

South Carolina
DEPARTMENT OF HEALTH AND HUMAN SERVICES
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May 18, 2011

Phys Hosp.
MC Pharm

MEDICAID BULLETIN

TO: Providers Indicated

SUBJECT: 17 Alpha Hydroxyprogesterone Caproate

In February 2011, the Food and Drug Administration (FDA) issued approval for Makena™, a commercially produced 17-alpha hydroxyprogesterone caproate (17-P) product. The FDA issued guidance on March 30, stating that “it does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compound products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products.” The South Carolina Board of Pharmacy has indicated a similar position.

The South Carolina Department of Health and Human Services (SCDHHS) will continue to reimburse providers for the use of compounded 17-P that is compounded in a manner consistent with the FDA’s recommendation. Reimbursement for the compounded product will be paid at the rate of \$20 per unit (250mg injection). Providers should continue to bill using the Healthcare Common Procedure Coding System (HCPCS) code J3490 (unclassified drug) with the TH modifier. Coverage is available beginning at 16 weeks gestation, continuing through 36 weeks for patients with a history of a prior preterm delivery. Other risk factors for preterm delivery do not qualify for reimbursement by SCDHHS.

Prior authorization will not be required for compounded 17-P, but providers are required to maintain documentation in each patient’s medical record for potential review from the agency’s Program Integrity Division. However, SCDHHS will require prior authorization for any prescription for Makena™, and the physicians must provide clinical justification and medical necessity documentation.

If you have any questions regarding this bulletin, please contact your Program Manager at (803) 898-2660. Thank you for your continued support and participation in the South Carolina Medicaid Program.

/S/
Anthony E. Keck
Director

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