PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

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

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

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

PHARMACIST TRAINING/EDUCATION:

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

REFERENCES

- **Standardized PrEP Prescription Template (*optional)***
- Preexposure Prophylaxis for the Prevention of HIV Infection in the United States- 2021 Update. Accessed September 15, 2025. Clinical Guidance for PrEP | HIV Nexus | CDC
- PrEP | HIV Basics | HIV/AIDS | CDC. Published July 11, 2022. Accessed September 15, 2025. Preventing HIV with PrEP | HIV | CDC

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

(CONFIDENTIAL-Protected Health Information)

Patient Information

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

Name on Documents_____ Name _____

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

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

Street Address _____

Phone ( ) _____ Email Address _____

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

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

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

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

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

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

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

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

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

(CONFIDENTIAL-Protected Health Information)

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

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

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

_____ _____
_____ _____
_____ _____
_____ _____
_____ _____

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

Section 4: What to Expect on HIV PrEP

The biggest risks of PrEP are:

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

Please be aware that:

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

Patient Signature:_____ **Date:**_____

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
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ALGORITHM A: ORAL PrEP INITIATION

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

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

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

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

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

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

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

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

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

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

Time of last potential exposure:	☐ **≤ 72 hours**	☐ **>72 hours to ≤ 4 weeks**		☐ **> 4 weeks**
Symptoms of possible acute HIV infection:	HIV Post-Exposure Prophylaxis (PEP) → PEP Protocol	☐ **NO symptoms** -Eligible for up to a 30-day supply of PrEP -Order HIV test now[1] -Counsel on acute retroviral syndrome symptoms	☐ **YES symptoms** (Communication Example B) → Refer	

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

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

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
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5) LABORATORY RESULTS- See Appendix A for detailed information on labs	
-Hepatitis B Vaccine series	□ completed
or	
-Hepatitis B serologies resulted:	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Serum creatinine	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Syphilis/Treponemal antibody	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Lipid Panel (F/TAF Only)	**□ resulted, ok for protocol □ resulted, elevated – may prefer Truvada and refer □ no result yet**
Are all required Baseline labs resulted (Tables 2 and 3 below)?	□ **YES** □ **NO**

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

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
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ALGORITHM B: ORAL PrEP CONTINUATION

1) HIV TEST

HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive
*HIV Ag/Ab must be RESULTED within 7 days prior to prescribing and dispensing

HIV RNA test resulted □ detected □ indeterminate □ not detected □ result pending □ none
May order HIV RNA as appropriate

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

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

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

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

3) MEDICAL and MEDICATION HISTORY

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

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

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

-See **Table 1: REQUIRED PrEP Labs**
-Serum creatinine □ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Syphilis/Treponemal antibody □ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia □ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Lipid Panel (F/TAF Only) □ resulted, ok for protocol □ resulted, elevated – may prefer Truvada and refer □ no result yet
- Required PrEP Continuation labs resulted ? □ YES □ NO

5) DETERMINE DURATION OF PrEP PRESCRIPTION

-Required BASELINE labs resulted? □ YES □ NO

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

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ORAL HIV PrEP RECOMMENDED REGIMENS:

Note: There are other FDA-Approved medications available and may be other dosing strategies for PrEP. Daily dosing of emtricitabine / tenofovir DF (Truvada®) and emtricitabine / tenofovir alafenamide (Descovy®) are the only regimens permitted for pharmacist prescribing at this time.

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

Table 1: ORAL PrEP Laboratory Requirements

REQUIRED:

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

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

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

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
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APPENDIX A- ALGORITHM A: ORAL PrEP INITIATION 4) LABORATORY- Required Baseline Labs

Hepatitis B Status

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

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

Renal Function Status

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

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

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

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

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

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

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
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APPENDIX B- ORAL ALGORITHM B: PrEP CONTINUATION 4) LABORATORY- Required Baseline Labs

Renal Function Status

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

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

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

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

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

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

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ALGORITHM C: INJECTABLE PrEP INITIATION

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

- Review Patient Intake Form Questions #1b and #1c Is the patient < 13 years old[i] Is the Patient < 77 **pounds** [ii] ☐ **If NO to both, proceed.**	☐ **If YES to either, refer.**

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

☐ **NO** history of HIV	☐ **YES** has history of HIV, refer

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

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

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

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

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

Refer and Report [2,3]

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

Time of last potential exposure:	☐ **≤ 72 hours**	☐ **>72 hours to ≤ 4 weeks**		☐ **> 4 weeks**
Symptoms of possible acute HIV infection:	HIV Post-Exposure Prophylaxis (PEP) PEP Protocol	☐ **NO symptoms** -Eligible for up to a 30-day supply of PrEP -Order HIV test now[1] -Counsel on acute retroviral syndrome symptoms	☐ **YES symptoms** (Communication Example B) Refer	

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

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

5) LABORATORY RESULTS- See Appendix C for detailed information on labs
-Syphilis/Treponemal antibody □ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia □ resulted, ok for protocol □ resulted, needs referral □ no result yet

Are all required Baseline labs resulted (Tables 2 and 3 below)? ☐ **YES** ☐ **NO**

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

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

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ALGORITHM D: INJECTABLE PrEP CONTINUATION

1) HIV TEST

HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive
*HIV Ag/Ab must be RESULTED within 7 days prior to prescribing and dispensing

HIV RNA test resulted □ detected □ indeterminate □ not detected □ result pending □ none
May order HIV RNA as appropriate

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

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

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

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

3) MEDICAL and MEDICATION HISTORY

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

Pregnancy	**Medication**
Review Patient Intake form #3e	Review Patient Intake form # 3f

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

-See **Table 1: REQUIRED PrEP Labs**
-Syphilis/Treponemal antibody □ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia □ resulted, ok for protocol □ resulted, needs referral □ no result yet

- Required PrEP Continuation labs resulted ? □ YES □ NO

5) DETERMINE DURATION OF PrEP PRESCRIPTION

-Required BASELINE labs resulted? □ YES □ NO

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

APPENDIX C – ALGORITHM C & D: INJECTABLE PrEP 4) LABORATORY – Required Labs

Syphilis/Treponemal Antibody Order lab at initial intake and every 60-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Report [1,2]
Gonorrhea and Chlamydia Screenings Order lab at initial intake and every 60-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D) Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.
[2] County Health Department Directory: https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Table 2: INJECTABLE HIV PrEP Laboratory Requirements

REQUIRED:

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

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

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

INJECTABLE HIV PrEP RECOMMENDED REGIMENS:

Cabotegravir

(CAB; Apretude®):

Dose*: 600 mg/3 ml injected intramuscularly (ventrogluteal via Ztrack injection technique method preferred) now, then repeat at 1 month, then every 2 months thereafter

FDA-Approved for: all HIV risk exposure risk indications, except if injection substance use is the only HIV risk

Preferred if: renal insufficiency, risk of renal insufficiency (e.g., uncontrolled hypertension or uncontrolled blood glucose), and/or bone density concerns for cisgender women

Cost: no generic, may require prior authorization, patient may be eligible for manufacturer assistance program -or- copay card

Lenacapavir

(LEN; Yeztugo®):

Dose:**

- Initiation:
  - Day 1: 927 mg subcutaneous injection (2 x 1.5mL injections) & 600 mg orally (2 x 300 mg tablets)
  - Day 2 : 600mg orally
- Continuation:
  - 927 mg subcutaneous injection every 6 months (26 weeks) from date of last injection ± 2 weeks.

FDA-Approved for: all HIV risk exposure risk indications, except if injection substance use is the only HIV risk.

Preferred if: renal insufficiency, risk of renal insufficiency (e.g., uncontrolled hypertension or uncontrolled blood glucose), and/or bone density concerns for cisgender women

Cost: no generic, may require prior authorization, patient may be eligible for manufacturer assistance program -or- copay card

Clinical Pearls:

- Ice can be applied before AND after, and patients can also take acetaminophen ibuprofen ahead of time to help mitigate pain. Icing or up to 10 minutes prior to injection (at both injection sites) is the main recommendation for reduction pain.
- It is not a problem to not feel the nodule. In the studies about 35% of patients didn't feel nodules at all with the first injection.

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

*Apretude® resources:
Dosing and Administration Guide - https://apretudehcp.com/resources
Video for Preparing and Administering Apretude® - https://apretudehcp.com/resources
** Yeztugo® resources:
Dosing and Administration Guide - YEZTUGO (lenacapavir) | YEZTUGO HCP
Video for Preparing and Administering Apretude® - YEZTUGO (lenacapavir) Dosing and Administration | YEZTUGO HCP

COMMUNICATION EXAMPLES:

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

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

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

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

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

This regimen consists of the following (check one):

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

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

☐ **Apretude® (cabotegravir) 600mg/3mL injectable**
- **Inject 3mL (600mg) intramuscularly now, then repeat at 1 month, #3 mL, 1 refill**
- **Inject 3mL (600mg) intramuscularly every 2 months, #3 mL, 0 refills**

☐ **Yeztugo® (lenacapavir) 300mg tablets & 927 mg injectable**
- **Take two tablets (2 x 300mg tablets) of oral lenacapavir AND inject 927mg (2 x 1.5mL injections) under the skin once on day 1, then ONLY take two tablets (2 x 300mg tablets) on day 2, #4 tablets & #3mL, 0 refills**
- **Inject 927mg (2 x 1.5mL injections) under the skin every 6 months (26 weeks) from the date of last inject ± 2 weeks, #3mL, 0 refills**

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

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

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

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

Provider pearls for HIV PrEP:

- **Oral** PrEP is prescribed for up to a 90 day supply for each prescription to align with appropriate lab monitoring guidelines.
- Truvada® is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada® ~~and~~ Descovy®, **Apretude® (cabotegravir) and Yeztugo® (lenacapavir)** are ~~both~~ safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada® is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacist monitoring of HIV PrEP and transition of care:

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

Oral PrEP Prescription

Optional-May be used by pharmacy if desired

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

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

Rx

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

-or-

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

Written Date: _____

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

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:
Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Injectable PrEP Prescription

Optional-May be used by pharmacy if desired

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

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

Rx

☐ **Apretude® (cabotegravir) 600 mg/3 mL injectable**
- ☐ **Inject 3 mL (600 mg) intramuscularly now, then repeat at 1 month, #3 mL, 1 refill**
- ☐ **Inject 3 mL (600 mg) intramuscularly every 2 months, #3 mL, 0 refills**

-or-

☐ **Yeztugo® (lenacapavir) 300 mg tablets & 927 mg injectable**
- ☐ **Take two tablets (2 x 300 mg tablets) of oral lenacapavir AND inject 927 mg (2 x 1.5 mL injections) under the skin once on day 1, then ONLY take two tablets (2 x 300 mg tablets) on day 2, #4 tablets & #3 mL, 0 refills**
- ☐ **Inject 927 mg (2 x 1.5 mL injections) under the skin every 6 months (26 weeks) from the date of last inject ± 2 weeks, #3 mL, 0 refills**

Written Date: _____

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

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	