State of California—Health and Human Services Agency
Department of Health Care Services

JENNIFER KENT
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

DATE: April 16, 2015

ALL PLAN LETTER 15-009
(SUPERSEDES ALL PLAN LETTER 13-016)

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: PROPER USE AND BILLING FOR MAKENA

PURPOSE:
The purpose of this All Plan Letter (APL) is to remind all Medi-Cal managed care health plans (MCPs) that their contracted providers must comply with existing policy regarding the drug Makena and compounded versions of 17-hydroxyprogesterone caproate (the active ingredient in Makena). This APL supersedes APL 13-016.[1]

BACKGROUND:
17-hydroxyprogesterone caproate injection is a drug used to treat women at risk for recurrent preterm birth. While there are numerous risk factors for preterm birth, for a certain subset of women who have a history of singleton spontaneous preterm births (defined as delivery prior to 37 completed weeks of gestation) and who are currently pregnant with a singleton pregnancy, Makena is the only Food and Drug Administration (FDA)-approved drug available.

In a statement issued on June 15, 2012, the Centers for Medicare & Medicaid Services (CMS) reminded states "…of their responsibility to cover FDA-approved products, such as Makena, that qualify as covered outpatient drugs under the Medicaid drug rebate program." CMS also noted, "any prior authorization procedures for such drugs must be administered in accordance with Section 1927(d) of the Social Security Act."

The FDA has issued multiple concurrent statements regarding the compounding of 17-hydroxyprogesterone caproate[2] and advises that "approved drug products, such as Makena, provide a greater assurance of safety and effectiveness than do compounded

[1] All Plan Letters are available at: http://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx
[2] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310215.htm.
http://www.fda.gov/downloads/NewsEvents/Newsroom/PressAnnouncements/UCM3 14387.pdf
http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-2-06-15-12.pdf

products." In a Question and Answer statement, the FDA addressed the issue as follows:

> **"Should health care professionals prescribe and patients take the FDA-approved drug product rather than the compounded product?**
>
> If there is an FDA-approved drug that is medically appropriate for a patient, the FDA-approved product should be prescribed and used. Makena was approved based on an affirmative showing of safety and efficacy. The company also demonstrated the ability to manufacture a quality product. The pre-market review process included a review of the company's manufacturing information, such as the source of the Active Pharmaceutical Ingredient (API) used in the manufacturing of the drug, proposed manufacturing processes, and the firm's adherence to current good manufacturing practice.
>
> Compounded drugs do not undergo the same premarket review and thus lack an FDA finding of safety and efficacy and lack an FDA finding of manufacturing quality. Therefore, when an FDA-approved drug is commercially available, the FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient *as compared to the FDA-approved commercially* available drug product."

POLICY:
Since February 2013, the Department of Health Care Services (DHCS) has maintained a policy identifying Makena as the drug of choice for women who have a history of singleton spontaneous preterm births (defined as delivery prior to 37 completed weeks of gestation) and who are currently pregnant with a singleton pregnancy. The use of compounded alternative products must be reserved only for those instances in which the FDA-approved product, Makena, is inadvisable due to certain conditions, such as an allergy, intolerance to its inactive ingredients, or other clinically-based contraindications. Routine use of the compounded alternative not only establishes a valid risk to the health of the patient but also places DHCS at risk of actions taken by CMS and/or the FDA.

The FDA-approved Makena product is the only product billable with the Healthcare Common Procedure Coding System (HCPCS) code J1725 as published by DHCS in the Medi-Cal Provider Manual (preg early).[3] If a provider determines that the use of the compounded form is medically necessary, it must be billed using HCPCS code J3490 (unclassified drugs), and the claim must be submitted with all appropriate documentation, including an invoice, National Drug Code, and medical justification for

[3] The Provider Manual section is available here: http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/pregearly_m00o03.doc.

use of the compounded product including the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code V23.41 (pregnancy with history of preterm labor).

Additionally, MCPs are required to offer services in an amount no less than what is offered to beneficiaries under Medi-Cal fee-for-service (FFS).[4] While most provider-administered drugs are considered a medical benefit in Medi-Cal FFS, Makena is one of the few exceptions where Medi-Cal FFS makes the drug available as a pharmacy benefit as well as a medical benefit. Because of this, MCPs must allow for Makena to be billed directly to the MCP. MCPs must also allow the Makena administration fee to be billed as a medical benefit. These requirements do not specify the mechanism by which Makena is provided and delivered to the providers for administration. The method for pharmacy dispensing and prescription delivery to the provider office may be determined by the MCP, which may include but is not limited to establishing a pharmacy network that dispenses and delivers Makena directly to the prescribing provider's office. As long as the requirement allowing Makena to be billed directly to the MCP is met, MCPs may also include an option that allows the administering provider to procure the drug from a source other than the specialty pharmacy, billing the drug as a medical benefit. These scenarios, while not being an exact replica of the Makena benefits provided by Medi-Cal FFS, meet the requirement for comparability to those benefits.

The FDA Prescribing Information for Makena includes instructions for initiating Makena between 16 weeks, zero days and 20 weeks, six days of gestation and continuing through 36 weeks, six days gestation.[5] In order for Makena to be available for timely initiation, MCPs must have procedures in place that allow for Makena to be authorized prior to 16 weeks, zero days gestation, though the amount of time prior may vary depending on the MCP network's ability to make the treatment available to the patient at 16 weeks, zero days gestation.

If you have any questions regarding this APL, please contact Anna Lee Amarnath, Medical Consultant II, Medical Quality and Oversight Section at (916) 449-5141 or AnnaLee.Amarnath@dhcs.ca.gov.

Sincerely,

Original Signed by Sarah C. Brooks

Sarah Brooks, Chief
Managed Care Quality and Monitoring Division
Department of Health Care Services

[4] Select the appropriate boilerplate contract at http://www.dhcs.ca.gov/provgovpart/Pages/MMCDBoilerplateContracts.aspx and see Exhibit A, Attachment 10, Section 1A and Section 8G.
[5] See http://www.makena.com/pdf/makena_pi.pdf