Indian Health Service
National Pharmacy and Therapeutics Committee
Medication Update

August 19, 2025

Authorized Alternative to Penicillin G Benzathine (Bicillin® L-A) for Treatment of Syphilis & Congenital Syphilis

A voluntary recall of specified lots of Bicillin® L-A (Penicillin G benzathine) injectable suspensions, namely the 1.2M units/2ml and 2.4M units/4 ml prefilled syringes, was issued by the manufacturer on July 10th, 2025 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]

To address this product shortage, the U.S. Food and Drug Administration (FDA) has temporarily authorized two Bicillin® L-A alternatives, **Lentocilin©** (benzathine benzylpenicillin tetrahydrate) and **Extencilline®** (benzathine benzylpenicillin), from foreign manufacturers to be imported by U.S. healthcare facilities in the interim.[2] These products are not FDA-approved, but are considered interchangeable to Bicillin® L-A in safety and effectiveness. As an intermediate term solution, ***Lentocilin©*** offers the Indian Health Service (IHS) a clinically-appropriate, cost-effective solution to remedy the limited supply of Bicillin® L-A for the treatment of syphilis and congenital syphilis in American Indian/Alaska Native (AI/AN) populations. IHS is in the process of procuring a supply of ***Lentocilin©*** from an FDA-approved distributer to meet current and projected needs. Facilities interested in purchasing Lentocilin© (at their cost) may use the traditional Form 413 ordering process from the IHS National Supply Service Center.

Product Information[3] - LENTOCILIN©

In terms of clinical indications and dosing for treatment of syphilis and congenital syphilis, Lentocilin© is deemed equivalent to Bicillin® L-A. However, subtle differences exist between the two product formulations, some of which are included below for clinician review and consideration.

Notably, the product labeling states that Lentocilin©:

- is supplied as powder for reconstitution (compared to prefilled disposable syringes for Bicillin® L-A)
- should be stored below 25ºC (room temperature), in the original package to protect from light and moisture. Following reconstitution, benzylpenicillin benzathine should be used immediately
- is only available in 1.2M unit intramuscular (IM) dose vials. The volume of Lentocilin© 1.2M units after reconstitution is around 4 mL (compared to 2 mL for Bicillin® L-A). Two IM injections may be needed
- must be administered exclusively by deep IM injection in the external upper quadrant of the buttock and an alternate site (other buttock) should be used in case of repeated doses
- contains soy phospholipids and may cause hypersensitivity reactions (urticaria, anaphylactic shock) in patients with a history of allergy to soybeans

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- *Complete and submit the report Online: www.fda.gov/medwatch/report.htm*
- *Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-332-0178*

Summary

In conclusion, there remains ample supply of an authorized penicillin G benzathine alternative for the IHS. The IHS has approved use of Lentocilin© in accordance with appropriate indications and dosing for the treatment of syphilis and congenital syphilis in AI/AN patients. All healthcare facilities planning to procure and utilize Lentocilin© should review its Prescribing Information prior to administration.

References:
1. U.S. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2021. Published July 23, 2021.
2. U.S. Centers for Disease Control and Prevention. Bicillin L-A. Sexually Transmitted Infections (STIs). Published July 18, 2025.
3. Lentocilin© (Benzathine Benzylpenicillin Tetrahydrate). PRESCRIBING INFORMATION. Laboratorios Aral, S.A. Portugal. June 11, 2024.