PREVENTATIVE CARE

POST-EXPOSURE PROPHYLAXIS FOR BACTERIAL SEXUALLY TRANSMITTED INFECTIONS (STI PEP)

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 <u>OAR 855-115-0330</u> and <u>OAR 855-115-0335</u> a pharmacist licensed and located in Oregon may prescribe post-exposure preventative treatment for chlamydia, gonorrhea, and syphilis (STI PEP).

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized STI PEP Patient Intake Form (pg. 2)
- Utilize the standardized STI PEP Assessment and Treatment Care Pathway (pg. 3-6)
- Utilize the standardized STI PEP Prescription Template optional (pg. 7)
- Utilize the standardized STI PEP Provider Fax (pg. 8)
- Utilize the standardized STI PEP Patient Informational Handout (pg. 9-10)

PHARMACIST TRAINING/EDUCATION:

- No required training/education
- Recommended: Completion of an educational training program of at least 1 hour related to the prescribing of STI PEP or STI curriculum, to include related trauma-informed care*.
 - DoxyPEP: Who, When, and How. https://www.iasusa.org/events/webinar-2023-luetkemeyer/ International Antiviral Society–USA (IAS–USA); Program is Accreditation Council for Pharmacy Education (ACPE) accredited
 - National STD Curriculum (A free educational website from the University of Washington STD Prevention Training Center). https://www.std.uw.edu/

RESOURCES:

Doxycycline for STI PEP Implementation Toolkit. National Coalition of STD Directors.
 https://www.ncsddc.org/wp-content/uploads/2023/07/Doxycycline-as-STI-PEP-Toolkit-July-2023.pdf (accessed 1/5/2024)

^{*}The programs listed above do not include specific training on trauma-informed care.

Post-Exposure Prophylaxis for Bacterial STIs (STI PEP) Self-Screening Intake Form (CONFIDENTIAL-Protected Health Information)

Date			// Age
Legal	Name	Preferred Name	
Sex A	ssigned at Birth (circle) M / F	Gender Identification	on (circle) M / F / Other
Prefe	rred Pronouns (circle) She/Her/Hers, He/Him/His, They	/Them/Their, Ze/Hir/Hirs, Other	•
Stree	t Address		
	e () E	mail Address	
	hcare Provider Name P	mail Addresshone ()	Fax ()
	ou have health insurance? Yes / No	nsurance Provider Name	,
•		yes, please list	
		, co, p. caco not	
1.	Are you UNDER 13 years old?		□ Yes □ No
2.	Do you identify as gay, bisexual, or a man who has sex	with men?	□ Yes □ No
	Do you identify as a transgender woman?		□ Yes □ No
3.	a) Has a healthcare provider EVER tested or diagnose	d you with a chlamydia OR	☐ Yes ☐ No ☐ Not sure
	gonorrhea OR syphilis infection?		
	b) If yes, how recently? What we	re the results?	_
	c) How many infections have you experienced within	the last 12 months?	
4.	a) Have you ever failed to complete treatment for ch	amydia OR gonorrhea OR syphil	is ☐ Yes ☐ No ☐ Not sure
	infection, or had the treatment not work?		
	b) What treatments (if any) have you tried for past ar	nd/or current chlamydia OR	
	gonorrhea OR syphilis infections? Please list them	here:	
	,,		
5.	Symptom review: Do you currently have:		
	- Abnormal discharge (color, smell, consistency, etc.) fr	om penis	□ Yes □ No
	- Burning sensation when peeing (urination)	P -	□ Yes □ No
	- Anal itching, discharge, or bleeding		□ Yes □ No
	- One or multiple sores in, on, or around penis, anus, o	r rectum: or rash anywhere	□ Yes □ No
	- Soreness in rectum, or painful bowel movements	, , , , , , , , , , , , , , , , , , ,	□ Yes □ No
	- Pain and swelling in one or both testicles		□ Yes □ No
	- Other symptoms (describe):		163 2 140
6.	Have you used antibiotics in the last month?		☐ Yes ☐ No ☐ Not sure
7.	a) Do you have oral, anal, or vaginal sexual contact W	ITHOUT a condom?	□ Yes □ No
, ·	If yes, how recently (date)?	moor a condom.	/ /
	Did this activity happen more than once in the	nast 12 months?	□ Yes □ No
	b) In the future, will you have oral, anal, or vaginal se	•	
	c) Have you had multiple sex partners in the past 12 i		□ Yes □ No
	d) Do you (will you) engage in group sex or chem-sex		□ Yes □ No
	e) Do you (will you) participate in sexual activities du		□ Yes □ No
	festivals, or similar?	ing weekend events, cluises,	L 163 L INO
8.	Have you had an exposure due to unwanted physical co	ontact or a sevual assault?	☐ Yes ☐ No ☐ Not sure
	a) Are you currently taking HIV Pre-Exposure Prophylax		□ Yes □ No □ Not sure
9.	, , , , , , , , , , , , , , , , , , , ,	·	
10	b) Do you use HIV Post-Exposure (HIV PEP) medication.		☐ Yes ☐ No ☐ Not sure
10.	Do you have a health condition involving your esophag	us, intestines, or liver?	☐ Yes ☐ No ☐ Not sure
11.	Do you have any other medical problems?		☐ Yes ☐ No ☐ Not sure
	If yes, list them here:		
4.5			
12.	Are you currently taking any medications, supplements		☐ Yes ☐ No ☐ Not sure
	If yes, list them here:		_

Oregon Board of Pharmacy v. 06/2024

_ Date_____

Signature___

1) STI PEP patient population eligibility for enrollment in protocol (Form Q: #1-2)

- Q1: If patient less than 13 years of age -> REFER to medical provider (doxycycline contraindicated if <8 years old)
- b. Q2: If patient identifies as gay, bisexual, a man who has sex with men (GBMSM), or transgender woman (TGW) who has sex with men -> Continue algorithm (Step 2)
 - If not -> DEFER prescribing STI PEP; advise to continue condom use. Refer to medical provider if non-protocol-eligible patient wants STI PEP. Studies do not support the use of STI PEP in other patient populations.

2) Bacterial Sexually Transmitted Infection (STI) Screen and Risk Assessment: chlamydia OR gonorrhea OR syphilis infection (Form Q: #3-7)

		Sexual Behavior or Activity	
		Q7a: Reports <i>condomless</i> anal, oral, or vaginal sexual contact with ≥ 1 cis-male or trans-female partner in the past 12 months	Q7a: DOES NOT report <i>condomless</i> anal, oral, or vaginal sexual contact with ≥ 1 cis-male or trans-female partner in the past 12 months
	Q3a-c: Has had one (1) or more chlamydia OR gonorrhea OR syphilis infections within 12 months	Prescribe STI PEP	Consider STI PEP Q7b: If expects to have condomless sex in future: -> prescribe STI PEP.
Infection	Q3a-c: Has <i>NOT</i> had one (1) or more chlamydia OR gonorrhea OR	Consider STI PEP	Consider STI PEP
History	tory syphilis infections within 12 months	If history of, or expectation for: Q7c: multiple sex partners, OR Q7d: group sex/ chem-sex, OR Q7e: participating in sexual activities that are known to increase likelihood of exposure to STIs, e.g., during weekend events, cruises, and festivals: -> prescribe STI PEP.	If history of, or expectation for: Q7c: multiple sex partners, OR Q7d: group sex/ chem-sex, OR Q7e: participating in sexual activities that are known to increase likelihood of exposure to STIs, e.g., during weekend events, cruises, and festivals: -> prescribe STI PEP.

a. **EXCEPTIONS**:

- Q4: If history of failing to complete treatment for chlamydia OR gonorrhea OR syphilis infection-> NOTIFY medical provider.
- Q4: If patient completed treatment for chlamydia OR gonorrhea OR syphilis and infection did not resolve -> REFER to medical provider
- Q5: If experiencing symptoms consistent with current STI: Abnormal discharge (color, smell, consistency, etc.) from penis; Burning sensation when peeing (urination); Anal itching, discharge, or bleeding; One or multiple sores in, on, or around penis, anus, or rectum; or rash anywhere; Soreness in rectum, or painful bowel movements; Pain and swelling in one or both testicles.
 - If YES to any of these symptoms -> REFER for diagnosis and active treatment of possible STI.
- Q7: If condomless sexual contact reported:
 - < 72 hours ago: direct patient to take doxycycline immediately after receipt of prescription
 - > 72 hours ago: direct patient not to use doxycycline; REFER to medical provider for assessment. May continue to provide STI PEP for future sexual activity.

b. SCREENING: IF PATIENT MEETS CRITERIA FOR PRESCRIBING STI PEP:

- Q3a-b: Recommend to patient they undergo bacterial STI testing at anatomic sites of exposure at baseline before initiation of STI PEP
 - o If patient had STI testing AND has not had sexual contact since test:
 - History of negative testing may serve as baseline (patient to provide records)
 - o Provide lab order for BASELINE screen: nucleic acid amplification test for gonorrhea and chlamydia at anatomic sites of exposure, and serologic testing for syphilis.
 - o Pharmacy may prescribe STI PEP without baseline results.
 - If STI testing is positive for chlamydia OR gonorrhea OR syphilis -> REFER for diagnosis and active treatment of possible STI.

3) Comprehensive therapy assessment (Form Q: #7-9)

- a. Q8: SEXUAL ASSAULT VICTIM/SURVIVOR? If the patient experienced a sexual assault, continue with the algorithm to prescribe STI PEP and then refer the patient to the emergency department for a sexual assault workup.
 - Oregon licensed pharmacists are mandatory reporters of child abuse (ORS Chapter 419B).
 Pharmacists must report any instance where they become aware of or have reason to believe child abuse has occurred. Pharmacists should also report elder abuse and vulnerable adult abuse.
 Reports must be made to the Oregon Department of Human Services @ 1-855-503-SAFE (7233).
- b. Q9: Assess for the need for HIV PEP and encourage the use of HIV PrEP
 - If not currently utilizing HIV PrEP or HIV PEP, offer patient to complete respective Patient Intake Forms for these statewide protocols.
- c. Q7a-e: Counsel on risk reduction strategies including:
 - Condom use for every instance of sexual contact
 - Consideration of reducing the number of partners

4) Medication and Disease State Screen (Form Q: #10-12)

- a. Q10: History of gastrointestinal (GI) conditions (e.g., esophagitis, diarrhea, Crohn's, etc.) -> Use caution. Have the patient contact pharmacy or medical provider if experiencing exacerbation of condition.
- b. Q11-12: Review medication history for duplicative therapy and/or drug-drug, drug-disease state interactions

5) Assess and Initiate Therapy:

All therapies are equally effective for STI PEP. Choice of therapy should be based on patient safety, preference, availability, and cost.

- Doxycycline hyclate delayed release 200 mg (1 tab) OR Doxycycline hyclate or monohydrate immediate release 100 mg (2 tabs/caps taken simultaneously)
 - Doxycycline 200 mg should be taken ideally within 24 hours but no later than 72 hours after condomless oral, anal or vaginal sexual contact
 - Doxycycline can be taken as often as every day, depending on frequency of sexual activity, but individuals should not take more than 200 mg within a 24 hour period
 - Suggested maximum initial quantity: #14 doses of 200 mg; NO Refills
 - Adjust quantity on individual assessment through shared decision making (sexual contact frequency)

6) Complete Patient Encounter

Advise:

- Take doxycycline exactly and prescribed and only for its intended purpose.
- Seek advice from a medical care provider if STI symptoms develop despite use of STI PEP.
 - If diagnosed with an STI while using STI PEP, patient should be treated according to standard CDC STI Treatment Guidelines
- Potential side effects (phototoxicity, esophagitis and esophageal discomfort, gastrointestinal intolerance) and methods to mitigate side effects.

- Potential for development of antimicrobial resistance in other pathogens and commensals.
- Importance of separating the doxycycline dose by at least 2 hours from antacids and supplements that contain calcium, iron, magnesium or sodium bicarbonate.
- Counsel on risk reduction strategies including:
 - Condom use for every instance of sexual contact
 - o Consideration of reducing the number of partners

Encourage:

- Vaccines which protect against sexually transmitted or sexually associated infections according to current local eligibility and ACIP Guidance
 - MPX Vaccine (Jynneos)
 - Meningococcal Vaccine (MenACWY)
 - o Hepatitis A/ Hepatitis B
 - o HPV

Document: All required elements

7) Monitoring and Continuation of Therapy

- a. Continuing therapy with STI PEP may be provided upon evidence of negative STI testing at every 3-month intervals (maximum 6-month interval)
 - Provide patient lab order for routine STI screening at 3-month intervals: nucleic acid amplification test for gonorrhea and chlamydia at anatomic sites of exposure, and serologic testing for syphilis.
 - Patient may instead receive STI screening labs via another medical provider and submit results to pharmacy
 - It is recommended to screen for HIV in HIV-negative patients. See Step 3 above.
 It is possible that patients are having labs collectively completed under order of another provider.
- b. If no STI is currently present, prescribe continuing therapy for STI PEP.

Medication considerations:

Doxycycline:

- Warnings/Precautions: Potential patient harm is associated with known side effects of taking doxycycline. It is well tolerated but may cause symptoms such as diarrhea and yeast infections. More rare side effects may include:
 - Intracranial hypertension (monitor for vision changes)
 - Skin reactions: Monitor for rash development
- Contraindications for doxycycline use: (consider other therapy)
 - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other tetracyclines

References:

- Doxycycline. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Accessed January 5, 2024. http://www.micromedexsolutions.com
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial STI Prevention.
 https://www.cdc.gov/std/treatment/guidelines-for-doxycycline.htm Division of STD Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (accessed 1/5/2024)
 - Molina JM, Charreau I, Chidiac C, et al. Post-exposure prophylaxis with doxycycline to prevent sexually transmitted infections in men who have sex with men: an open-label randomised substudy of the ANRS IPERGAY trial. Lancet Infect Dis. 2018 Mar;18(3):308-317.
 - o Luetkemeyer AF, Donnell D, Dombrowski JC, et al. Postexposure doxycycline to prevent bacterial sexually transmitted infections. N Engl J Med. 2023 Apr 6;388(14):1296-1306. DoxyPEP Reference (Conference Data- needs to be updated when paper available)
 - o Jean-Michel Molina, Beatrice Bercot, Lambert Assoumou, Algarte-Genin Michele, Emma Rubenstein, Gilles Pialoux, et al. ANRS 174 DOXYVAC: An Open-Label Randomized Trial to Prevent STIs in MSM on PrEP. CROI [Internet]. 2023 Feb 19;Seattle, Washington. Available from: https://www.croiconference.org/abstract/anrs-174-doxyvac-an-open-label-randomized-trial-to-prevent-stis-in-msm-on-prep/
 - Stewart J, Oware K, Donnell D, Violette L, Odoyo J, Simoni J, et al. Self-reported adherence to event-driven doxycycline postexposure prophylaxis for sexually transmitted infection prevention among cisgender women. STI and HIV 2023 World Congress, Chicago, IL. 2023 Jul 24; Seattle, Washington. Available from:
 https://www.croiconference.org/abstract/doxycycline-postexposure-prophylaxis-for-prevention-of-stis-among-cisgender-women/
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention. https://www.regulations.gov/document/CDC-2023-0080-0002 Centers for Disease Control and Prevention, Regulations.gov (accessed 1/5/2024)
- Guidelines for the Use of Doxycycline Post Exposure Prophylaxis for Bacterial STI Prevention. https://www.youtube.com/watch?v=2hYvrrK W58 Centers for Disease Control and Prevention (accessed 1/5/2024)
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention; Request
 for Comment and Informational Presentation. https://www.federalregister.gov/documents/2023/10/02/2023-21725/guidelines-for-the-use-of-doxycycline-post-exposure-prophylaxis-for-bacterial-sexually-transmitted Centers for Disease Control and Prevention,
 FederalRegister.gov (accessed 1/5/2024)

Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Optional -May be used by pharmacy if desired

atient Name:	Date of birth:
ddress:	
ty/State/Zip Code:	Phone number:
<	
Doxycycline (hyclate or monohydrate	e) 100mg tablets or capsules
	th as soon as possible within 72 hours after x. Max 2 tablets/capsules per 24 hours.
Quantity: 28	
Refills: 0	
	-or-
Doxycycline hyclate delayed release	200 mg tablets
Sig: Take 1 tablet by mouth as soon a anal, or vaginal sex. Max 1 tablet pe	as possible within 72 hours after condomless oral, er 24 hours.
Quantity: 14	
Refills: 0	
en Date:	
	Prescriber Signature:
nacy Address:	Pharmacy Phone:
	-or-
Patient Referred	
:	

Provider Notification

Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Pharmacy Name: Pharmacy Address:			
Pharmacy Phone: Pharmac	y Fax:		
Dear Provider	(name) () _	(FAX)	
Your patient	/ (name)/_	/(DOB) h	nas been
prescribed STI Post-Exposure Prophylaxis (STI PEP) by $_$, RPH. This
regimen was filled on/ (Date) for approximately months//		d follow-up STI testing is	recommended in
This regimen consists of the following (check one):			
 Take 2 tabs/caps by mouth as soon as possible with tab per 24 hours. Doxycycline hyclate delayed release 200 mg table Take 1 tab by mouth as soon as possible with tab per 24 hours. 	S		-
Your patient has been provided orders for baseline te	ting for, and/or indicate	ed the following:	
<u>Test Name</u> <u>Date of Test</u>			Needs referral
Syphilis/Treponemal antibody://	□ reactive □ indetermin	nate □ non-reactive	□ Yes
 Gonorrhea/Chlamydia:// Urinalysis result: Pharyngeal test re □ reactive □ indeterminate □ reactive □ indeterminate 		l test result: tive indeterminate	□ Yes
□ non-reactive □ non-reactive		reactive	

Provider Pearls for STI PEP:

to know about STI PEP.

• STI PEP is prescribed for up to a 30-dose or approximately 90-day supply for each prescription to align with appropriate lab monitoring guidelines.

We recommend evaluating the patient, confirming the results, and treating as necessary. Listed below are some key points

- An NIH-funded study found that doxycycline as STI Post-Exposure Prophylaxis (PEP) reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals taking HIV PrEP (Pre-Exposure Prophylaxis). Doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57% in people living with HIV (PLWH) (Source: N Engl J Med 2023; 388:1296-1306). This current efficacy data only applies to gay and bisexual men and other men who have sex with men (GBMSM) and transgender women; studies among heterosexual cis-gender women are ongoing.
- Patients using doxycycline as STI PEP should still engage in regular sexual health testing, including being screened for gonorrhea, chlamydia, syphilis, and HIV (if not known to be living with HIV) every three (to six) months. If a person utilizing doxycycline as STI PEP is diagnosed with an STI, they should be treated according to the 2021 CDC STI treatment guidelines.

Pharmacist Monitoring of STI PEP and Transition of Care:

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

This prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

If you have additional questions, please contact the prescribing pharmacy. For information about STI PEP, please visit the CDC website.

Patient Information

Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Pharmacy Name:	Pharmacist Name:	
Pharmacy Address:		
Pharmacy Phone Number:		

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

To help prevent certain sexually transmitted bacterial infections (STI) like chlamydia, gonorrhea, and syphilis, you have been prescribed doxycycline. Listed below is the medication you have been prescribed and some key points to remember about this medication.

Medications:

Doxycycline

Key Points:

What is STI PEP?

- STI PEP means taking the antibiotic doxycycline after sex, to prevent getting an STI. It is like a morning-after pill, but for STIs.
- It has been found that using doxycycline as STI PEP reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals also taking HIV PrEP (Pre-Exposure Prophylaxis). For people living with HIV, doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57%. This current data is specific to gay and bisexual men, and other men who have sex with men, and transgender women; studies among heterosexual cis-gender women are ongoing.
- If you use doxycycline as STI PEP, it's important to continue regular sexual health testing every three to six months for gonorrhea, chlamydia, syphilis, and HIV (if not known to be living with HIV). If you are using doxycycline as STI PEP and are diagnosed with an STI, you will need to follow treatment directions for that STI, which may include different antibiotics.

When should I take STI PEP?

• Doxycycline 200 mg should be taken ideally within 24 hours but no later than 72 hours after condomless sex. Condomless sex means oral, anal or vaginal/front-hole sex where a condom isn't used for the entire time.

What about when I have sex again?

• If you have sex again within 24 hours of taking doxycycline, take another dose 24 hours after your last dose. You can take doxycycline as often as every day when you are having condomless sex but don't take more than 200 mg every 24 hours.

How should I take STI PEP?

- Take doxycycline with plenty of water or something else to drink so that it does not get stuck when you swallow. If your stomach is upset by doxycycline, taking it with food may help.
- Avoid calcium, antacids, or multivitamins 2 hours before after taking doxycycline.
- Please do not share your doxycycline with others.

Patient Information

Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Pharmacy Name:	Pharmacist Name:	
Pharmacy Address:		
Pharmacy Phone Number:		

What are the possible side effects of doxycycline (STI PEP)?

- Some people are more sensitive to the sun when they take doxycycline, so wear sunscreen.
- Irritation to your esophagus (swallowing tube). If it occurs, alert your pharmacist or healthcare provider.
- Diarrhea is possible (it depends on how many doses per week you take). If severe or lasting more than a couple days, consult your pharmacist or healthcare provider.
- Yeast infections: Report any of the following presentations to your healthcare provider:
 - Mouth: white-colored patches and soreness
 - Penile-inverted vagina (front hole) of transgender women: white-colored, possibly malodorous discharge, and/or itching
 - Skin (skinfolds) or in the navel: bright-red rash, sometimes with breakdown of skin and small pustules, and itching
 - o Anus: raw, white or red, and itchy
- Report any vision changes... it might be a sign of high pressure inside the skull.
- Other types of skin rashes... follow up with a medical provider immediately if this appears.

Reminders

- Call us if you run out of doxycycline, if you are having any side effects, or if you think you may have an STI. We may need to refer you to a different healthcare provider.
- Please continue to get tested for STIs every 3 months AND whenever you have STI symptoms.
- STI PEP doesn't protect against other viral infections like monkeypox or HIV.

Follow-up and Next Steps

1. Make plans with pharmacy or a different healthcare provider to get STI screening every 3 months.

Resources used to create this document:

 $\frac{\text{https://www.ncsddc.org/wp-content/uploads/2023/08/Doxycycline-as-STI-PEP-Toolkit-August-2023.pdf}{\text{https://www.sfcityclinic.org/sites/default/files/2023-02/Doxy-PEP%20info%20sheet%2012.9.22.pdf}}$

Luetkemeyer AF, Donnell D, Dombrowski JC, et al. Postexposure doxycycline to prevent bacterial sexually transmitted infections. N Engl J Med. 2023 Apr 6;388(14):1296-1306.