

Network Notification – Humana Healthy Horizons in Louisiana

Notice date: May 1, 2023

To: Humana Healthy Horizons® in Louisiana Provider Network

From: Humana Healthy Horizons in Louisiana

Subject: Coverage of Makena (17-Alpha Hydroxprogesterone Caproate) for Prevention of Preterm Birth

On April 28, 2023, the Louisiana Department of Health (LDH) released Information Bulletin 23-8 in which it provided information about its decision to end coverage for Makena and its generics.

This decision stems from a recent U.S. Food and Drug Administration (DFA) decision to withdraw its approval of Makena due to:

- Lack of evidence that it reduces the risk of recurrent spontaneous preterm birth, and
- Because the medication no longer is shown to be effective, and
- Because the benefits do not outweigh the risks for the indications for which the FDA previously granted its approval

The drug previously was approved under the accelerated approval pathway to reduce the risk of preterm birth in pregnant women who have a history of spontaneous preterm birth.

The FDA decision (on April 6, 2023) applies to brand name (Makena) and generic versions of this medication.

As such, also as of April 6, 2023, Makena and its generics are no longer approved, cannot lawfully be distributed in interstate commerce, and no longer are covered by Louisiana Medicaid.

Access LDH informational bulletins via its Provider & Plan Resources webpage.