

## Q&A: Extencilline® Availability

- **Q: What is the purpose of the Food and Drug Administration's (FDA) announcement regarding Extencilline®?**
  - A: The [FDA](#) has announced the availability of Extencilline® as a temporary solution to address the ongoing shortages of Bicillin LA®. Extencilline® has been determined to be equivalent to Bicillin LA® and is currently authorized and marketed in other countries.
- **Q: How can health care providers obtain Extencilline®?**
  - A: Health care providers can place an order for Extencilline® by contacting Direct Success at [Distribution@dsuccess.com](mailto:Distribution@dsuccess.com) or [1-877-404-3338](tel:1-877-404-3338). For additional information, they can also reach out to Provepharm, the U.S. distribution partner, at [medicalaffairs@provepharm.com](mailto:medicalaffairs@provepharm.com) or [610-601-8600](tel:610-601-8600).
- **Q: Are there any differences in the preparation and administration of Extencilline® compared to Bicillin LA®?**
  - A: Yes, the preparation and administration of Extencilline®, as well as the contraindications for prescribing, differ from those for Bicillin LA®. Health care providers should refer to the [Dear Health Care Provider Letter](#) for specific instructions.
- **Q: Is Extencilline® available for purchase in the United States?**
  - A: Yes, Extencilline® is available by prescription in the United States. It can be purchased through Direct Success, the sole distributor of Extencilline®.
- **Q: What are the pricing and availability details for Extencilline®?**
  - A: Extencilline® will be available in two forms, 1.2 MIU and 2.4 MIU - 1 glass ampoule(s) of solvent of 5 ml. The wholesale acquisition cost (WAC) for the 1.2 MIU is \$250.00 per vial, and for the 2.4 MIU is \$500.00 per vial.
- **Q: Is there a minimum purchase requirement?**
  - A: There is a minimum purchase requirement of 5 vials for both product strengths.
- **Q: Is Extencilline® eligible for 340B?**
  - A: Extencilline® is not currently available at 340B pricing. We are awaiting further clarity on pricing information.
- **Q: Will this be reimbursed through Medicaid, Medicare, or private insurance?**
  - A: It is unclear which insurance plans would cover Extencilline®. We have received preliminary information that there will be a Federal Financial Participation (FFP) match on Extencilline® and that it will be covered under Medicaid under the "prescribed drugs" section. For the Arizona Health Care Cost

Containment System (AHCCCS) , the claim will have to be billed under HCPCS code J0561 Penicillin G Benzathine, 100,000 units.

- **Q: Does Extencilline® meet the definition of a CMS Covered Outpatient Drug?**
  - A: No, Extencilline® is not FDA approved therefore it does not meet the definition of a CMS Covered Outpatient Drug.
- **Q: What is the significance of obtaining FFP for Extencilline®?**
  - Although Extencilline® does not qualify for a federal rebate, AHCCCS can still obtain the Federal Financial Participation (FFP) match.
- **Q: Will states be able to collect the federal rebate for Extencilline®?**
  - Centers for Medicare & Medicaid Services (CMS) will provide a response at a later date regarding whether states will be able to collect the federal rebate for Extencilline® and if an exception will be made under the CMS Covered Outpatient Drug federal requirements.
- **Q: Where can health care providers find additional clinical guidance and support?**
  - A: Health care providers can refer to the [Centers for Disease Control and Prevention \(CDC\) STI Treatment Guidelines](#) for appropriate management of syphilis cases, including staging. They can also seek clinical decision-making support from the STD Clinical Consultation Network.
- **Q: Will there be any updates or changes regarding Extencilline® availability in the future?**
  - A: As the programmatic implications of this announcement are being resolved, updates may be provided. It is recommended to stay informed and refer to the July 2023 letter on priority actions during this time.
- **Q: How much supply is currently available?**
  - A: We do not know how much Extencilline® will be available at this time.
- **Q: When does the imported supply expire?**
  - A: The expiration date for the imported supply is 31 OCT 2025.
- **Q: What should health care providers do if they have additional questions or concerns?**
  - A: Health care providers can reach out to the relevant authorities for any pricing, distribution, availability, or clinical concerns. They can also contact Provepharm, the U.S. distribution partner, for additional information related to the Extencilline® product.

Try to link?:

[Clinical Reminders during Bicillin L-A® Shortage](#)  
[Instruction on how to prepare and administer Extencilline®](#)