

To: CAHAN San Diego Participants

Date: July 16, 2025

From: Public Health Services

Health Advisory Update #4: Update on Bicillin® L-A Availability and New Recall

Key Messages

- According to the Food and Drug Administration (FDA), availability of long-acting penicillin G benzathine (Bicillin® L-A) 1.2- and 2.4-million-unit (MU) prefilled syringes is limited, and the timeline for resumption of normal supply is unknown.
- Pfizer has issued a voluntary recall of some lots of Bicillin® L-A (1.2 and 2.4 MU doses) distributed between December 1, 2023, and June 24, 2025, due to particulates identified during visual inspection.
- Extencilline® and Lentocilin© were approved by the FDA for temporary importation in response to previous Bicillin® L-A shortages and remain available.
- Providers experiencing shortages of injectable benzathine penicillin G should prioritize use for pregnant people
 who require syphilis treatment and babies exposed to syphilis in utero and consider alternative treatment
 options such as doxycycline for non-pregnant individuals.

Situation and Background

On July 10, 2025, Pfizer announced an anticipated <u>near-term stockout</u> for long-acting injectable penicillin G benzathine (Bicillin® L-A) that will affect the 1.2 million units (MU)/2mL (600,000 units/mL) and 2.4 MU/4mL (600,000 units/mL) prefilled syringes. The company also announced a <u>voluntary drug recall</u> affecting lots of Bicillin® L-A distributed from December 11, 2023 through June 24, 2025, including 1.2 and 2.4 MU prefilled syringes. Pfizer initiated this recall due to particulates identified during visual inspection and completed a Health Hazard Assessment that indicated that the potential risk from use of the impacted product is medium. To date, Pfizer has not received reports of any adverse events associated with this issue. Currently the impact of the recall on Pfizer's production timeline is unknown, but the company has committed to providing an update no later than mid-August.

The Food and Drug Administration (FDA) has updated its <u>website</u> to reflect limited availability of the 1.2 and 2.4 MU formulations of Bicillin® L-A due to a delay in shipping of the drug. In response to previous Bicillin® L-A drug shortages, which were already reported through this network (see health advisories from <u>4-25-23</u>, <u>6-15-23</u>, and <u>3-26-24</u>), the FDA has allowed the temporary importation of <u>benzathine benzylpenicillin (Extencilline®)</u> and <u>benzathine benzylpenicillin tetrahydrate (Lentocilin©)</u>. While these injectable penicillin formulations are considered interchangeable with Bicillin® L-A for syphilis treatment, there are important differences between these formulations and Bicillin® L-A, which are noted in the resources in the FDA section below. Bicillin® C-R, also manufactured by Pfizer, is <u>not</u> interchangeable with Bicillin® L-A and should <u>not</u> be used for syphilis treatment.

Actions Recommended

- 1. **Check** your inventory of Bicillin® L-A to determine if your supply includes any of the affected lots, as these should not be used.
 - o If you have any of the affected lots in your inventory, discontinue use, stop distribution, and quarantine the product immediately.
 - Follow the <u>instructions provided by Pfizer</u> to return affected lots.

- 2. **Monitor** your inventory of Bicillin® L-A and contact your wholesaler(s) to determine availability. Consider Extencillin® or Lentocilin© if you are unable to obtain Bicillin® L-A. For patients with the highest medical necessity (i.e., patients with confirmed congenital syphilis or risk of congenital syphilis), request Bicillin® L-A directly from Pfizer using the Medical Request Process.
- 3. If using Extencilline® or Lentocilin©, *review* information regarding reconstitution, storage, administration, and precautions as they differ in some respects to those of Bicillin® L-A (see Dear Healthcare Provider letters in FDA section of Resources).
- 4. If your supply of Bicillin® L-A is limited and you are unable to obtain imported alternative injectable penicillin formulations, *refer* to existing guidance regarding prioritization of Bicillin® L-A and *consider use* of alternative treatment such as doxycycline for non-pregnant people who require syphilis treatment.
- 5. **Contact** the HIV, STD, and Hepatitis Branch if you have trouble obtaining Bicillin L-A®, Extencilline®, or Lentocilin© by calling (619) 692-8501. For clinical questions related to treatment of syphilis, call (619) 609-3245. Both numbers are monitored Monday through Friday from 8:00am to 5:00pm, excluding County holidays.

Resources

Pfizer:

- Bicillin© L-A Recall Letter July 10, 2025
- Availability Update for Bicillin® L-A (penicillin G benzathine injectable suspension) 1.2 million Units/2mL (600,000 units/mL) and 2.4 million Units/4mL (600,000 units/mL) Prefilled Syringes – July 10, 2025

County of San Diego:

- Health Advisory: Potential Access Challenges to Bicillin L-A® April 25, 2023
- Health Advisory Update #2: Bicillin® L-A Shortage June 15, 2023
- Health Advisory Update #3: Extension of Bicillin® L-A Shortage March 26, 2024

California Department of Public Health:

- Health Advisory Bicillin® L-A (Benzathine Penicillin G) Shortage June 2023
- Dear Colleague Letter Special Considerations for the Treatment of Syphilis using Alternative Therapies in Non-pregnant Persons - September 2023
- Health Advisory Extension of Long-Acting Benzathine Penicillin G (Bicillin® L-A) Shortage March 2024

FDA:

- Penicillin G Benzathine Injection FDA Drug Shortages Website
- Dear Healthcare Provider Letter: Temporary Importation of Extencilline, (benzathine benzylpenicillin) Powder and diluent for reconstitution for injection, 1,200,000 units and 2,400,000 units with Foreign, non-U.S.
 Labeling to Address Supply Shortage
- Dear Healthcare Provider Letter: Temporary Importation of Lentocilin©, (Benzathine Benzylpenicillin Tetrahydrate) Powder and diluent for suspension for injection, 1,200,000 units with Foreign, non-U.S. Labeling to Address Supply Shortage

Thank you for your participation.

CAHAN San Diego

County of San Diego Health & Human Services Agency

HIV, STD, and Hepatitis Branch

Phone (for providers, M-F 8AM-5PM): (619) 692-8501 (lab/treatment histories and staging/treatment recommendations), (619) 609-3245 (clinical consultations for challenging cases); Fax: (619) 692-8541

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