

## Bicillin L-A<sup>®</sup> 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

In July 2025, there was a voluntary recall of specific referenced lots of Bicillin<sup>®</sup> L-A (Penicillin G Benzathine Injectable Suspension) by King Pharmaceuticals LLC., a subsidiary of Pfizer. Recalled lots can be found at [Pfizer: Bicillin Recall Letter \(PDF\)](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](https://www.pfizerhospitalus.com/sites/default/files/news_announcements/Bicillin%20Recall%20Letter.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 [National Overview of STIs in 2023 \(https://www.cdc.gov/sti-statistics/annual/summary.html\)](https://www.cdc.gov/sti-statistics/annual/summary.html)), CDC anticipates a limited supply of Bicillin<sup>®</sup> L-A moving forward. Penicillin is the only recommended treatment for pregnant patients and babies with congenital syphilis. Given this information, CDC recommends prioritizing Bicillin<sup>®</sup> 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<sup>®</sup>, and forecast need moving forward. Tools to help determine pattern of use to forecast need are available at [Bicillin Forecasting and Inventory \(www.ncsddc.org/resource/bicillin-forecasting-and-inventory/\)](http://www.ncsddc.org/resource/bicillin-forecasting-and-inventory/).
3. Continue to contact distributors to procure Bicillin L-A<sup>®</sup>, 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<sup>®</sup> L-A and encourage the use of alternative effective antimicrobials for treatment of other infections. If supply is limited, consider Bicillin L-A<sup>®</sup> alternatives such as Extencilline and Lentocilin<sup>©</sup>, which were approved by FDA for temporary importation due to prior shortages and remain available.
5. Communicate forecasted supply of Bicillin L-A<sup>®</sup> 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<sup>®</sup> for:

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

- People with contraindications to doxycycline.
- Pediatric-aged patients with a history of acute rheumatic fever (ARF) who require monthly injections of Bicillin L-A® for group A *Streptococcus* ARF prophylaxis.

**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.

## **MDH allocation recommendations**

This document provides a framework for the allocation of Bicillin L-A®; it is intended to guide care delivery and organizational response during this period of shortage. **It aims to provide a basis for consistent response to this situation among institutions and systems across the State of Minnesota, to promote transparency, fairness, and a whole community approach to response, to provide the best care possible to all patients throughout the state of Minnesota and to promote the population's health.**

It is based on common ethical values that have been affirmed in Minnesota through processes of stakeholder and public engagement process regarding crisis response. It incorporates the input of a statewide expert panel of physicians, pharmacists, ethicists, and MDH staff, convened by the Metro Health & Medical Preparedness Coalition at the request of health professionals involved in managing the shortage. This document is not legal advice, it does not carry the force or effect of law, and it should not be construed as a statement of legal or regulatory requirements or protections. Health care facilities or systems implementing strategies to manage drug shortages and other crisis situations are strongly encouraged to consult with their legal counsel, and coordinate their efforts with health system leadership, Health Care Coalition (HCC) partners, and MDH.

As of December 2025, Bicillin® L-A (penicillin G benzathine injectable suspension) availability:

- Pfizer began shipping prefilled syringes to wholesalers fall 2025 at a pace equal to 35% historic demand (1.2 million Units/2 mL) and 40% historic demand (2.4 million Units/4 mL). Due to the backlog of orders this is estimated to be meeting 5-10% of historical demand.

- Pfizer plans to begin shipping Bicillin L-A® pediatric 600,000 Units/mL prefilled syringes in December 2025.
- The Bicillin L-A® shortage is expected to continue through Q3 2026.
- For more information, visit [Availability Update for Bicillin® L-A \(penicillin G benzathine injectable suspension\) Prefilled Syringes \(PDF\)](https://www.pfizerhospitalus.com/sites/default/files/news_announcements/Availability%20Update%20for%20Bicillin%20L-A%208.21.25.pdf) ([https://www.pfizerhospitalus.com/sites/default/files/news\\_announcements/Availability%20Update%20for%20Bicillin%20L-A%208.21.25.pdf](https://www.pfizerhospitalus.com/sites/default/files/news_announcements/Availability%20Update%20for%20Bicillin%20L-A%208.21.25.pdf)).

## Syphilis epidemiologic trends

- In 2024, syphilis cases decreased by 9% nationally and in Minnesota compared to 2023.
- Nationally and in Minnesota, however, congenital syphilis cases continued to increase, with an 11% increase in cases in Minnesota in 2024 compared to 2023.
- Similar trends have continued for 2025.

Minnesota forecasting based on historic demand and syphilis trends (estimated doses (2.4 million Units/mL) per month statewide):

- An estimated 11 doses per month to treat all pregnant cases statewide.
- An estimated three pediatric doses per month to treat congenital syphilis statewide.
- An estimated three doses per month to treat those with contraindications to doxycycline.
- In total, an estimated 17 doses per month to treat all priority patients (pregnant cases, infants, and those with contraindications to doxycycline) statewide
  - This is an estimated 7% of historic need in Minnesota.
- Very small number of pediatric-aged patients statewide with a history of acute rheumatic fever (ARF) who require monthly injections of Bicillin L-A® for group A Streptococcus ARF prophylaxis. Dosing ranges are based on weight and are either 600,000 units or 1.2 million units per dose every 28 days. This group fits within the 7% of historic need estimates above.
- As supply is released at 35-40% historic need, and CDC's priority populations encompass an estimated 7% of historic need, it is anticipated that there will be additional supply available, however, not an adequate supply to treat all syphilis cases statewide.

## Priority populations

Bicillin L-A® should be allocated to the priority populations identified below, to fulfill the duty to promote the best care possible during the shortage, protect the population's health by working to limit transmission of syphilis, and promote fairness and a whole community approach to response.

Allocation of Bicillin L-A® should consider the forecasting outlined here. As supply in the state expands beyond the estimated doses to treat the CDC's priority populations, allocation should expand beyond those populations to the additional groups outlined in the Bicillin L-A® Shortage Priority Tiers Guidance below. Treatment should not be withheld from patients unless supply is so

limited that allocation cannot be expanded, based on the best available data. Note that these priority tiers are also structured to steward limited supply. Partners of pregnant cases represent a small percentage of potential cases overall and inadequate treatment of partners of pregnant cases could lead to reinfection. Patients with primary and secondary syphilis and those with early latent (non-primary/non-secondary) syphilis have higher public health risk of transmissibility and require fewer doses of Bicillin L-A® compared to those with late latent/unknown duration syphilis and so should be prioritized over those in the latter group.

## Allocation within priority tiers

If there is insufficient supply to treat all patients in the next priority tier, providers should prioritize patients within that tier with significant adherence challenges to doxycycline, which may be affected by housing and transportation, and those living with HIV.

Decisions about treatment allocation priorities should not be based upon nonclinical considerations such as:

- Socioeconomic or personal characteristics, included but not limited to, race/ethnicity, age or incarceration status
- Ability to pay
- Whether the patient regularly receives care from a particular health facility or system
- First come, first served
- Judgments that some people have greater “quality of life” than others
- Judgments that some people have greater “social value” than others

Allocation decisions will, in some cases, need to consider whether a patient's circumstances impede their ability to comply with a regimen of doxycycline. This decision-making process addresses the question of what treatment option will be most effective for this patient, and so is best thought of as ethically appropriate clinical decision-making. When factors such as housing, transportation and distance from a healthcare service make adherence a challenge for some patients, it is ethically justifiable to take these factors into consideration when allocating doses on a case-by-case basis within tiers. In contrast, denying patients access to a treatment simply due to nonclinical factors—e.g., because they do not regularly receive care from a particular health system, or due to perceptions about their social value or worthiness—would not be ethically appropriate.

## Case by case discussion and shared decision-making

Assessing a patient's priority for allocation of Bicillin L-A® may require determining whether the patient has significant challenges impeding adherence to a regimen of doxycycline. To promote respectful and fair care, providers should not make assumptions about whether individual patients face such challenges; rather, they should engage in a process of shared decision-making with patients. If after discussion providers remained concerned about the ability for a patient to adhere to the doxycycline regimen, clinicians are supported in recommending Bicillin L-A® for specific cases,

dependent on availability. While facilities/systems are responsible for developing their own communication strategies, discussions with patients should:

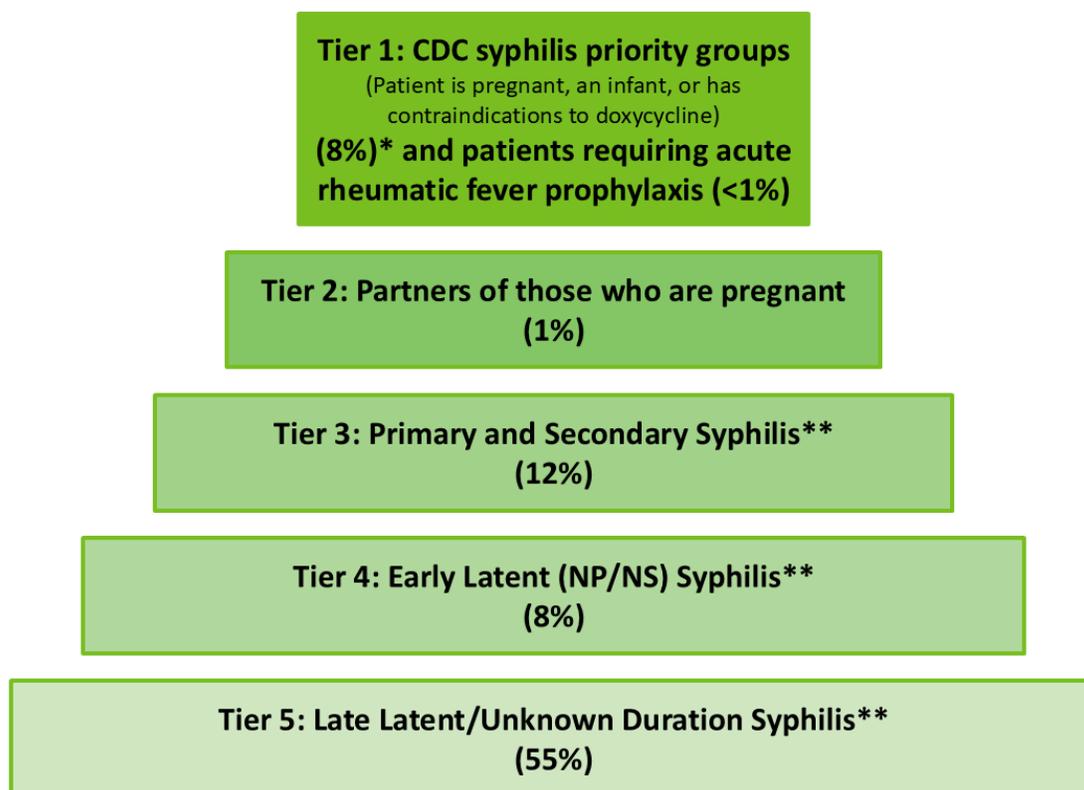
- Acknowledge that a nationwide shortage of Bicillin L-A® is currently affecting care of patients with syphilis
- Clearly outline the requirements of adherence to doxycycline
- Explore potential challenges to adherence with doxycycline and whether incentives for follow-up appointments, if available, may support doxycycline adherence

Facilities/systems may consider adding automated prompts to the electronic health record to promote this type of shared decision-making.

**Health systems/facilities should partner to consider how best to fairly support patients who should be prioritized for allocation but cannot access treatment.** While all health

systems/facilities/providers in the state are affected by the shortage of this treatment resource, the severity of shortages may vary across facilities/providers. If any provider in the state is caring for a patient who qualifies for prioritized allocation of Bicillin L-A®, but lacks supply to provide treatment, that provider may reach out to the Regional Healthcare Preparedness Coordinator (RHPC) for the Metro Region at 612-873-9911 to help identify available supply for that patient. The RHPC for the Metro Region will help connect providers statewide to available doses of treatment. Please note organizations need to discuss cost implications as some organizations qualify for 340B pricing and others do not.

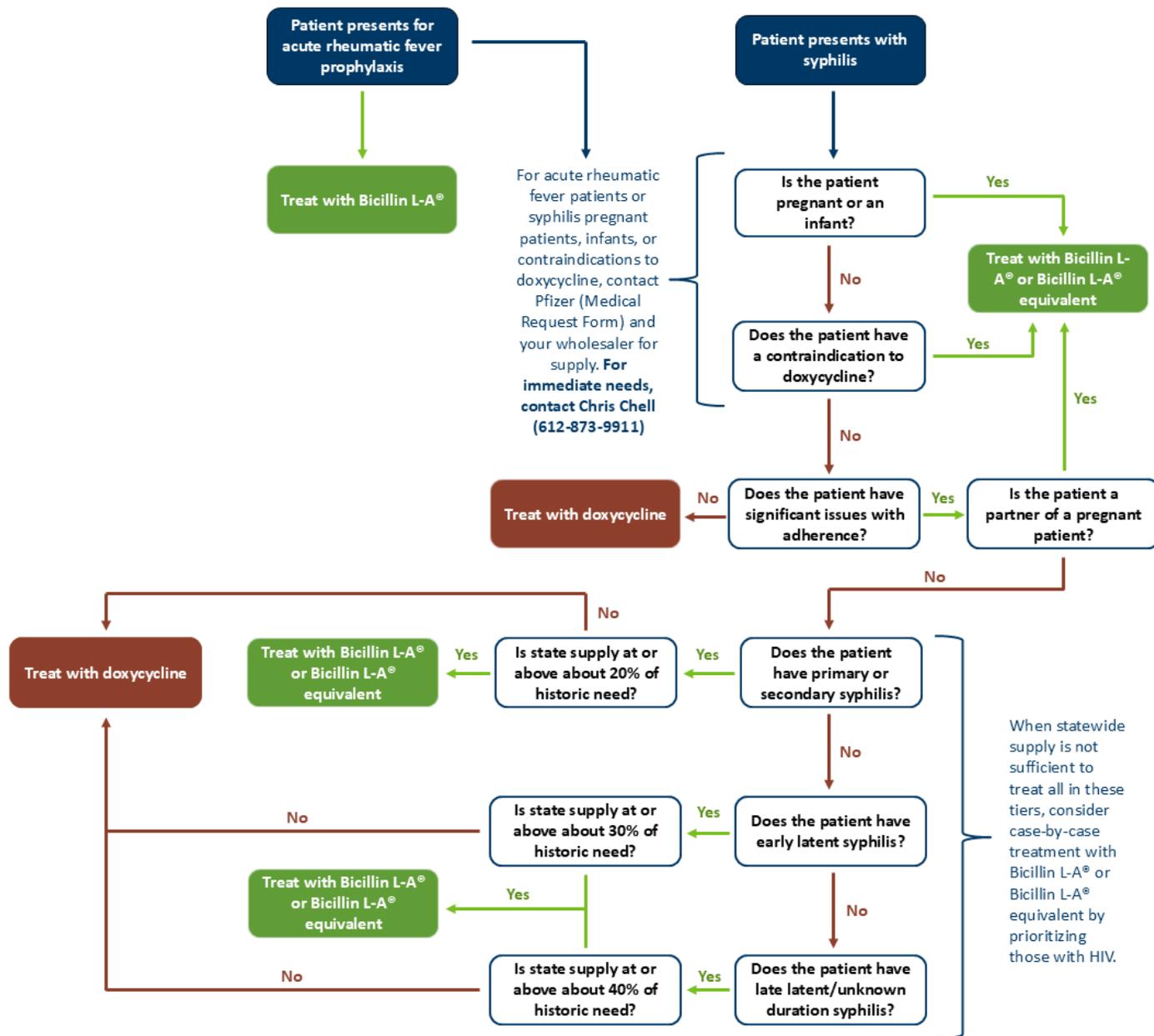
### Bicillin L-A® Prioritization Tiers Guidance



\*Percentage of historical need. Percentages do not add up to 100%, estimating 20% doxycycline adherence among tiers 3 to 5.

\*\*Offer doxycycline. Advance through tiers 3 to 5 based on supply. As supply allows advancement to the next tier, prioritize those with significant adherence challenges to doxycycline and those living with HIV.

### Prioritization Framework



### Additional information

- Additional information about the Bicillin L-A® anticipated shortage and prioritization recommendations are available on [CDC: Bicillin L-A® \(https://www.cdc.gov/sti/php/from-the-director/2025-07-bicillin-recall.html\)](https://www.cdc.gov/sti/php/from-the-director/2025-07-bicillin-recall.html).
- [CDC: Sexually Transmitted Infections Treatment Guidelines, 2021 \(www.cdc.gov/std/treatment-guidelines/syphilis.htm\)](http://www.cdc.gov/std/treatment-guidelines/syphilis.htm)

BICILLIN L-A® RECALL AND ANTICIPATED SHORTAGE

- For clinical questions and trainings, contact the [STD Clinical Consultation Network \(www.stdccn.org\)](http://www.stdccn.org) and the National STI Curriculum training webinars at [National STI Curriculum \(www.std.uw.edu\)](http://www.std.uw.edu).
- Sign up to the [HIV/STD Prevention and Data Updates \(https://public.govdelivery.com/accounts/MNMDH/subscriber/new\)](https://public.govdelivery.com/accounts/MNMDH/subscriber/new) distribution list to receive notices about health issues, new publications, or STI/HIV/TB events from MDH.

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

1/15/2026

*To obtain this information in a different format, call: 651-201-5414.*