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

TOBY DOUGLAS
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

DATE: November 14, 2013

ALL PLAN LETTER 13-016

TO: ALL MEDI-CAL MANAGED CARE PLANS

SUBJECT: PROPER USE OF 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), as published by the Department of Health Care Services (DHCS) in the Medi-Cal Provider Manual (preg early).[1]

Specifically, the manual instructs providers to use the Healthcare Common Procedure Coding System (HCPCS) code J1725 for billing of 17-hydroxyprogesterone caproate injections; however, HCPCS code J1725 **is not** to be used for the billing of compounded 17-hydroxyprogesterone caproate. If a provider determines that 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 (NDC), and medical justification for 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).

DHCS has learned that some MCPs routinely use the compounded form of 17-hydroxyprogesterone caproate and reserve the Food and Drug Administration (FDA) approved formulation (Makena) for instances in which the compounded formulation is proven to not be effective or indicated. This is directly contrary to DHCS's requirement to use the FDA-approved product unless medical necessity for the compounded version is established.

To ensure that all Medi-Cal beneficiaries receive the equivalent benefit, and to ensure the safety and efficacy of treatments provided to all Medi-Cal beneficiaries, DHCS is

[1] Select "Provider Manuals" at http://www.medi-cal.ca.gov/. Then select "Obstetrics," and click on the ZIP button next to "Pregnancy Early." Open the file that is inside the ZIP folder.

issuing this APL to instruct all MCPs to adhere to the DHCS policy for the provision of 17-hydroxyprogesterone caproate.

BACKGROUND:
In a statement issued 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 and advised that "approved drug products, such as Makena, provide a greater assurance of safety and effectiveness than do compounded 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?***
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> *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.*

In order to comply with these directives from both CMS and the FDA, DHCS developed a policy for 17-hydroxyprogesterone caproate, establishing the FDA-approved Makena product as the only product billable with the HCPCS code J1725. If the compounded alternative is to be dispensed, providers are required to use HCPCS Code J3490 and to provide medical justification establishing its clinical necessity.

17-hydroxyprogesterone caproate injection is a drug used to treat women at risk for recurrent preterm birth. Many of these women are Medi-Cal beneficiaries, a majority of

whom are now covered by MCPs. While there are numerous risk factors for preterm birth, for a certain subset of women who have a history of singleton spontaneous preterm birth (defined as delivery prior to 37 completed weeks of gestation) and who are currently pregnant with a singleton pregnancy, Makena is the only FDA-approved drug available.

Since February of 2013, DHCS has maintained a 17-hydroxyprogesterone caproate coverage policy identifying Makena as the drug of choice and requiring its use in the above diagnosis unless proven to be contraindicated in a particular instance. The use of compounded alternative products must be reserved to only those instances in which the Makena product is contraindicated. 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 announcements and informational bulletins from CMS and FDA regarding the use of Makena and compounded alternatives are available on the following webpages:

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310215.htm.

http://www.fda.gov/downloads/NewsEvents/Newsroom/PressAnnouncements/UCM314387.pdf

http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-2-06-15-12.pdf

If you have any questions regarding this APL, please contact Dr. Sarah Royce, Chief, Medical Policy Section, at (916) 650-0113 or Sarah.Royce@dhcs.ca.gov.

Sincerely,

Original Signed by Margaret Tatar

Margaret Tatar, Assistant Deputy Director
Health Care Delivery Systems