

JUST THE FAX

www.molinahealthcare.com

July 13, 2023

Page 1 of 2

THIS CA UPDATE HAS BEEN SENT TO THE FOLLOWING: COUNTIES:

COUNTIES

- ☑ Imperial☑ Riverside/San Bernardino
- ☑ Los Angeles
- □ Orange
- Sacramento
- 🛛 San Diego

LINES OF BUSINESS:

- 🛛 Molina Medi-Cal
- Managed Care □ Molina Medicare
- Molina Medicare
 Molina Marketplace
 (Covered CA)

PROVIDER TYPES:

- Medical Group/ IPA/MSO
 Primary Care
- ⊠ IPA/MSO
- ⊠ Directs

Specialists

- ☑ Directs
- \boxtimes IPA
- ⊠ Hospitals
 - Ancillary
- □ CBAS □ SNF/LTC
- □ Home Health
- □ Other

RETIRED: Proper Use and Billing of Makena APL 15-009

This is an advisory notification to Molina Healthcare of California (MHC) network providers regarding the drug Makena and compounded versions of 17-hydroxyprogesterone caproate (the active ingredient in Makena).

This notification is based on retired All-Plan Letter (APL) 15-009, which can be found in full on the Department of Health Care Services (DHCS) website at: https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2015/APL15-009.pdf.

What you need to know:

The Food and Drug Administration (FDA) approved Makena under the accelerated approval pathway in 2011 based on a determination that its sponsor had demonstrated a drug effect on an intermediate clinical endpoint that was reasonably likely to predict clinical benefit. This drug was approved 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Approvals of these drugs have been withdrawn because the drugs are no longer shown to be effective, and the benefits do not outweigh the risks for the indication for which they were approved.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, please refer to the Makena FDA webpage at: <u>https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information.</u>

When this is happening:

Effective April 6, 2023, Makena and its generics are **no longer approved** and cannot lawfully be distributed in interstate commerce.

What if you need assistance?

If you have any questions regarding the notification, please contact your Molina Provider Services Representative below:

Service County Area	Provider Services Representative	Contact Number	Email Address
California Hospital Systems	Deletha Foster	909-577-4351	Deletha.Foster@molinahealthcare.com
Los Angeles	Clemente Arias	562-517-1014	Clemente.Arias@molinahealthcare.com
	Christian Diaz	562-549-3550	Christian.Diaz@molinahealthcare.com
Los Angeles / Orange County	Maria Guimoye	562-549-4390	Maria.Guimoye@molinahealthcare.com
Sacramento	Jennifer Rivera Carrasco	562-542-2250	Jennifer.RiveraCarrasco@molinahealthcare.com
San Bernardino	Luana McIver	909-501-3314	Luana.Mciver@molinahealthcare.com
San Bernardino / Riverside County	Vanessa Lomeli	909-577-4355	Vanessa.Lomeli2@molinahealthcare.com
Riverside County	Mimi Howard	562-549-3532	Smimi.Howard@molinahealthcare.com
San Diego / Imperial County	Briana Givens	562-549-4403	Briana.Givens@molinahealthcare.com
	Carlos Liciaga	858-614-1591	Carlos.Liciaga@molinahealthcare.com
	Salvador Perez	562-549-3825	Salvador.Perez@molinahealthcare.com