

New Mexico Department of Health

NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT DRUG SHORTAGE OF BICILLIN L-A® FOR THE TREATMENT OF SYPHILIS

July 14, 2025

Background

On July 10, 2025, Pfizer issued a recall for multiple lot numbers of Benzathine penicillin G (Bicillin L-A[®]). On July 14, 2025, the FDA issued a drug shortage alert for the product. FDA DRUG SHORTAGE ALERT . Pfizer is currently working to determine the impact of the recall on their production timeline. Providers should prepare for a possible extended shortage.

This drug shortage is of public health importance because Bicillin L-A[®] is the only recommended treatment for pregnant people infected with or exposed to syphilis. Nationwide, congenital syphilis rates have increased 203 % in the past five years. According to 2023 CDC disease surveillance data, New Mexico is second in the country for rates of congenital syphilis.

While Bicillin L-A® remains the treatment of choice for all patients with syphilis, the CDC has recommended that healthcare providers prioritize the use of Bicillin L-A® to treat pregnant people and babies with congenital syphilis. If warranted due to Bicillin L-A[®] shortage, healthcare providers may consider the use of Extencilline[®], Lentocilin[®], or alternative treatment with doxycycline for non-pregnant individuals.

For indications outside of syphilis, healthcare providers should utilize Extencilline®, Lentocilin®, or alternative treatments. For example, alternative treatments should be utilized for strep throat.

Recommendations

Healthcare providers should closely monitor their inventory of Bicillin L-A[®]. Providers should use their clinical judgement to further prioritize the use of Bicillin L-A[®]. If warranted due to the drug shortage, healthcare providers may consider use of Extencilline®, Lentocilin® or alternate treatment with doxycycline. Bicillin L-A® remains the treatment of choice for all patients with syphilis and should be used when supply allows.

New Mexico Department of Health has provided an example of a prioritization strategy below that healthcare providers may consider utilizing in their efforts to ensure CDC priority populations have access to treatment for the duration of the drug shortage.

Bicillin L-A® Prioritization

Healthcare providers may consider prioritization of the following individuals diagnosed with syphilis for treatment with Bicillin L-A[®]:

- Pregnant individuals ٠
 - Bicillin L-A[®] is the only acceptable treatment for this group
- Babies with congenital syphilis •
- Sexual partners of pregnant individuals
- Individuals with an allergy to doxycycline •
- Individuals who have already initiated treatment with a 3-week course of Bicillin L-A® •

Bicillin L-A® Medical Request

Effective immediately, all Bicillin L-A[®] 1.2 million units and 2.4 million units will be available for direct shipment only through Pfizer's Medical request process. Pfizer will distribute available inventory in accordance with its medical request process, which requires that customers complete a <u>medical request form</u> to request product on a per patient basis. Pfizer will only fulfill product for patients with confirmed congenital syphilis or risk of congenital syphilis. Completed forms should be emailed to <u>PISupplyContinuity@pfizer.com</u>.

For more information please review the Pfizer Availability Update for Bicillin LA Letter: <u>https://www.pfizerhospitalus.com/sites/default/files/news_announcements/Bicillin%20Supply%20Update%20July</u> <u>%202025_0.pdf</u>

Ordering Lentocilin®

To address the shortages of Bicillin L-A[®] in the United States, Mark Cuban Cost Plus Drug Company in coordination with the U.S. Food and Drug Administration (FDA) are temporarily importing Lentocilin© (Benzathine Benzylpenicillin Tetrahydrate) Powder and diluent for suspension for injection, 1,200,000 units into the United States. Benzathine benzylpenicillin is another name for Penicillin G benzathine.

To place an order, please contact TopRx at support@toprx.com or 1-800-542-8677.

For more information review the FDA Healthcare Provider Letter regarding Lentocilin[®] <u>https://www.fda.gov/media/182165/download?attachment</u>

Ordering Extencilline ®

To address the shortages of Bicillin L-A[®] in the United States, Laboratories Delbert & Provepharm Inc. in coordination with the U.S. Food and Drug Administration (FDA) are temporarily importing Extencilline[©] (Benzathine Benzylpenicillin) Powder and diluent for suspension for injection, 1,200,000 units and 2,400,000 units into the United States. Benzathine benzylpenicillin is another name for Penicillin G benzathine.

To place an order, please contact one of the authorized distributors below:

Mckesson Corporation, Cencora Global Procurement Ltd., Cardinal Health, Morris & Dickson, Anda Inc., Henry Schein, OptumRx, Direct Success Inc.

For more information please review the FDA Healthcare Provider Letter regarding Extencilline [®] <u>https://www.fda.gov/media/180283/download?attachment</u>

Instructions on how to prepare and administer Extencilline [®]: <u>https://www.fda.gov/media/175365/download</u>

Syphilis Alternate Treatment

If warranted due to the drug shortage, healthcare providers may consider treatment with doxycycline for nonpregnant individuals. Treat with doxycycline as follows:

- Early syphilis (primary, secondary, or early latent): Doxycycline 100mg by mouth twice daily for 14 days.
- Late syphilis (late latent or unknown duration): Doxycycline 100mg by mouth twice daily for 28 days.

Doxycycline is an FDA Pregnancy Category D medication. It is not an alternative treatment for pregnant individuals. Bicillin L-A[®] is the only recommended treatment for pregnant people infected with or exposed to syphilis.

Further Considerations

- Follow RPR titers to ensure a 4-fold decrease is achieved in 6 to 12 months.
- Patients receiving alternative treatment with doxycycline should receive education on the importance of adherence.
- Prioritization strategy will be periodically re-assessed to match the available supply.

For consultation, including results from previous testing, providers can call the NMDOH Help Line at 1-833 SWNURSE (1-833-796-8773). Healthcare providers should not hesitate to call with questions regarding syphilis staging, treatment and prioritization efforts. Syphilis is a reportable condition in New Mexico.

References:

<u>FDA Drug Shortages</u> <u>CDC - STD Treatment - Drug notices.</u> <u>CDC STI Treatment Guidelines</u> <u>Sexually Transmitted Disease Surveillance, 2021 (cdc.gov)</u>

<u>New Mexico Health Alert Network</u>: To register for the NM Health Alert Network, please visit the following site <u>New Mexico</u> <u>Health Alert Network (HAN) Registration & Access Portal - New Mexico (readyop.com)</u>. Please fill out the registration form completely and click Submit at the bottom of the page, to begin receiving Important health alerts, advisories, and updates.

<u>Please Note</u> that our system also utilizes text messaging to notify members of important health information. Due to FCC Regulation changes that are designed to decrease the amount of unwanted spam text messages sent each year to citizens, please save, this phone number (**855**) **596-1810** as the **"New Mexico Health Alert Network"** default phone number for your account used for text messages on the mobile device(s) you register with us.