



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: June 6, 2023

HEALTH ADVISORY: BICILLIN L-A MANUFACTURING AND SUPPLY SHORTAGE COINCIDING WITH CONTINUED SYPHILIS INCREASES

- In April 2023, the Centers for Disease Control and Prevention (CDC) and the NYSDOH released information that some local health departments and medical facilities were unable to procure enough penicillin G benzathine (Bicillin L-A®) – the first-line recommended treatment for syphilis - for their jurisdictions.
- The manufacturer anticipated resolving the issue within two months time; however, since April, there has been additional manufacturing delays (see CDC's notice on page two)
- New York State has recently learned of diminished supply of Bicillin L-A® in multiple regions including several counties with high syphilis morbidity.
- With rising syphilis and congenital syphilis diagnoses across the State, the NYSDOH strongly encourages providers to review their existing Bicillin L-A® inventory and reserve Bicillin L-A® for pregnant persons and infants with congenital syphilis if inventories are running low. Doxycycline is the alternative recommendation and providers should closely follow patients to encourage completion of the medication course.

GUIDANCE AND RECOMMENDATIONS FOR CLINICIANS:

The following immediate steps are recommended:

1. Inventory your existing stock of Bicillin L-A®.
2. Plan accordingly to ensure that you have enough to treat per the [CDC's treatment recommendations](#).
3. Make alternate plans i.e., use doxycycline for non-pregnant persons while you work to replenish your stocks.
4. Schedule a follow-up with patient's post-doxycycline course completion to verify if treatment has been completed and there has been decline in titer, indicating infection is adequately treated.
5. If you are experiencing a shortage, please immediately notify OSHE (STDC@health.ny.gov) with the name of your county and Bicillin L-A® shortage in the subject line. We will immediately notify the CDC.
6. Report shortages to Pfizer Supply Continuity Team at 844-646-4398 (select 1 and then select 3).

The NYSDOH will continue to provide updates and alert you of any resolution to this supply shortage.

Bicillin L-A® Shortage

The US Food and Drug Administration (FDA) has listed penicillin G benzathine injectable suspension products (Bicillin L-A®) on [their drug shortage webpage](#), noting limited supply due to increased demand. The FDA website includes an expected duration for the shortage. CDC continues to monitor the situation and will post updates as needed.

Bicillin L-A® is the first-line recommended treatment for syphilis and the only recommended treatment option for some patients.

During this time, programs should:

Continue to follow [CDC's treatment recommendations](#). Penicillin G benzathine (Bicillin L-A®) is the only recommended treatment for pregnant people infected with or exposed to syphilis.

Doxycycline 100mg PO BID for two weeks (for early syphilis) or for four weeks (for late latent or syphilis of unknown duration) is an alternative for the treatment of non-pregnant people with a penicillin allergy.

Prioritize the use of Bicillin L-A® to treat pregnant people and babies with congenital syphilis.

To help CDC continue to monitor the situation, notify DSTDP (stdshortages@cdc.gov) of:

Shortages or stock-outs of Bicillin L-A® in the jurisdiction.

Situations in which patients diagnosed with syphilis are not being treated due to the inability to procure Bicillin L-A® in the jurisdiction.

Report any shortages to the Pfizer Supply Continuity Team at 844-646-4398 (select 1 and then select 3).

Adapted from: <https://www.cdc.gov/std/treatment-guidelines/syphilis.htm#print>

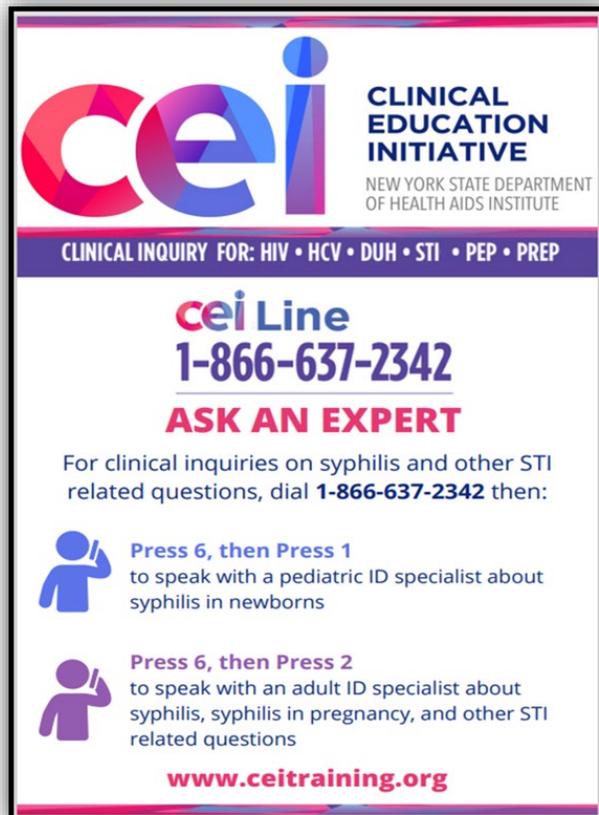
For any questions, please contact the NYSDOH OSHE at (518) 474-3598 or stdc@health.ny.gov with questions; or for additional assistance.

CONTINUED INCREASES OF SYPHILIS AND CONGENITAL SYPHILIS:

The NYSDOH issued a [health advisory](#) in June of 2021 with a follow up [Dear Provider Letter](#) in 2022 describing continued increases of syphilis and congenital syphilis. Since that time, these trends have continued. The rate of primary and secondary syphilis among females has increased over 240% over the last five years. And though data are not yet final, congenital syphilis diagnoses increased 200% between 2017 and 2022 with at least ten syphilitic stillbirths reported since 2013. New York State reported the highest single year number of congenital syphilis cases in over 20 years in 2022 with 53 reported cases (data not final and are subject to change). Further, communities of color continue to be disproportionately impacted with higher rates of syphilis and congenital syphilis. These trends have continued to escalate in the first half of 2023 and the Bicillin L-A® shortage will compound these challenges.

For access to free clinical education or to request a training on syphilis or congenital syphilis, please go to [Clinical Education Initiative \(CEI\) Training](#). For access to free clinical materials including palm cards with information on syphilis in pregnancy and congenital syphilis, please go the [CEI Health Center of Excellence- Materials Order Form](#).

Lastly, for clinical inquiries on syphilis and other STI, please see below for information on CEI's call line:



The graphic is a vertical rectangular box with a white background and a thin black border. At the top left is the CEI logo, consisting of the letters 'cei' in a stylized font where the 'c' is red and the 'ei' are blue. To the right of the logo is the text 'CLINICAL EDUCATION INITIATIVE' in bold blue letters, followed by 'NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE' in smaller blue letters. Below this is a dark blue horizontal bar with white text that reads 'CLINICAL INQUIRY FOR: HIV • HCV • DUH • STI • PEP • PREP'. The main text in the center reads 'cei Line' in blue, followed by '1-866-637-2342' in large blue font. Below that is the heading 'ASK AN EXPERT' in bold red letters. A paragraph follows: 'For clinical inquiries on syphilis and other STI related questions, dial 1-866-637-2342 then:'. There are two items listed, each with a small icon of a person on a phone. The first item has a blue icon and text: 'Press 6, then Press 1 to speak with a pediatric ID specialist about syphilis in newborns'. The second item has a purple icon and 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 is the website 'www.ceitraining.org' in red.

cei CLINICAL EDUCATION INITIATIVE
NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE

CLINICAL INQUIRY FOR: HIV • HCV • DUH • STI • PEP • PREP

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NYS Recommendations for Screening of Syphilis During Pregnancy, Diagnosis and Treatment of Syphilis/ Congenital Syphilis, and Additional Resources

Current NYS Recommendations for Screening of Syphilis during Pregnancy:

- NYS Public Health Law (PHL) mandates syphilis screening of pregnant persons at the time pregnancy is first identified and again upon delivery.
- Effective May 3, 2024, New York State will additionally require third trimester syphilis screening (pursuant to Chapter 57 of the Laws of 2023) though it is highly recommended providers implement this additional screening as soon as possible. requiring syphilis screening at 28 weeks of pregnancy for all pregnant persons, or as soon thereafter as reasonably possible but no later than at 32 weeks of pregnancy.
- Providers are encouraged to pair third trimester syphilis screening with the strongly recommended third trimester HIV screening.
- **Make sexual health discussions a routine part of every prenatal visit**, regardless of the outcome of the first syphilis test. Screen for syphilis and other Sexually Transmitted Infections (STIs) as warranted (changes in sex partners or behaviors, STI status of sex partners, etc.).
- Providers are encouraged to link partners of pregnant persons to HIV, syphilis, and other STI testing.
- Determine the pregnancy status of all persons of reproductive age diagnosed with syphilis.
- When requesting laboratory tests/screening for syphilis, please indicate in the requisition form that the person is pregnant. This will help public health programs and ensure partner services (PS) are made available to persons with syphilis diagnosis.
- Consider screening for syphilis in patients who present with symptoms of unknown origin such as unexplained rashes, sores, or lesions.

New York City Department of Health and Mental Hygiene (NYCDOHMH):

- In addition to NYS mandate for syphilis screening at first prenatal care examination (NYS PHL § 2308) and at delivery (10 NYCRR § 69-2.2), Article 11 of the Health Code has been amended to add a new Section 11.33. This section requires New York City healthcare providers to test pregnant persons for syphilis at 28 weeks of pregnancy, or as soon thereafter as reasonably possible, but no later than at 32 weeks of pregnancy. The rule also requires providers to document the test results and a treatment plan in the patient's medical records.

Current NYS Recommendations on the Diagnosis and Treatment of Syphilis and Congenital Syphilis:

- To diagnose syphilis, laboratory testing must include both treponemal and nontreponemal tests. Unless specified by the provider, the sequence of these tests (i.e., treponemal or nontreponemal test first) differs across laboratories and results must be carefully interpreted to distinguish current syphilis infection from previous infection. It is important that providers understand their syphilis screening algorithm. See the Centers for Disease Control and Prevention's (CDC) 2021 STI Treatment Guidelines for more information: <https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf>.

- In cases where the laboratory evidence of syphilis is inconclusive or ambiguous, pregnant persons should be presumed infected (with or without symptoms) unless syphilis can be ruled out through evidence of treatment and patterns in follow-up antibody titers documented in the medical record.
- Providers are encouraged to work with the local health department (LHD) to consult the syphilis registry, and to help inform syphilis diagnosis and treatment decisions.
- Treat all females with confirmed or suspected syphilis of any stage, or syphilis exposure, according to current CDC guidelines. The only recommended treatment option for pregnant persons remains Penicillin G benzathine (BicillinLA). Pregnant persons who report a penicillin allergy can be considered for further allergy testing to assess risks for IgE allergic reactions and should, as needed, be desensitized and treated with penicillin. See the CDC's 2021 STI Treatment Guidelines for more information: <https://www.cdc.gov/std/treatment-guidelines/syphilis-pregnancy.htm>
- Treatment for syphilis in infants is determined based on maternal history of syphilis infection and treatment, and current laboratory and physical examination results. Consult the CDC 2021 Sexually Transmitted Infections Treatment Guidelines for Congenital Syphilis: <https://www.cdc.gov/std/treatment-guidelines/congenital-syphilis.htm>
- All infants diagnosed with congenital syphilis should be physically and serologically monitored closely in the months following birth.
- Per NYSDOH Communicable Disease reporting requirements, immediately report new positive prenatal or delivery syphilis tests to the LHD by phone, followed by submission of the confidential case report form (DOH-389). The state or LHD can assist in following-up with patients and their partners to ensure access to care. Information is available at: <https://www.health.ny.gov/forms/doh-389.pdf> and https://www.health.ny.gov/forms/instructions/doh-389_instructions.pdf

Additional Resources STIs and Congenital Syphilis:

- Guidance for Healthcare Providers About Rising Syphilis Diagnoses and Congenital Syphilis Increases, Provider letter, January 25, 2022
https://www.health.ny.gov/diseases/aids/providers/health_advisories/docs/syphilis_increase_guidance.pdf
- NYSDOH, AIDS Institute, Office of Sexual Health and Epidemiology (OSHE) Health Alert June 2, 2021
https://www.health.ny.gov/diseases/communicable/std/docs/health_advisory_syphilis.pdf
- CDC Sexually Transmitted Infections Treatment Guidelines 2021: Congenital Syphilis
<https://www.cdc.gov/std/treatment-guidelines/congenital-syphilis.htm>
- CDC 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 FAQ
<https://www.acog.org/womens-health/faqs/chlamydia-gonorrhea-and-syphilis>
- NYSDOH, AI, Clinical Education Initiative (CEI)
<https://ceitraining.org/>