United Healthcare Community Plan

Coverage of Makena (17-Alpha Hydroxyprogesterone Caproate) for Prevention of Pre-Term Birth

Effective immediately, the U.S. Food and Drug Administration (FDA) withdrew approval of Makena, due to lack of evidence that it reduces the risk of recurrent spontaneous preterm birth (PTB). This decision applies to both brand name and generic versions of the medication.

The drug had been approved under the accelerated approval pathway to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth.

Approvals of these drugs have been withdrawn because the drugs are no longer shown to be effective, and the benefits do not outweigh the risks for the indication for which they were approved. For additional information, see Makena Information on FDA.gov.

Effective April 6, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce, and they are no longer covered by Louisiana Medicaid.

LDH has published Informational Bulletin 23-08 for your reference - IB23-08.pdf (la.gov)Questions or concerns regarding this bulletin can be addressed by contacting United Healthcare Community Plan at 1-866-675-1607.