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PUBLIC HEALTH ADVISORY

To: Health Care Providers

From: Dr. Isaac Benowitz, State Epidemiologist

Subject: Bicillin L-A Recall and Recommendations for Syphilis Treatment

Date / Time: Wednesday, July 30, 2025, at 11:15AM

Priority: Normal

Pages: 2

Message ID: 2025PHADV020

Bicillin L-A Recall and Recommendations for Syphilis Treatment

Summary

Pfizer has issued a voluntary recall of certain lots of penicillin G benzathine injectable suspension (Bicillin L-A) due to particulates identified during visual inspection. Health care organizations should confirm whether any of their current stock of Bicillin L-A has been affected by the recall. The U.S. Centers for Disease Control and Prevention (U.S. CDC) has provided information on <u>priority actions</u> to take following the recall. The Maine Center for Disease Control and Prevention (Maine CDC) is currently monitoring the situation and recommends that the remaining stock of Bicillin L-A be preserved for treatment of syphilis in pregnant persons.

Bicillin L-A Recall

On July 10, 2025, Pfizer announced a <u>voluntary recall</u> of certain lots of penicillin G benzathine injectable suspension (Bicillin L-A) due to particulates identified during visual inspection. To date there have not been any adverse events associated with this issue and there is no indication of reduced efficacy or need for retreatment. The affected product lots were distributed between December 11, 2023, and June 24, 2025. Pfizer anticipates a near-term stockout of Bicillin L-A as a result of this voluntary recall.

Recommendations for Clinicians

The Maine CDC recommends the following actions:

- Review the <u>recall notice</u> from Pfizer to determine if your lots of Bicillin L-A are impacted and follow guidance issued by the manufacturer.
- Monitor your supply of Bicillin L-A and forecast your need. <u>Contact Pfizer</u> to request product through their Medical Request Process.
- Consider using doxycycline for syphilis treatment in non-pregnant persons and preserving Bicillin L-A for treatment of pregnant persons, as penicillin is the only recommended treatment for pregnant persons.
 See the <u>U.S. CDC STI Treatment Guidelines</u> for more information.
- The U.S. Food and Drug Administration (FDA) has approved the importation of <u>Extencilline</u> and <u>Lentocilline</u> to address ongoing shortages of Bicillin L-A. Extencilline has been determined to be equivalent to Bicillin

- L-A and is currently authorized and marketed in other countries. Please note that the preparation and administration of Extencilline, and the contraindications for prescribing, differ from those for Bicillin L-A.
- Accurately stage syphilis infections to ensure appropriate use of antimicrobials. Early syphilis (primary, secondary, and early latent) only requires one dose of 2.4 million units of Bicillin L-A. See the <u>U.S. CDC STI Treatment Guidelines</u> for more information on staging syphilis infections. Resources for appropriately staging syphilis can be found from the <u>National STD Curriculum</u> and the <u>New York City Department of Health and Mental Hygiene</u> Bureau of Sexually Transmitted Infections/New York City STD Prevention Training Center. Providers who need clinical decision-making support can contact the <u>STD Clinical Consultation Network</u>.
- If you are unable to obtain Bicillin L-A to treat pregnant patients with syphilis, please contact the Maine CDC at 800-821-5821.
- Preventing new syphilis infections is one way to reduce use of scarce Bicillin-LA doses. Consider offering DoxyPEP, which has been shown to reduce bacterial STIs in men who have sex with men and transgender women. In three large randomized controlled trials, 200 mg of doxycycline taken within 72 hours after sex has been shown to reduce syphilis and chlamydia infections by >70% and gonococcal infections by approximately 50%. For more information on DoxyPEP, see <u>U.S. CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention.</u>

Recommendations for Health Systems

Consider working with antimicrobial stewardship leaders to institute systems-level approaches to limit the
use of Bicillin L-A and encourage the use of alternative effective antimicrobials for treatment of other
infections.

Resources

- U.S. CDC Priority Actions Following Bicillin L-A Recall: https://www.cdc.gov/sti/php/from-the-director/2025-07-bicillin-recall.html
- FDA Drug Shortage Information for Penicillin G Benzathine Injection:
 https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?Al=Penicillin%20
 G%20Benzathine%20Injection&st=c
- U.S. CDC STI Treatment Guidelines: https://www.cdc.gov/std/treatment-guidelines/default.htm
- STD Clinical Consultation Network: https://www.stdccn.org/controller/Public/AddPublicConsultRequestStep1