

## COUNTY OF SAN LUIS OBISPO HEALTH AGENCY PUBLIC HEALTH DEPARTMENT

### **PROVIDER HEALTH ADVISORY**

**Date:** July 15, 2025

**Contact:** Rick Rosen, MD, MPH, <u>frosen@co.slo.ca.us</u>, 805-781-5500

### **Bicillin® L-A Recall and National Shortage**

King Pharmaceuticals LLC., a subsidy of Pfizer, has initiated a voluntary recall of specific lots of Bicillin® L-A due to particulates identified during visual inspection: <a href="https://www.pfizerhospitalus.com/sites/default/files/news-announcements/Bicillin%20Recall%20Letter.pdf">www.pfizerhospitalus.com/sites/default/files/news-announcements/Bicillin%20Recall%20Letter.pdf</a>

### For more detailed information, please find attached:

- Letter to customers: A letter Pfizer shared with Bicillin® L-A customers on July 10, 2025 is attached below. This letter describes Pfizer's interim medical request process instructions for Bicillin® L-A customers.
- California Department of Public Health (CDPH) Health Advisory (3/18/2024): The attached health advisory from March 2024 remains the recommended prioritization plan for long-acting penicillin-based syphilis treatments (including Bicillin® L-A, <a href="Extencilline®">Extencilline®</a>, and Lentocilin®) during the current shortage.

### Please prioritize long-acting penicillin-based treatments

Bicillin® L-A, Extencilline®, and Lentocilin® are the only recommended treatments for all pregnant people with syphilis and certain infants exposed to syphilis in pregnancy. Healthcare providers and entities should **prioritize long-acting penicillin-based treatments for the treatment of pregnant people with syphilis and infants exposed to syphilis in utero.** Oral doxycycline is an appropriate alternative treatment for non-pregnant adults with primary, secondary, early/late latent syphilis and syphilis of unknown duration.

### For questions or consultation

- If you are experiencing a Bicillin® L-A shortage and/or having trouble obtaining Bicillin® L-A or Extencilline® medications, please contact the County of San Luis Obispo Public Health Department at 805-781-5500.
- For clinical questions related to the treatment of syphilis during the Bicillin® L-A shortage, providers may also contact the <u>STD Clinical Consultation Network</u> or the CDPH STD Control Branch (STDCB) at 510-620-3400 or <a href="mailto:stdcb@cdph.ca.gov">stdcb@cdph.ca.gov</a>

**Pfizer Inc.**66 Hudson Boulevard East New York, NY 10001



July 10, 2025

# Availability Update for Bicillin<sup>®</sup> L-A (penicillin G benzathine injectable suspension) 1.2 million Units/2 mL (600,000 units/mL) and 2.4 million Units/4 mL (600,000 units/mL) Prefilled Syringes

Dear Customer,

Pfizer Hospital is committed to providing timely supply information so that you can plan for patient care. As such, we want to notify you that we are anticipating a near-term stockout for Bicillin® L-A (penicillin G benzathine injectable suspension) 1.2 million Units/2 mL (600,000 units/mL) and 2.4 million Units/4 mL (600,000 units/mL) Prefilled Syringes due to a voluntary recall issued July 10, 2025, impacting lots distributed from December 11, 2023 through June 24, 2025.

Pfizer is still working to determine the impact of the recall on our production timeline. Consistent with our ongoing efforts to provide timely and transparent supply updates to our customers—and understanding the importance of this product to patients and health care professionals—we are sharing preliminary availability information now, with the commitment to provide an update no later than mid-August.

**During this interim period, Pfizer is implementing its Medical Request Process, effective immediately.** The purpose of this process is to ensure that available inventory in Pfizer's distribution centers is distributed equitably to hospitals and clinics treating patients with the highest medical necessity, which, based on prior Centers for Disease Control (CDC) guidance during Bicillin<sup>®</sup> L-A shortages, is to prioritize product only for patients with confirmed congenital syphilis and risk of congenital syphilis.

### **Medical Request Process Instructions for Customers:**

- Effective immediately, Bicillin<sup>®</sup> L-A (penicillin G benzathine injectable suspension)
   1.2 million Units/2 mL (600,000 units/mL) and 2.4 million Units/4 mL (600,000 units/mL)
   Prefilled Syringes will be available for <u>direct shipment only</u> through Pfizer's Medical
   Request Process. However, customers should first check with local wholesalers and
   within their hospital system for any potential remaining inventory before making a
   medical request.
- 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.



- The <u>medical request form</u> must be completed by the institution and authorized and emailed by the treating Health Care Provider or Director of Pharmacy <u>on a per patient</u> basis to receive product.
- Completed forms should be emailed to PISupplyContinuity@pfizer.com.
- Requests will be reviewed and filled in the order they are received and only with the required documentation. Cut off time for overnight requests is 3 p.m. (CT), and no deliveries will occur on Sundays.

Again, Pfizer will share additional information on supply outlook as soon as possible, and no later than mid-August. In addition, we encourage you to check our <u>Availability Report</u>, updated frequently and accessible <u>PfizerHospitalUS.com</u>, for the latest information on product status.

Thank you for your patience as we work through this limited supply situation. During this interim period, for product availability questions, please reach out to your Pfizer Hospital sales representative or account executive. Alternatively, the Supply Continuity Team can be contacted between 7 a.m. and 6 p.m. (CT) at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]). For medical inquiries, please contact Pfizer Medical Information at 1-800-438-1985.

Thank you,

**Kevin Martyn**Portfolio Director, Prefilled Syringes
Pfizer Hospital U.S.





TOMÁS J. ARAGÓN, M.D., Dr.P.H.
State Public Health Officer & Director

### State of California—Health and Human Services Agency California Department of Public Health



### **Health Advisory**

TO: Healthcare Providers

Extension of Long-Acting Benzathine Penicillin G (Bicillin® L-A) Shortage
3/18/2024

### **Key Messages**

- The FDA and Pfizer announced extension of the long-acting benzathine penicillin G (Bicillin® L-A) shortage, with supplies now estimated to not recover until the 4th quarter of 2024.
- Healthcare providers and entities should continue to prioritize long-acting penicillin-based treatments (Bicillin® L-A and Extencilline®) for the treatment of pregnant people with syphilis and infants exposed to syphilis in utero.
- Oral doxycycline is an appropriate alternative treatment for non-pregnant adults with primary, secondary, early/late latent syphilis and syphilis of unknown duration.

### **Background**

The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) previously announced the long-acting benzathine penicillin G (Bicillin® L-A) shortage and estimated recovery of supplies not before the 2nd quarter of 2024. Unfortunately, the time for expected recovery of supplies has now been extended to the 4th quarter of 2024. This change is reflected on both the FDA drug shortage webpage and Pfizer injectable product availability report (PDF)[1][2]. Bicillin® L-A and Extencilline® (PDF) are the only recommended treatments for all pregnant people with syphilis and certain infants exposed to syphilis in pregnancy. With continued concern about the number of pregnancies and infants affected by syphilis in California, it is of utmost importance that effective treatments be prioritized for these populations.

### Recommendations

Given this extension of the Bicillin® L-A shortage and continued uncertainty regarding the availability of long-acting penicillin-based syphilis treatments, CDPH recommends the following:

- Prioritize Bicillin® L-A over Extencilline® for infants exposed to syphilis in utero due to the larger volumes required of Extencilline® injections. If no Bicillin® L-A is available, then Extencilline® can be used in infants.
- Prioritize Bicillin® L-A and, if necessary, Extencilline® for pregnant people with syphilis infection (or exposure).
- Prioritize Bicillin® L-A and Extencilline® for patients with contraindications to doxycycline (e.g., anaphylaxis, hemolytic anemia, Stevens Johnson syndrome).

- Conserve Bicillin® L-A and Extencilline® by using alternative drugs for the treatment of primary, secondary, early/late latent syphilis and syphilis of unknown duration in non-pregnant adults as well as for other infectious diseases (e.g., streptococcal pharyngitis) where oral medications or other effective antimicrobials are available.
- CDPH has posted a Health Advisory with the acceptable alternative regimens for the treatment of primary, secondary, early/late latent syphilis and syphilis of unknown duration in non-pregnant adults[3]. <u>Alternative regimens for non-pregnant adults</u> <u>include:</u>
  - Doxycycline 100 mg PO BID for 14 days is an acceptable alternative for those with primary, secondary, or early latent syphilis.
  - Doxycycline 100 mg PO BID for 28 days is an acceptable alternative for those with late latent syphilis or syphilis of unknown duration.

#### Resources

- If needed, more information regarding the procurement and use of Extencilline® can be found in the recent CDPH Dear Colleague Letter (PDF)[4]. Contact your local health department if you are experiencing difficulty obtaining Bicillin® L-A or Extencilline®.
- For clinical questions related to the treatment of syphilis during the Bicillin® L-A shortage, please contact the Sexually Transmitted Diseases (STD) Clinical Consultation Network, your local health department, or CDPH STD Control Branch at (510) 620-3400 by phone or stdcb@cdph.ca.gov by email.

### References

- [1] U.S. Food and Drug Administration: Drug Shortage Webpage
- [2] Pfizer: Injectable Product Availability Report (PDF)
- [3] CDPH Health Advisory: Bicillin® L-A (Benzathine Penicillin G) Shortage
- [4] CDPH Dear Colleague Letter: Powdered Benzathine Benzylpenicillin (Extencilline®) for the Treatment of Syphilis (PDF)

California Department of Public Health
PO Box, 997377, MS 0500, Sacramento, CA 95899-7377
Department Website ( cdph.ca.gov )

