



<b>ISSUE DATE</b>  June 21, 2011	<b>EFFECTIVE DATE</b>  July 18, 2011	<b>NUMBER</b> *See Below
<b>SUBJECT</b>  Prior Authorization of Makena – Pharmacy Services		<b>BY</b>   Izanne Leonard-Haak, Acting Deputy Secretary Office of Medical Assistance Programs

**PURPOSE:**

The purpose of this bulletin is to inform providers that the Department of Public Welfare (Department):

1. Will continue to make payment for compounded hydroxyprogesterone caproate.
2. Will require prior authorization of prescriptions for Makena.
3. Is issuing new handbook pages that include instructions on how to request prior authorization of Makena.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

**BACKGROUND:**

On February 3, 2011, the U.S. Food and Drug Administration (FDA) approved the drug Makena (hydroxyprogesterone caproate) for the reduction of the risk of certain preterm births in women who had at least one prior preterm birth. Prior to the FDA approval of Makena, the Department provided coverage of compounded hydroxyprogesterone caproate for such high-risk women.

On March 30, 2011, the FDA announced that it does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid

*01-11-11	09-11-12	27-11-09
02-11-06	11-11-06	30-11-06
03-11-07	14-11-07	31-11-12
08-11-13	24-11-10	32-11-06

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at [www.dpw.state.pa.us/PartnersProviders](http://www.dpw.state.pa.us/PartnersProviders)

prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products. To view the FDA news release, please see

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm>

On that same date, March 30, 2011, the Centers for Medicare and Medicaid Services (CMS) issued guidance to all States stating that in light of the FDA news release concerning the status of compounded hydroxyprogesterone caproate, States can choose to pay for the extemporaneously compounded hydroxyprogesterone caproate. On April 28, 2011, The American College of Obstetricians and Gynecologists (ACOG) and Society for Maternal-Fetal Medicine (SMFM) posted a statement on the ACOG website supporting the use of the compounded version of the drug as a safe and cost effective therapy in reducing the risk of certain preterm births in women who have had at least one prior preterm birth. To view the ACOG statement, please see [http://www.acog.org/from\\_home/misc/20110428MakenaLtr.pdf](http://www.acog.org/from_home/misc/20110428MakenaLtr.pdf)

### **DISCUSSION:**

Based upon the FDA news release, the CMS guidance, and the ACOG statement that there is no evidence that Makena is more effective or safer than the compounded hydroxyprogesterone caproate, the Department will continue making payment for the compounded hydroxyprogesterone caproate and require prior authorization of Makena. The guideline to prior authorize Makena is that the prescribing provider cannot locate a pharmacy that is willing to compound hydroxyprogesterone caproate. Before prior authorizing Makena, the Department's pharmacy staff will assist the prescribing provider in attempting to locate a pharmacy willing to compound hydroxyprogesterone caproate.

The requirement for prior authorization and the guideline to prior authorize Makena are undergoing a public review and comment period. If the Department receives comments that warrant modification to the current prior authorization guidelines, the Department will modify those guidelines and re-issue the handbook pages.

### **PROCEDURE:**

The procedures for prescribers to request prior authorization of all prescriptions for Makena are located In SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the prior authorization guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Makena) in reviewing the prior authorization request.

NOTE: Emergency supply does not apply to Makena.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:** [Prior Authorization of Pharmaceutical Services Handbook - Updated pages](#)

SECTION II  
Makena