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DHEC Health Advisory

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Penicillin G Benzathine (Bicillin L-A®) Shortage

Summary

The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) have announced a nationwide shortage of penicillin G benzathine (Bicillin L-A®), which is the first-line recommended treatment for syphilis and the only recommended treatment option for some patients.^{1,2} The South Carolina Department of Health and Environmental Control (DHEC) is aware of in-state provider concerns regarding obtaining Bicillin L-A® and is working closely with federal partners to monitor and mitigate the impact of this shortage to the extent possible. DHEC does not have preferential access to obtaining the drug.

Recommendations for Health Care Providers

During this time, providers should do the following:

- Prioritize the use of Bicillin L-A® for treatment of pregnant women infected with or exposed to syphilis.
 - Bicillin L-A® is the **only** treatment recommended for pregnant women that has been proven to prevent congenital syphilis.
 - Pregnant women who are allergic to penicillin should be referred for desensitization and treatment per the 2021 CDC STI Treatment Guidelines (<https://www.cdc.gov/std/treatment-guidelines/default.htm>).³
- Do **NOT** substitute Bicillin L-A® with Bicillin C-R®.
- During this shortage, Bicillin L-A® should **not** be used to treat conditions other than syphilis, such as streptococcal pharyngitis/tonsillitis, unless there are absolute contraindications to all other appropriate medications. Other drugs such as penicillin V, amoxicillin, or azithromycin should be used.
- For primary, secondary, early latent, or late latent syphilis during this drug shortage, alternative oral regimens should be preferred for all non-pregnant patients unless they have proven non-compliance with medication regimens and are not in a controlled environment such as a correctional/detention facility where compliance can be monitored. Alternative regimens of these non-pregnant patients are per the 2021 CDC STI Treatment Guidelines:³
 - Primary, secondary, or early latent syphilis – Doxycycline 100 mg orally twice daily for 14 days.

- Late latent syphilis or syphilis of unknown duration – Doxycycline 100 mg orally twice daily for 28 days.
- For congenital, ocular, and neurosyphilis – treat with intravenous aqueous penicillin G according to the 2021 CDC STI Treatment Guidelines.³
- For tertiary syphilis with normal CSF exam, treat with Bicillin L-A® according to the 2021 CDC STI Treatment Guidelines.³
- Review patients' syphilis testing and treatment history to confirm that patients with reactive syphilis serology have an **active** syphilis infection, especially patients with low nontreponemal titers.
- Consider alternative treatment of non-pregnant individuals who have had sexual contact with a person who is diagnosed with syphilis, according to the 2021 CDC STI Treatment Guidelines:³
 - Doxycycline 100 mg orally twice daily for 14 days.
- Consider prescribing doxycycline as post-exposure prophylaxis (doxy-PEP) to prevent syphilis infections among appropriate patients living with HIV and patients who are currently taking HIV pre-exposure prophylaxis (HIV PrEP). A single 200 mg dose of delayed-release doxycycline taken within 72 hours of possible exposure demonstrates significant reductions in syphilis, gonorrhea, and chlamydia infections in these populations. More information about doxy-PEP can be found here:
 - <https://www.nih.gov/news-events/news-releases/nih-funded-study-finds-doxycycline-reduces-sexuallytransmitted-infections-two-thirds>
 - <https://aidsetc.org/blog/doxy-peg-doxycycline-sti-prevention>

Further Actions if a Provider or Facility Experiences Bicillin L-A® Shortages:

- Notify DHEC at PARKSLN@DHEC.SC.GOV and the CDC STD Division at stdshortages@cdc.gov of any shortage or low inventories (less than 30-day supply) of Bicillin L-A® in your facility.
- Request Bicillin L-A® allocation prioritization to the Pfizer Supply Continuity Team at 844-646-4398 (select 1 and then select 3).
- If you have a high priority patient for whom there is no appropriate alternative treatment and you do not have access to a dose of Bicillin L-A®, you may consult a DHEC physician at (803) 422-1016 for consideration of referring the patient to DHEC.
 - Be prepared to securely email the patient's most recent office note and their lab result. If DHEC determines there are no alternatives for the patient and the agency has sufficient supply of the drug, they will accept the patient consult. All other medical care for the patient will remain the responsibility of the referring provider.

DHEC Contact Information for Reportable Diseases and Reporting Requirements:

Reporting of **syphilis and congenital syphilis** is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61- 20) as per the DHEC 2023 List of Reportable Conditions available at: <https://scdhec.gov/sites/default/files/Library/CR-005869.pdf>.

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

DHEC Partner Services Staff Contact Information:

State Program Manager

- **Bernard Gilliard**
Office: (803) 898-0452
Email: gilliab@dhec.sc.gov

Region Field Operations Managers

- **Lowcountry**
Allendale, Bamberg, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper, Orangeburg

Robert Glover
Office: (843) 412-7316
Email: gloverrl@dhec.sc.gov

- **Pee Dee**
Clarendon, Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter, Williamsburg

Connie Cooper
Office: (843) 250-0638
Email: cooperca@dhec.sc.gov

- **Midlands**
Aiken, Barnwell, Chester, Edgefield, Fairfield, Lancaster, Lexington, Kershaw, Newberry, Richland, Saluda, York

Marcus Lara
Office: (803) 576-2862
Email: larama@dhec.sc.gov

- **Upstate**
Abbeville, Anderson, Cherokee, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Spartanburg, Union

Tammy Lyons
Office: (864) 227-5979
Email: lyonstc@dhec.sc.gov

References

1. U.S. Centers for Disease Control and Prevention (2023 June 13). *Availability of STI Testing and Treatment Products*. <https://www.cdc.gov/std/treatment/drug-notice.htm>.
2. U.S. Food and Drug Administration (2023 July 7). *Current and Resolved Drug Shortages and Discontinuations Reported to FDA: Penicillin G Benzathine Injectable Suspension*. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillin%20G%20Benzathine%20Injectable%20Suspension&st=c&tab=tabs-1.
3. U.S. Centers for Disease Control and Prevention (2023 June 13). *2021 STI Treatment Guidelines: Syphilis*. <https://www.cdc.gov/std/treatment-guidelines/syphilis.htm>.

Categories of Health Alert messages:

Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service	Provides general information that is not necessarily considered to be of an emergent nature.