

ANDREW M. CUOMO Governor HOWARD A. ZUCKER, M.D., J.D. Commissioner SALLY DRESLIN, M.S., R.N. Executive Deputy Commissioner

- TO: Obstetrics, Gynecology, Local Health Departments, Primary Care, Infectious Disease, Community Health Centers, Pediatric Medicine, Family Planning Providers, Urgent Care, Emergency Medicine, Family Medicine, Infectious Disease, Internal Medicine, Ophthalmology
- FROM: New York State Department of Health Bureau of Sexual Health and Epidemiology
- DATE: March 2019

Health Advisory: Current and Recent Sexually Transmitted Infections (STI) Drug Shortages Update

Overview: This advisory contains information on shortages in the availability of certain medications used to treat STIs.

Background: The incidence of STIs is increasing in New York State and the United States (U.S.), with increases observed in syphilis, congenital syphilis, gonorrhea, and chlamydia. STIs can lead to serious health consequences in affected individuals, and outcomes can be particularly severe in cases involving maternal transmission to offspring. It is crucial that providers of prenatal care have up-to-date information regarding STI-related prevention and neonatal care. Supply shortages of first-line therapies for treating and preventing STIs may limit capacity to prevent STIs in neonates.

Erythromycin (0.5%) Ophthalmic Ointment

On March 5, 2019, the Food and Drug Administration (FDA) released a report on a shortage of erythromycin (0.5%) ophthalmic ointment in some areas of the U.S. Erythromycin (0.5%) ophthalmic ointment currently recommended and the only drug cleared by the FDA for the prophylaxis of gonococcal ophthalmia neonatorum. **Please note that, currently, shortages in New York State have not yet been reported to the New York State Department of Health.**

If erythromycin ointment is not available, the Centers for Disease Control and Prevention (CDC) recommends that neonates at risk for exposure to *N. gonorrhoeae* during delivery (especially those born to a mother at risk for gonococcal infection or with no prenatal care) be administered ceftriaxone 25–50 mg/kg IV or IM, not to exceed 125 mg in a single dose.

For more information, please see: <u>https://www.cdc.gov/std/tg2015/gonorrhea.htm.</u>

Other topical medications are not recommended:

- Tetracycline ophthalmic ointment and silver nitrate are no longer available in the U.S.;
- Gentamicin was reported to be potentially associated with chemical conjunctivitis during the last erythromycin shortage;
- Povidone-iodine has limited data on its benefits and harms.

It is important to remember that prenatal screening and maternal treatment are the best methods for preventing gonococcal ophthalmia neonatorum among newborns. Per CDC guidelines, all pregnant women < 25 years of age and women \geq 25 at increased risk should be screened for *N. gonorrhoeae* at their first prenatal care visit and again in the third trimester if risk continues during pregnancy. Also, all females treated for gonorrhea should be retested three months following treatment.

Current information regarding the availability of erythromycin (0.5%) ophthalmic ointment is available at <u>https://www.accessdata.fda.gov/scripts/drugshortages/</u>.

Ceftriaxone Diluents

Diluents for Ceftriaxone are in limited supply. Ceftriaxone is the last remaining known effective antimicrobial for the treatment of uncomplicated gonorrhea and dual therapy with azithromycin is recommended to mitigate the emergence of ceftriaxone resistance in the U.S. The usual preparation for ceftriaxone is a powder form reconstituted with an appropriate diluent. One percent lidocaine without epinephrine is the preferred diluent recommended by most STI clinical experts to minimize significant patient discomfort from the intramuscular injection. The full product insert for ceftriaxone lists other diluents for consideration. The FDA continues to work closely with manufacturers and to update its website related to the availability of all the diluents.

Diluents currently in shortage: <u>1% lidocaine without epinephrine</u>, <u>sterile water</u>, and <u>0.9%</u> <u>sodium chloride</u>.

A complete list is available at https://www.accessdata.fda.gov/scripts/drugshortages/

Penicillin G benzathine (Bicillin L-A®) and Penicillin G procaine

After a protracted shortage, **Penicillin G benzathine (Bicillin L-A®) is back to normal supply levels and has been moved by the FDA to a resolved shortage status.**

As Penicillin G benzathine is the only recommended treatment for syphilis in adults in the 2015 CDC STD Treatment Guidelines, NYSDOH recommends the following:

• Continue to report to NYSDOH any challenges in procuring Penicillin G benzathine product so that the NYSDOH can monitor any supply problems given the unprecedented current levels of syphilis in NYS.

Note: Doxycycline is an alternative treatment for non-pregnant patients and only if a medical contraindication exists such as an IgE mediated allergy to penicillin. Efficacy of doxycycline has not been well-studied, is considered less effective than penicillin and, if utilized, close follow-up of the patient is indicated.

 For questions about STD clinical management, contact the on-line National Network of STD Clinical Prevention Training Centers (NNPTC) STD Clinical Consultation Network (<u>https://www.stdccn.org/</u>).

Finally, **Penicillin G procaine is now available at normal supply levels and the FDA has recently moved it to the resolved shortage status.** Penicillin G procaine is an alternative regimen for outpatient treatment of neurosyphilis and congenital syphilis.

Please contact the NYSDOH Bureau of Sexual Health and Epidemiology at (518) 474-3598 or <u>stdc@health.ny.gov</u> if you encounter any problems obtaining these products or for additional assistance.

Additional Resources:

CDC STD Drug Notices – <u>https://www.cdc.gov/std/treatment/drug-notices.htm</u> USFDA Drug Shortages – <u>https://www.fda.gov/Drugs/DrugSafety/DrugShortages/</u> CDC 2015 STD Treatment Guidelines – <u>https://www.cdc.gov/std/tg2015/</u>