

FDA Decision to Withdraw FDA-Approval of Makena® & Generic Hydroxyprogesterone caproate Injectables

Purpose of this communication:

- Effective April 6, 2023, the U.S. Food and Drug Administration (FDA) announced the final decision to withdraw approval of Makena and its generics (hydroxyprogesterone caproate). These drugs were previously approved under the FDA accelerated approval pathway. The decision was issued jointly by the FDA Commissioner and Chief Scientist.

What do I need to know?

- While the FDA approval of Makena and its generics (hydroxyprogesterone caproate injectables) have been withdrawn, the FDA recognizes that there is a supply of hydroxyprogesterone caproate product that has already been distributed. Patients who have questions should talk to their healthcare provider. For additional information, see [Makena Information on FDA.gov](#).
- Reference the grid below for health plan specific information:

Health Plan	Information
Optima Health	<ul style="list-style-type: none">• Claims for HCPCS codes J1726 and J1729 with dates of service (DOS) on or after April 7, 2023 will be denied.
Horizon	<ul style="list-style-type: none">• No new service registrations will be issued for Start of Care (SOC) dates on or after April 7, 2023 unless it is a retro-request with an initial SOC date of April 6, 2023 or earlier.• Members on service on or after April 7, 2023 may remain on service as long as providers have adequate supply on hand and the ordering physician has approved continued care.• Refer to the Horizon website and the related compounding policy which currently states compounded drugs are eligible for approval if all components are FDA approved.

What do I need to do?

- Please review the following notice: https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena?utm_medium=email&utm_source=govdelivery
- Ensure patients on service are in contact with their ordering physician.
- If you have additional questions, reach out to your dedicated Provider Relations contact.

Thank you in advance for your cooperation and continued partnership.