



Dear STD Program Colleagues,

Penicillin G benzathine is the recommended treatment for syphilis and the only recommended treatment for pregnant women infected or exposed to syphilis. Pfizer, the sole manufacturer of Bicillin L-A<sup>®</sup> (penicillin G benzathine) in the United States is experiencing a manufacturing delay of this product. The Center for Disease Control and Prevention's (CDC) Division of STD Prevention (DSTDP) is working with the United States Food and Drug Administration's (FDA) Drug Shortage Staff and Pfizer to address this situation.

Pfizer is currently releasing weekly allocations to wholesale distributors to prevent stock outs. Normal supplies are expected to resume by July 2016. Until normal quantities of Bicillin L-A<sup>®</sup> (penicillin G benzathine) are available, CDC suggests the following:

- 1) Take inventory
  - a. Monitor local supply of Bicillin L-A<sup>®</sup> (penicillin G benzathine)
  - b. Determine local pattern of penicillin G benzathine use
  - c. Continue to contact distributors to procure penicillin G benzathine as appropriate. If product reaches a critical supply level of three weeks or less, notify the Pfizer Supply Continuity Team at 844.804.4677 to inquire about an emergency supply. Also, alert your DSTDP project officer.
  
- 2) Implement a usage strategy, if inventory is less than 2 months of product based on projected use.
  - a. Discourage the use of penicillin G benzathine for treatment of other infectious diseases (e.g. streptococcal pharyngitis) where other effective antimicrobials are available.
  - b. Encourage the adherence to the recommended dosing regimen of 2.4 million units of penicillin G benzathine IM for the treatment of primary, secondary and early latent syphilis (early syphilis) as outlined in the [2015 STD Treatment Guidelines](#). Additional doses to treat early syphilis do not enhance efficacy including patients living with HIV infection.
  - c. Identify inventories that have ample product based on the usage pattern and facilitate movement of product as has been done in the past, if feasible, in your jurisdiction.
  - d. Purchase product at the state level to be distributed to facilities with less than 2 months of product. CDC will approve the use of STD-AAPPS funds for emergency purchases of product, if the usage strategy documents urgent need. Please send your request for approval, clearly documenting urgent need, to your DSTDP project officer.

- 3) Communicate with healthcare providers and pharmacists
  - a. Notify health care providers and pharmacists of the limited availability Bicillin L-A® (penicillin G benzathine) so they are aware and can plan. Ask them to report to you any shortages.
  - b. Inform clinicians with questions about syphilis clinical management to contact an ID specialist or the on-line National Network of STD Clinical Prevention Training Centers (NNPTC) STD Clinical Consultation Network (<https://www.stdccn.org>).
  
- 4) Communicate with DSTDP
  - a. Notify your DSTDP project officer of any shortage of penicillin G benzathine so CDC can continue to monitor this situation and provide situational awareness to FDA and Pfizer.

More information on syphilis treatment and clinical management can be found in the [2015 STD Treatment Guidelines](http://www.cdc.gov/std/tg2015/syphilis.htm) (<http://www.cdc.gov/std/tg2015/syphilis.htm>). CDC is not recommending any changes to these treatment recommendations for patients with syphilis.

Additional information on the availability of penicillin G benzathine can be found at <http://www.cdc.gov/std/treatment/drugnotices/bicillinshortage.htm> or on the [FDA's Drug Shortage website](#)

DSTDP is planning a conference call with STD Programs in the coming weeks to provide additional updates, answer questions, and allow programs the opportunity to share relevant information with other each other. In the meantime, if you have any questions about these recommendation, please contact your DSTDP project officer.

Sincerely,

Gail Bolan, MD  
Director  
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National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention