

****Pharmacy Provider Notice #300 –Makena Market Withdrawal****

April 10th, 2023

The U.S. Food and Drug Administration made the following announcement regarding the drug Makena on Thursday, April 6th, 2023:

“Today, the U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.”

In accordance with this decision, the Kentucky Department for Medicaid Services will no longer approve new requests for Makena or its generics. DMS will permit those currently taking the medication to continue therapy with prescriber approval and as supply permits.

Thank you for helping Kentucky Medicaid members maintain access to cost effective medications by selecting drugs on the preferred drug list whenever possible. For any additional information or questions that you may have, please contact Magellan Medicaid Administration at kyproviders@magellanhealth.com for Fee-for-Service members or the Kentucky MedImpact team at KYMCOPBM@medimpact.com for Managed Care Organization (MCO) members.

Sincerely,

ShaLeigh Hammons, CPhT

ShaLeigh Hammons, CPhTkym

Account Manager I

kyproviders@magellanhealth.com

FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena. Accessed April 7, 2023. <https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena#:~:text=Today%2C%20the%20U.S.%20Food%20and,history%20of%20spontaneous%20preterm%20birth.>

Kentucky Medicaid Fee-for-Service Pharmacy Program’s Contact Information

Clinical Support Center 1-800-477-3071

| Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information | | |
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| Pharmacy Support Center | 1-800-432-7005 Sunday – Saturday 24 hours a day | Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this Call Center. |
| Provider Services | 1-877-838-5085 Monday – Friday 8:00 a.m. – 4:30 p.m. | Please contact Provider Services if you have questions about enrollment or when updating your license or bank information. |
| Member Services | 1-800-635-2570 Monday – Friday 8:00 a.m. – 5:00 p.m. | Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates. |