AmeriHealth Caritas Next | FirstChoice Next — A Product of Select Health of South Carolina, Inc.

Provider Alerts

Important information for our Next providers.

To: **AmeriHealth Caritas Next and First Choice Next Providers**

Date: **April 20, 2023**

Subject: **FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena**

On April 6th, 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.

The FDA approved Makena under the accelerated approval pathway in 2011 based on a determination that the sponsor had demonstrated a drug effect on an intermediate clinical endpoint that was reasonably likely to predict clinical benefit. The agency's approval included a requirement that the sponsor conduct a post marketing confirmatory study. The ensuing confirmatory study did not verify clinical benefit and the FDA's Center for Drug Evaluation and Research (CDER) proposed withdrawing the drug's approval in 2020. The sponsor requested a hearing, which was held in October 2022.

Please see the link below for more details.
https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena