

### Additional Patient Considerations

- Do not take more than 200mg of doxycycline within 24 hours.
- Drink with plenty of water and take with food to help avoid upset stomach (nausea, vomiting, diarrhea).
- Do not lay down for at least 30 minutes after taking doxycycline to avoid irritation and esophageal ulceration.
- Avoid dairy products, calcium, antacids, or multivitamins 2 hours before or after taking doxycycline.
- Discuss potential side effects (which are more likely with more frequent DoxyPEP use): photosensitivity (wear sunscreen), GI symptoms, pill esophagitis, yeast infection, and, rarely, benign intracranial hypertension.

### Coverage for DoxyPEP

We have not heard of any problems with patients accessing doxycycline through their insurance as it should be covered by all major insurance plans. Co-pays may be possible for people with private insurance. For those that are uninsured, online pharmacy coupon programs might help reduce the costs.

DoxyPEP is a covered medication for people enrolled in the PrEP Assistance Program (PrEP-AP) or AIDS Drug Assistance Program (ADAP).

### Resources

- National Coalition of STD Directors (NCSDD) DoxyPEP Command Center: <https://www.ncsddc.org/resource/doxy-as-sti-pep-command-center/>
- CDC Considerations for DoxyPEP: <https://www.cdc.gov/std/treatment/guidelines-for-doxycycline.htm>
- CDC PrEP Guidelines: [bit.ly/CDC\\_PrEPguide](https://bit.ly/CDC_PrEPguide)
- California Prevention Training Center (CPTC): <https://californiapctc.com/>
- Division of HIV and STD Programs: <http://publichealth.lacounty.gov/dhsp/>
- GetPrePLA: <https://getprepla.com/>
- Ending the HIV Epidemic: <https://www.lacounty.hiv/>

### References

• DOXYPEP Study: Luetkemeyer AF, Donnell D, Dombrowski JC, Cohen S, Grabow C, Brown CE, Malinski C, Perkins R, Nasser M, Lopez C, Vittinghoff E, Buchbinder SP, Scott H, Charlebois ED, Havlir DV, Soge OO, Celum C; DoxyPEP Study Team. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. *N Engl J Med.* 2023 Apr 6;388(14):1296-1306. doi:10.1056/NEJMoa2211934. PMID: 37018493; PMCID: PMC10140182.

• ANRS 174 DOXYVAC Study: Molina J. M., Bercot B., Assoumou L., et al. ANRS 174 DOXYVAC: an open-label randomized trial to prevent STIs in MSM on PrEP. *Abstract 119.* CROI; 2023 Feb 19-22; Seattle, WA. <https://www.croiconference.org/abstract/anrs-174-doxycycline-an-open-label-randomized-trial-to-prevent-stis-in-msm-on-prep/>

• ANRS IPERGAY Study: Molina J. M., 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;18(3):308-317.

• DPEP Study: Stewart J, Bukusi E, Sesay FA, Oware K, Donnell D, Soge OO, Celum C, Odoyo J, Kwena ZA, Scoville CW, Violette LR, Morrison S, Simoni J, McClelland RS, Barnabas R, Gandhi M, Baeten JM. Doxycycline post-exposure prophylaxis for prevention of sexually transmitted infections among Kenyan women using HIV pre-exposure prophylaxis: study protocol for an open-label randomized trial. *Trials.* 2022 Jun 16;23(1):495. doi:10.1186/s13063-022-06458-8. PMID: 35710444; PMCID: PMC9201793.

• Doxycycline FDA Label Package Insert for Doryx® (doxycycline hyclate) and Doryx® MPC Delayed-Release Tablets. February 2018. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/050795s026lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/050795s026lbl.pdf)

### What is DoxyPEP?

Doxycycline Post-Exposure Prophylaxis (DoxyPEP) is taking doxycycline within 72 hours of sexual exposure to decrease the incidence of acquiring bacterial sexually transmitted infections (STIs) such as chlamydia (CT), gonorrhea (GC), and syphilis.

### DoxyPEP Efficacy

- DoxyPEP has been studied in men who have sex with men (MSM), transgender women (TGW), and cisgender women (CGW), and has not been studied in transgender men.
- In the DoxyPEP trial published in the *New England Journal of Medicine* (April 2023), MSM and TGW who were on HIV PrEP or have HIV had an overall 65% reduction in STI incidence.
  - The breakdown of risk reduction of individual STIs per quarter in those that received DoxyPEP are listed below:

| Population              | Overall STI Risk Reduction | Chlamydia | Syphilis | Gonorrhea |
|-------------------------|----------------------------|-----------|----------|-----------|
| MSM and TGW on HIV PrEP | 66%                        | 88%       | 87%      | 55%       |
| MSM and TGW with HIV    | 62%                        | 74%       | 77%      | 57%       |

### Recommend DoxyPEP to patients if they:

- Identify as **gay, bisexual, and other men who have sex with men and transgender women who had a history of 1 bacterial STI in the last 12 months**
- Have **frequent condomless sex with multiple partners** and are at elevated risk of an STI

### Consider prescribing to patients if they:

- Identify as a member of a demographic group for whom efficacy of DoxyPEP has not been demonstrated (cisgender women, transgender men, and cisgender men who have sex with women with history of condomless sexual intercourse)
- Are interested in DoxyPEP after shared decision making (i.e., consideration of current evidence in their demographic group)

## Take Home Messages

- STI rates are increasing across Los Angeles County (LAC) and are an urgent public health priority that can be addressed with appropriate screening, treatment, and biomedical prevention.
- LAC Public Health strongly supports the use of DoxyPEP, even as studies regarding potential antibiotic resistance continue.
- DoxyPEP is a safe, inexpensive, and highly effective biomedical prevention tool that can reduce bacterial STIs.

## Baseline Assessment for DoxyPEP

- ✓ **3-site gonorrhea and chlamydia NAAT (genital, pharyngeal, rectal) and syphilis screen**
  - If positive, then treat according to CDC STI treatment guidelines.
- ✓ **Consider HIV test (4th generation Ag/Ab recommended)**
  - DoxyPEP is safe to take if living with HIV.
  - If there is concern for acute HIV exposure within the last 30 days or recent flu-like illness (possibly indicate acute HIV), then also consider ordering HIV RNA PCR.
- ✓ **Consider complete blood count (CBC), liver function tests (LFTs), and renal function annually**
- ✓ **Pregnancy test**
  - If positive, then do not prescribe doxycycline. Doxycycline is contraindicated in pregnancy.
- ✓ **For those that are interested in HIV PrEP, please refer to CDC's HIV PrEP Guidelines**
  - DoxyPEP is safe to take along with HIV PrEP (oral or injectable form).

## Prescribing DoxyPEP

- Doxycycline 200mg can be taken within 72 hours, ideally within 24 hours, of sexual encounter.
- Available formulations:
  - Doxycycline hyclate delayed release 200mg (1 tab); OR
  - Doxycycline hyclate or monohydrate immediate release 100mg (2 tabs taken simultaneously).
- Consider a 30-day supply to take as needed with 2 refills.
- **ICD-10 Diagnosis Code: Z20.2 Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission.**

## Follow-Up Assessment

- ✓ **Screen for STIs every 3-4 months**
  - If positive, then treat according to CDC STI treatment guidelines (enclosed)
  - Since *Treponema pallidum* (bacteria responsible for syphilis) has a long incubation period and serologic testing window period, presumptive treatment for syphilis is recommended if suspected regardless of DoxyPEP use.
- ✓ **Pregnancy test**
  - If positive, then do not prescribe doxycycline. Doxycycline is contraindicated in pregnancy.
- ✓ **Discuss and provide HIV PrEP or HIV treatment as indicated**

## Patient Counseling

- DoxyPEP has been shown to reduce the risk of STIs, but it's not 100% effective.
- Patients will still need to get screened and treated for STIs if positive.
- DoxyPEP does not protect against viral infections such as HIV, HPV, Mpox, or HSV.

## Dosing Schedule

**Example:** Sex on Sunday; take dose by Wednesday.



**Example:** Sex Sunday through Tuesday; take initial dose within 24 hours (by Monday), and daily doses through Tuesday. Last dose should be no later than 72 hours after last sexual encounter (by Friday).

