



April 17, 2023

**RE: Makena® market withdrawal**

On April 6, 2023, the U.S. Food and Drug Administration (FDA) withdrew approval of Makena® (hydroxyprogesterone caproate injection) which was indicated to reduce the risk of preterm birth in women with a history of spontaneous preterm birth. The FDA's Obstetrics, Reproductive, and Urologic Drugs Advisory Committee concluded the treatment did not help reduce the risk of preterm birth in women with a history of spontaneous preterm birth. This decision was based on results of the required confirmatory trial, the PROLONG trial, which did not meet either co-primary endpoint of reducing preterm birth nor improving neonatal outcomes in women with a previous singleton spontaneous preterm birth. For further information, please visit the FDA's webpage on Makena®: <https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena>.

The American College of Obstetricians and Gynecologists (ACOG) issued a Practice Advisory regarding the prevention of recurrent preterm birth in April 2023, which aligns with the FDA withdrawal of Makena®. Additional details about the ACOG Practice Advisory can be found at: <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/04/updated-guidance-use-of-progesterone-supplementation-for-prevention-of-recurrent-preterm-birth>.

Effective April 10, 2023, SoonerCare ended coverage Makena® and compounded hydroxyprogesterone caproate injection based on FDA withdrawal. Our records indicate you are a provider or prescriber of hydroxyprogesterone caproate. While the Oklahoma Health Care Authority understands the need and desire to prevent preterm births, SoonerCare cannot cover medications which have been proven to be ineffective and are no longer FDA approved. There are currently no clinically proven medications indicated for reducing the risk of preterm births in women with a history of spontaneous preterm births.

Thank you for the services you provide to Oklahomans insured by  
SoonerCare!

---

**SOONERCARE PHARMACY SERVICES • PHARMACY MANAGEMENT CONSULTANTS**



**ADDRESS**

4345 N. Lincoln Blvd.  
Oklahoma City, OK 73105



**WEBSITES**

oklahoma.gov/ohca  
mysoonerca.org



**PHONE**

Admin: 405-522-7300  
Helpline: 800-987-7767