DEPARTMENT OF HEALTH

Bicillin L-A® Recall and Anticipated Shortage

Please distribute widely to health care system sites and colleagues in pharmacy, infectious diseases, infection prevention, STI clinics, primary care, emergency department staff, obstetrics/gynecology, and all other health care providers who might see patients with syphilis.

Background

There is a new voluntary recall of specific referenced lots of Bicillin[®] L-A (Penicillin G Benzathine Injectable Suspension) by King Pharmaceuticals LLC., a subsidiary of Pfizer. Recalled lots can be found at <u>Pfizer: Bicillin Recall Letter (PDF)</u>

(www.pfizerhospitalus.com/sites/default/files/news_announcements/Bicillin%20Recall%20Lett er.pdf). CDC is not aware of any adverse events associated with this issue and there is no indication at this time of reduced efficacy or need for retreatment.

Considering this recall and high levels of syphilis diagnoses in the United States (as detailed in the <u>National Overview of STIs in 2023 (https://www.cdc.gov/sti-</u>

<u>statistics/annual/summary.html</u>), CDC anticipates a limited supply of Bicillin[®] L-A moving forward. Penicillin is the only recommended treatment for pregnant women and babies with congenital syphilis. Given this information, CDC recommends prioritizing Bicillin[®] L-A for treating patients who are pregnant and for infants with congenital syphilis.

Recommendations for health care facilities

- 1. Identify whether you have current inventory of the recalled product and follow **the guidance issued by the manufacturer.**
- 2. Take inventory, monitor local supply of Bicillin L-A[®], and forecast need moving forward. Tools to help determine pattern of use to forecast need are available at <u>Bicillin Forecasting</u> <u>and Inventory (www.ncsddc.org/resource/bicillin-forecasting-and-inventory/)</u>.
- 3. Continue to contact distributors to procure Bicillin L-A[®], as appropriate. **Contact Pfizer to request product** through their Medical Request Process if the distributor has no supply.
- 4. Consider involving antimicrobial stewardship leaders to help 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. If supply is limited, consider Extencilline and Lentocilin[©] which were approved by FDA for temporary importation due to prior shortages and remain available.
- 5. Communicate forecasted supply of Bicillin L-A[®] to STI and other relevant health care providers in your facility.

Recommendations for health care providers

MDH recommends health care providers prioritize Bicillin® L-A for:

• All pregnant patients with syphilis (or exposure) and infants with possible congenital syphilis

• People with contraindications to doxycycline.

Non-pregnant patients can be treated with:

- Doxycycline 100 mg PO BID for 14 days for primary, secondary or early latent syphilis
- Doxycycline 100 mg PO BID for 28 days for late latent or syphilis of unknown duration.

Remind patients that treatment is only effective if taken as directed.

Follow patients to ensure treatment is completed and schedule follow-up visits with patients to verify a decline in syphilis serologic evaluation per the CDC.

In addition to prioritizing pregnant patients, infants, and those with contraindications to doxycycline as above, during a shortage, health care providers can consider Bicillin L-A for use in non-pregnant patients with significant concerns for adherence to doxycycline (including challenges such as housing instability, substance use, or other concerns). Decisions should be made on a case-by-case basis, considering the extent of supply available.

If your site is experiencing a Bicillin[®] L-A shortage or has any questions or concerns about Bicillin L-A[®] access for priority populations, please contact MDH at 651-201-5414 and request to speak to someone in the STI/HIV Partner Services Unit.

Additional information

- Additional information about the Bicillin L-A[®] anticipated shortage and prioritization recommendations are available on <u>CDC: Bicillin L-A[®] (https://www.cdc.gov/sti/php/from-the-director/2025-07-bicillin-recall.html)</u>.
- <u>CDC: Sexually Transmitted Infections Treatment Guidelines, 2021</u> (www.cdc.gov/std/treatment-guidelines/syphilis.htm)
- For clinical questions and trainings, contact the <u>STD Clinical Consultation Network</u> (www.stdccn.org) and the National STI Curriculum training webinars at <u>National STI</u> <u>Curriculum (www.std.uw.edu)</u>.
- Sign up at Syphilis (https://www.health.state.mn.us/diseases/syphilis/index.html) to receive notices about health issues, new publications, or STI/HIV/TB events from MDH.

Minnesota Department of Health www.health.state.mn.us

07/25/2025 To obtain this information in a different format, call: 651-201-5414.