## Medication Update



July 24, 2025

# \*UPDATE\*: Limited Supply of Penicillin G Benzathine (Bicillin® L-A) for treatment of Syphilis

On July 10<sup>th</sup>, 2025, Pfizer Inc., the manufacturer of Penicillin G Benzathine, initiated a <u>voluntary recall</u> of specified lots of Bicillin® L-A injectable suspensions, namely the 1.2M units/2ml and 2.4M units/4 ml prefilled syringes, due to particulates identified during visual inspection. Penicillin G Benzathine remains the first-line recommended treatment for syphilis per U.S. Centers for Disease Control and Prevention guidelines.¹ Additionally, Penicillin G Benzathine continues to be listed on both the <u>FDA Drug Shortage list</u> and <u>ASHP Drug Shortage list</u>, with the Indian Health Service (IHS) Pharmaceutical Prime Vendor (PPV) also reporting limited supplies. The IHS National Supply Service Center (NSSC) is actively monitoring the situation and working to identify and make available Penicillin G Benzathine when possible. The NSSC is advising all interested IHS facilities to submit requests for Bicillin® L-A product supply directly to Pfizer using the "<u>Bicillin L-A Medical Request Form</u>".

#### **Priorities:**

In light of a national shortage of Penicillin G Benzathine, IHS providers need to consider prioritization of this medication at all healthcare facilities. IHS treatment recommendations (listed in order of priority) include the following:

- Pregnant and HIV infected patients with syphilis (and their contacts) as well as infants with congenital syphilis should receive priority for treatment with Penicillin G Benzathine. Penicillin G Benzathine (Bicillin® L-A) is the only recommended treatment for pregnant patients infected with or exposed to syphilis.
- 2. Other persons with early syphilis (primary, secondary, early latent) should be treated with Penicillin G Benzathine (and their contacts) if supplies are adequate to cover high risk patients listed under priority #1. Sexual partners should also be offered Penicillin G Benzathine if supplies are adequate.
- 3. If Penicillin G Benzathine supplies are inadequate to cover patients listed as priority #2, treat early syphilis (primary, secondary, early latent) with **doxycycline 100 mg po bid for 14 days** and late latent syphilis or latent syphilis of uncertain duration with doxycycline 100 mg po bid for 28 days.
- 4. **Ceftriaxone 1 gm IV daily for 10 days** may be an acceptable second-line alternate treatment for primary and secondary syphilis. Use of ceftriaxone for latent syphilis is not well defined and consultation with an Infectious Disease specialist is recommended.

### Additional considerations:1

Syphilis is a systemic disease caused by *T. pallidum*. The disease has been divided into stages on the basis of clinical findings, which guide treatment and follow-up. Persons who have syphilis might seek treatment for signs or symptoms. Primary syphilis classically presents as a single painless ulcer or chancre at the site of infection but can also present with multiple, atypical, or painful lesions. Secondary syphilis manifestations can include skin rash, mucocutaneous lesions, and lymphadenopathy. Tertiary syphilis can present with cardiac involvement, gummatous lesions, tabes dorsalis, and general paresis.

Latent infections (i.e., those lacking clinical manifestations) are detected by serologic testing. Latent syphilis acquired within the preceding year is referred to as early latent syphilis; all other cases of latent syphilis are classified as late latent syphilis or latent syphilis of unknown duration.

#### References:

1. U.S. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2021. Published July 23, 2021.