

February 3, 2015
MB# 15-004

MEDICAID BULLETIN

Phys
Pharm
Hosp
MC

TO: Providers Indicated

SUBJECT: Coverage of Hydroxyprogesterone Injection

On December 20, 2013, the South Carolina Department of Health and Human Services (SCDHHS) issued Medicaid Bulletin 13-047 regarding hydroxyprogesterone caproate. On July 3, 2014, the Food and Drug Administration issued updated guidance in regards to hydroxyprogesterone caproate. In the new guidance, the FDA provided that its March 2011 statement related to hydroxyprogesterone caproate was superseded by its June 2012 statements in which the FDA “recommended using an FDA-approved drug product, such as Makena, instead of a compounded drug except when there is a specific medical need (e.g. an allergy) that cannot be met by the approved drug.” In addition, the FDA stated that it “is not aware of any scientifically reliable evidence demonstrating that compounding 17P without a preservative or in an oil base different than the one used in Makena produces a significant difference for an identifiable group of patients”. The FDA’s updated guidance is available at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm402614.htm>

Procedures for Coverage by Fee-For-Service

SCDHHS will continue to reimburse for both Makena[®] and compounded hydroxyprogesterone caproate without prior authorization. Although the physician may choose which treatment he or she prefers, if a physician requests compounded hydroxyprogesterone caproate, but it is unavailable, coverage will be provided for Makena[®] instead. SCDHHS and its Medicaid Managed Care Organizations (MCOs) will provide reimbursement directly to pharmacy providers for these products ordered by a prescriber. SCDHHS and its MCOs will also directly reimburse physicians for these products when purchased and administered through the “buy and bill” process. For information on reimbursement, coding and rates, see www.scdhhs.gov. Coverage is allowed only for women with a singleton pregnancy with a history of singleton spontaneous preterm birth. Coverage is available from 16 through 36 weeks gestation if treatment begins between 16 and 20 weeks gestation. Other risk factors for preterm delivery do not qualify for coverage by SCDHHS. While prior authorization is not

required, prescribers must maintain documentation in each patient's medical record for review by SCDHHS. This bulletin applies to services provided to beneficiaries who are enrolled in fee-for-service Medicaid. Claims for participants enrolled in the fee-for-service program should be billed directly to Medicaid. If you have any questions regarding this policy, please contact the Provider Service Center at (888) 289-0709.

Procedures for Coverage by an MCO

MCOs will also reimburse for both Makena[®] and compounded hydroxyprogesterone caproate. Physicians should indicate the requested product in the space provided on the Universal 17-P Authorization form. This form can be found on the SCDHHS website located at the following link https://msp.scdhhs.gov/managedcare/sites/default/files/Universal%2017_P_0.pdf. Although the physician may choose which treatment he or she prefers, if the physician requests compounded hydroxyprogesterone caproate, but it is unavailable, coverage will be provided for Makena[®] instead. MCOs will reimburse directly to pharmacy providers for these products ordered by a prescriber and directly reimburse physicians for these products when purchased and administered through a "buy and bill" process. Coverage is allowed only for women with a singleton pregnancy with a history of singleton spontaneous preterm birth. Coverage is available from 16 through 36 weeks gestation if treatment begins between 16 and 20 weeks gestation. Other risk factors for preterm delivery do not qualify for coverage by SCDHHS. If you have any questions regarding coverage by your MCO or the processing of requests for Makena[®] or compounded hydroxyprogesterone caproate, please contact the person indicated at the numbers below.

Absolute Total Care

1441 Main Street, 9th Floor
Columbia, SC 29201
Phone: (866) 433-6041

Advicare of South Carolina

531 South Main Street, Suite RL-1
Greenville, South Carolina 29601
Phone: 1-888-781-4371

BlueChoice Healthplan Medicaid SC

PO Box 6170
Mail Code AX-400
Columbia, SC 29260
Phone: (866) 902-1689

First Choice by Select Health

4390 Belle Oak Drive, Suite 400
North Charleston, SC 29405
Phone: (866) 610-2773

Molina Healthcare of South Carolina

4105 Faber Place Drive, Suite 120
North Charleston, SC 29405
Phone: (855) 237-6178

WellCare of South Carolina

200 Center Point, Ste. 180
Columbia, SC 29210
Phone: (888) 588-9842

Thank you for your continued support of the South Carolina Healthy Connections Medicaid Program.

/s/
Christian L. Soura
Interim Director