



## Department of Health

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**To:** Sexual Health Clinics, Family Planning Providers, Hospitals, Emergency Rooms, Community Health Centers, Urgent Care Centers, College Health Centers, Local Health Departments, Community Based Organizations, Internal Medicine, Obstetrics and Gynecology, Pediatric, Adolescent Medicine, Dermatology, Family Medicine, Infectious Disease, Primary Care Providers and Clinical Labs

**From:** New York State Department of Health (NYSDOH), AIDS Institute, Office of Sexual Health & Epidemiology (OSHE) and the Office of the Medical Director (OMD)

**Date:** January 16, 2024

### **HEALTH ADVISORY UPDATE: Continuing national shortage of BICILLIN L-A® and suggested approaches to treatment.**

Since the release of an earlier [Health Advisory](#) issued on June 6, 2023 which detailed manufacturing delays resulting in nationwide shortage of Benzathine Penicillin G (Bicillin L-A®) complicating the treatment of persons diagnosed with syphilis, syphilis diagnoses have continued to increase and [The Food & Drug Administration](#) states the manufacturing shortage will extend into the second quarter of 2024 with normalization in supplies being realized in mid-year 2024 (information as of September 11, 2023).

The shortage in procuring Bicillin L-A® by local health departments and medical facilities has made the efforts to bring the disease under control even more challenging. This update is intended to underscore the treatment recommendations issued in the earlier advisory, and to provide an alternative course depending upon the threshold of inventory.

It is recommended that providers:

- continue to prioritize the use of Benzathine Penicillin G (Bicillin L-A®) to treat pregnant people and babies with congenital syphilis as Benzathine Penicillin G (Bicillin L-A®) is the only recommended treatment for pregnant people infected with or exposed to syphilis;
- prescribe Doxycycline 100mg PO BID (by mouth twice a day) for two weeks (for early syphilis) or for four weeks (for late latent or syphilis of unknown duration) for the treatment of non-pregnant people including for those with penicillin allergy;
- follow the recommended or alternative regimen per the [Centers for Disease Control and Prevention Sexually Transmitted Infections Treatment Guidelines, 2021](#) for treatment of neurosyphilis, ocular syphilis, and otosyphilis.

In addition, the following approach from [Arizona Department of Health Services](#) may be employed depending on the threshold of inventory (existing and/or anticipated):

<b>Benzathine Penicillin (PCN) G Thresholds and Recommendations for Persons Infected with Syphilis</b>		
<b>Thresholds</b>	<b>Definition</b>	<b>Recommendations*</b>
Critical Threshold	The facility/jurisdiction has a supply that is equal to or less than the projected number of doses needed to treat all pregnant clients from now until the end of the shortage.	If you have reached your critical threshold, all non-pregnant persons should receive an alternative therapy. Benzathine PCN should be reserved only for pregnant persons, all other persons should receive another recommended alternative therapy.**
Semi-critical	The facility/jurisdiction has a supply that is at least 2.5 times the number of doses needed to treat all pregnant clients from now until the end of the shortage.	If you have reached your semi-critical threshold, benzathine PCN should be reserved for pregnant persons and their partner(s). All other persons should be treated using another recommended alternative therapy.**
Sub-optimal	The facility/jurisdiction has a supply less than optimal (not enough to treat all cases using benzathine PCN G) but greater than semi-critical levels (enough to treat all pregnant persons and their partners) between now and the end of the shortage.	If you have reached your sub-optimal threshold, you may need to begin providing alternative therapies** for non-pregnant syphilis cases using the prioritization matrix and FAQs below.
Optimal	The facility/jurisdiction has adequate doses for treating the projected number of patients who present with syphilis, regardless of stage.	If you are within your optimal threshold, benzathine can be used for all clients who present with syphilis.

<b>Benzathine Penicillin G Conservation Prioritization Matrix for Persons Infected with Syphilis</b>		
<b>Thresholds</b>	<b>Level</b>	<b>Population</b>
Critical Threshold	1	Persons who are pregnant
Semi-critical	2	Level 1 plus partners of persons who are pregnant
Sub-optimal	3	Levels 1-2 plus persons who may struggle to complete the full course of treatment (no safe space to store medications, memory issues, etc.)
Sub-optimal	4	Levels 1-3 plus staged as primary, secondary, or early non-primary/non-secondary
Optimal	5	All persons infected with syphilis

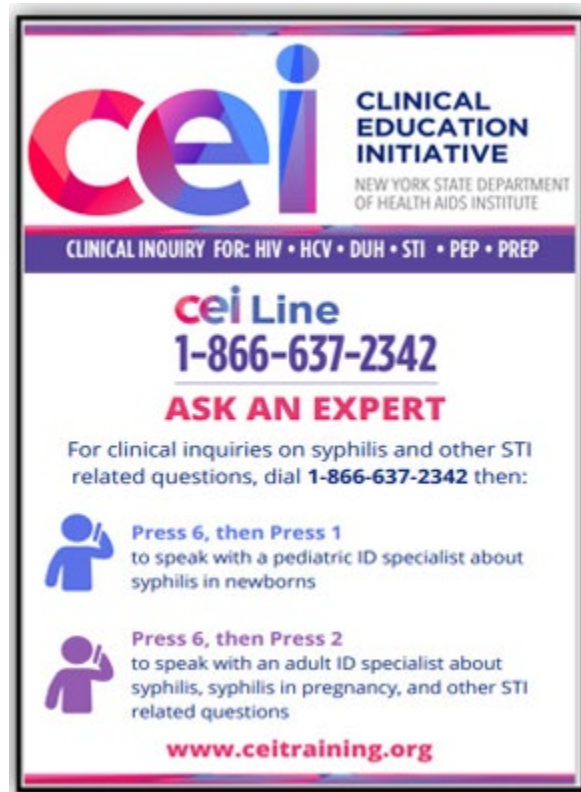
\*\*The term 'alternative therapy' references those alternative treatments referenced in the [Centers for Disease Control and Prevention Sexually Transmitted Infections Treatment Guidelines, 2021](#)

Frequently Asked Questions: Can combination therapy be utilized for treatment of late, latent or syphilis of unknown duration with Benzathine Penicillin G (Bicillin L-A®) and doxycycline?

Treatment for late, latent or syphilis of unknown duration may be started with Benzathine Penicillin G (Bicillin L-A®) and completed with a 28-day course of doxycycline 100 mg PO BID^ (by mouth twice a day)

^ Some experts utilize 21 days of Doxycycline 100 mg PO BID initiated on Day 7 after a single dose of Benzathine Penicillin G (Bicillin L-A®) or 14 days of Doxycycline 100 mg PO BID (by mouth twice a day) initiated 7 days after a 2<sup>nd</sup> dose of Benzathine Penicillin G (Bicillin L-A®).

If treating providers are considering a combination treatment and have limited experience on how to employ this, we strongly recommend that they consult with clinical experts via the Clinical Education Initiative's (CEI's) call line:



The graphic is a vertical rectangular advertisement for the CEI Line. At the top left is the CEI logo, which consists of the letters 'cei' in a stylized font with a blue dot above the 'i'. To the right of the logo is the text 'CLINICAL EDUCATION INITIATIVE' and 'NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE'. Below this is a dark blue horizontal bar with white text that reads 'CLINICAL INQUIRY FOR: HIV • HCV • DUH • STI • PEP • PREP'. The main body of the graphic is white with blue and red text. It features the text 'cei Line' in blue, followed by the phone number '1-866-637-2342' in a larger blue font. Below the phone number is the phrase 'ASK AN EXPERT' in red. Underneath, there is a line of text: 'For clinical inquiries on syphilis and other STI related questions, dial 1-866-637-2342 then:'. There are two blue icons of a person on the left side, one above the other. The top icon is next to the text 'Press 6, then Press 1 to speak with a pediatric ID specialist about syphilis in newborns'. The bottom icon is next to the text 'Press 6, then Press 2 to speak with an adult ID specialist about syphilis, syphilis in pregnancy, and other STI related questions'. At the bottom of the graphic is the website address 'www.ceitraining.org' in red.

### **Additional Resources Sexually Transmitted Infections and Congenital Syphilis:**

- Centers for Disease Control and Prevention Sexually Transmitted Infections Treatment Guidelines 2021: Congenital Syphilis <https://www.cdc.gov/std/treatment-guidelines/congenital-syphilis.htm>
- Centers for Disease Control and Prevention Sexually Transmitted Infections Treatment Guidelines 2021: Syphilis During Pregnancy <https://www.cdc.gov/std/treatment-guidelines/syphilis-pregnancy.htm>
- American College of Obstetrics and Gynecology: Chlamydia, Gonorrhea, Syphilis Frequently Asked Questions <https://www.acog.org/womens-health/faqs/chlamydia-gonorrhea-and-syphilis>
- New York State Department of Health, AIDS Institute, Clinical Education Initiative (CEI) <https://ceitraining.org/>