NRT* can be offered.	Refer to PCP; NRT* can be considered
9) Suicide Screening	Score of 0 on suicide screening. May prescribe bupropion or varenicline.	Score ≥ 1 on suicide screening. → Refer **Immediate** referral to PCP.	Call PCP office to notify them of positive suicide screening and determine next steps. After hours, refer to suicide hotline 1-800-273-8255

Prescribing Bupropion:	**Prescribing Varenicline:**
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.	0.5mg daily for 3 days then 0.5mg twice daily for 3 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 use in combination with other smoking cessation medications.

***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: o 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 o Weeks 7 to 9: Chew 1 piece of gum every 2 to 4 hours (maximum: 24 pieces/day) o Weeks 10 to 12: Chew 1 piece of gum every 4 to 8 hours (maximum: 24 pieces/day)
Nicotine Lozenges	• 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: o 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 o Weeks 7 to 9: 1 lozenge every 2 to 4 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day) o 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. • *Discontinuation of therapy:* 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 rolling 12 months

TREATMENT CARE PLAN:

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

TRAVEL MEDICATIONS

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 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pre-travel medications.
  - Malaria prophylaxis
  - Traveler's diarrhea
  - 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; and
- A minimum of 1 hour of travel medication continuing education (CE), every 2 years.

Travel Medication Self-Screening Patient Intake Form

Date: _____

PATIENT INFORMATION

Name: _____ Date of Birth: ____/____/____ Age: _____
Address: _____ Weight: _____

Telephone No.: ( ) _____E-Mail Address: _____

PCP/Healthcare Provider: _____Phone: ( ) _____ Fax: ( ) _____

TRAVEL SPECIFICS

Purpose of Trip: _____

Activities: _____

Departure Date: _____ Return Date: _____

Countries AND Cities to be Visited (In Order of Visits)	**Arrival Date**	**Departure 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

ALLERGIES

□ No known drug allergies □ No known food allergies

Drug Allergies: _____

_____

Food Allergies: _____

_____

VACCINE MEDICAL INFORMATION (add note to RPh here!!!**

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

Vaccinations	Yes – *(Enter vaccination date below)*	No	Not Sure
Hepatitis A	Dose 1: 2:		
Hepatitis B	Dose 1: 2: 3:		
Influenza			
Japanese Encephalitis			
Meningococcal Meningitis	Dose 1: 2:		
MMR (Measles, Mumps, Rubella)	Dose 1: 2:		
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_____

Travel Medications - Assessment and Treatment Care Pathway

STEP 1: Assess routine and travel vaccinations
STEP 2: Choose and issue prescription for appropriate prophylaxis medication, in adherence to the most current edition of the CDC's Health Information for International Travel ("Yellow Book") 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

                Pediatric Dosing:
                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®)
Adult dosing: Atovaquone/Proguanil 250mg/100mg
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

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)
      <u>Adult Dosing:</u> 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)

      <u>Pediatric Dosing:</u>
      - 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. <u>Acute Mountain Sickness</u>

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®)*

         <u>Adult Dosing:</u> 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

         <u>Pediatric Dosing:</u>

         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. <u>Motion Sickness</u>

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
      1. **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
         c. *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. ≥ 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

POST-EXPOSURE PROPHYLAXIS

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 855-020-0110, 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. 2-3)
  - Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 4-6)

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

CONSIDERATIONS from February meeting, with staff recommendations:

- *Can the trauma informed care element be obtained separately from the prescribing training program?*
  - *Staff recommends no, based on Committee recommendation and the sensitive nature of these conversations, directly connected to the pharmacist's professional ability to navigate the variable scenarios.*
- *Should training include motivational interviewing skills?*
  - *Steff recommends yes, based on Committee recommendation and the pharmacist's ability to gather relevant history from the Intake Form as well as via the face-to-face assessment/interaction.*

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

(confidential-protected health information)

Name_____Date of Birth_____ Age_____ Today's Date_____

Health Care Provider's Name_____

Do you have health insurance? *Yes / No* Name of Insurance Provider_____

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

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_____

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

Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication

Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg (Truvada)
  Sig: Take one tablet by mouth once daily in combination with Isentress for 30 days
  Quantity: #30
  Refills: none

AND

- Drug: raltegravir 400mg (Isentress)
  Sig: Take one tablet by mouth twice daily in combination with Truvada for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:
Lot:_____Expiration Date:_____

Notes:_____
_____
_____
_____

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

Name_____Date of Birth_____ Today's Date_____

1. Is the patient less than 13 years old?		Notes: According to the CDC PEP treatment guidelines, Truvada® plus Isentress® is a preferred regimen for individuals 13 years and older.
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. Is the patient known to be HIV-positive?		Notes:
Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.	No: Go to #3. Conduct 4th generation HIV fingerstick test if available (optional).	
3. What time did the exposure occur?		Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.
☐≤72 hours ago: go to #4	☐>72 hours ago: PEP not recommended. Refer patient to local primary care provider, infectious disease specialist, or public health department.	
4. Was the patient a survivor of sexual assault?		Notes:
Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #5) and then refer the patient to the emergency department for a sexual assault workup.**	No: 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.	

<table>
<tr><td colspan="2">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?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>Yes: Go to #10</td><td>No: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.</td></tr>
<tr><td colspan="2">10. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumurate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</td></tr>
<tr><td>Yes: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.</td><td>No. Go to #11</td></tr>
<tr><td colspan="2">11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records or AlertIIS. Dates:_____</td></tr>
<tr><td>Yes: Go to #13</td><td>No: Go to #12</td></tr>
<tr><td colspan="2">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:_____</td><td></td></tr>
<tr><td colspan="2">13. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min</td></tr>
<tr><td>Yes: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.</td><td>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.</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">Recommended regimen:</td></tr>
<tr><td>Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days

PLUS

Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days</td><td colspan="2">Notes:
There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time.
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.</td></tr>
</table>

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 ORS Chapter 419B. 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_____