PROVIDER QUICK POINTS
PROVIDER INFORMATION

BlueCross BlueShield Minnesota

May 10, 2023

Drug Approval Withdrawn: Makena® (hydroxyprogesterone caproate)

Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) is advising providers that the U.S. Food and Drug Administration (FDA) has withdrawn its approval of Makena® and its generics (hydroxyprogesterone caproate). Expanded outcomes data shows Makena is not effective. It does not reduce the risk of preterm birth in women with a history of spontaneous preterm birth. Detailed information is available on the FDA's website: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information

Blue Cross sent letters to members who had recently filled either the branded or generic version of this drug through their pharmacy coverage, advising the member to talk with their health care provider if they have any questions about the drug.

List of Drug Names with FDA Approval Withdrawn
• Makena® (hydroxyprogesterone caproate) intramuscular (IM) in oil 250 mg/ml in a single-dose and multi-dose vials • hydroxyprogesterone caproate intramuscular (IM) in oil 250 mg/ml in single-dose and multi-dose vials • Makena® (hydroxyprogesterone caproate) solution auto-injector 275 mg/1.1ml • hydroxyprogesterone caproate solution auto-injector 275 mg/1.1 ml

Questions?
Please contact provider services at **(651) 662-5200** or **1-800-262-0820**.

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