

To: Keystone First/Keystone First Community HealthChoices (CHC) Providers

Date: May 18, 2023

Re: Removal of Makena (hydroxyprogesterone caproate injection)

On April 6, 2023, the US Food and Drug Administration (FDA) announced the final decision to withdraw approval of Makena (hydroxyprogesterone caproate injection) and its generics. The FDA cited that 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 (reduction in risk of preterm birth in certain pregnant women).

Initially, 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.

What this means for you:

- Makena and its generics cannot lawfully be distributed in interstate commerce
- This drug and its generics (CPT codes **J1726** and **J1729**) will no longer be covered by Keystone First or Keystone First Community HealthChoices (CHC) effective immediately
- Makena and its generics have been removed from formulary coverage on the Pennsylvania Statewide Preferred Drug List (PA PDL); see <https://papdl.com> for additional PDL information
- The drugs are in the process of being removed by Pennsylvania Department of Human Services (PA DHS) from prior authorization criteria in the associated Progestational Agents PA PDL drug class

Additionally, if you have prescribed Makena or its generics prior to this FDA decision, please discuss this change with your patients as soon as possible.

Information is also available via the Makena information page on FDA.gov:

<https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information>

If you have any additional questions regarding this notice, please contact Pharmacy Services:

Plan Name	Telephone Number
Keystone First	1-800-588-6767
Keystone First Community HealthChoices	1-866-907-7088