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Nationwide Shortage of Bicillin® L-A (Benzathine Penicillin G)

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On April 29, 2016, a Bicillin® L-A (penicillin G benzathine suspension) drug shortage was announced by the Food and Drug Administration (FDA). There are manufacturing delays in both adult and pediatric injections. The back order is expected to resolve by July 2016. This is of concern because California is in the midst of very significant increases in syphilis, including syphilis in pregnant women and congenital syphilis in infants. Benzathine penicillin G is the recommended treatment for syphilis, and the only recommended treatment for pregnant women with syphilis.

During the shortage, when appropriate, refrain from the use of penicillin G benzathine for the treatment of other infectious diseases (e.g., streptococcal pharyngitis) where other effective antimicrobials are available.

Continue to adhere 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 (i.e., early syphilis) as outlined in the CDC STD Treatment Guidelines for syphilis: <http://www.cdc.gov/std/tg2015/syphilis.htm>. Additional doses to treat early syphilis do not enhance efficacy, including in patients living with HIV infection.

Additional considerations:

- Primary and secondary syphilis are the most infectious stages. Treatment is necessary to interrupt transmission.
- Patients with early latent syphilis and patients with latent syphilis of unknown duration with high titers should be considered potentially able to transmit syphilis.
- Complications of syphilis, including neurosyphilis and ocular syphilis, can occur at any stage, thus it is important to ensure complete and appropriate treatment of all patients with syphilis.



- Persons with HIV infection who have early syphilis might be at increased risk for neurologic complications.
- Benzathine penicillin G has the benefit of directly observed therapy and is not reliant on patient adherence to a 14- or 28-day regimen of twice-daily doxycycline, and therefore benzathine penicillin G is ideal for those in whom medication compliance or follow-up may be in question. Additionally, patients with contraindications to doxycycline should be considered priorities for benzathine penicillin G administration.
- Presumptive treatment of sex partners of patients with syphilis remains a high priority and should be managed per the CDC STD Treatment Guidelines.

Although alternative treatment options are available for some individuals, be informed:

- The dose for doxycycline is 100mg orally twice a day for 14 days for primary, secondary, and early latent syphilis, and 100mg orally twice a day for 28 days for late latent syphilis
- ***Doxycycline is contraindicated in pregnant women and young children.***
- Follow-up clinical and serologic evaluation should be performed after treatment at the recommended intervals per the CDC STD Treatment Guidelines
<http://www.cdc.gov/std/tg2015/syphilis.htm>.
- Other formulations of penicillin, including Bicillin® C-R, are **not** acceptable alternatives to Bicillin® L-A for syphilis treatment.
- Choice regarding use of Bicillin® L-A versus doxycycline should be made after considering likelihood of medication adherence, patient follow-up, and local availability of Bicillin® L-A.

Stay informed of the shortage by visiting the following web sites:

- FDA website announcing the Bicillin® L-A shortage:
[http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillin%20G%20Benzathine%20\(Bicillin%20L-A\)%20Injection&st=c&tab=tabs-1](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillin%20G%20Benzathine%20(Bicillin%20L-A)%20Injection&st=c&tab=tabs-1).
- CDC notice about the Bicillin® L-A shortage:
<http://www.cdc.gov/std/treatment/drugnotices/bicillinshortage.htm>.

For clinical questions related to the treatment of syphilis during the Bicillin® L-A shortage, please contact the CDPH STDCB Clinician Warm Line at (510) 620-3400 or submit an online consult to the STD Clinical Consultation Network at www.stdccn.org.