

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Giese</i>	DATE  <i>5-3-12</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER  <i>100426</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR  <i>cc: Mr. Scott Singleton, cleared 5/15/12, letter attached.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>5-15-12</i> DATE DUE _____ <input type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

**From:** judy russell <jrussell29154@yahoo.com>  
**To:** "Keck@scdhhs.gov" <Keck@scdhhs.gov>

**CC:** "Polattyj@scdhhs.gov" <Polattyj@scdhhs.gov>, "mburton@aap.net" <mburton@...

**Date:** 5/2/2012 1:40 PM

**Subject:** Makena

*Ben, pls ltr to be  
for response*

*JMR Jan  
5/3*

We would like to have access to Makena in the state of South Carolina similar to the way other states are covering Makena. If you can come to terms with the company, we would be in favor of it being added to South Carolina "Preferred Drug List."

Issues of concern are:

Availability of an FDA approved product and standardized therapy.

Active pharmaceutical ingredient for compounding is of Chinese origin and is questionable.

Access for all eligible patients including the uninsured, would be covered at no cost to the state.

Thank you for your attention in this matter.

The Physicians of Sumter OB-GYN (Thomas W. Hepfer, MD; Helen D. Latham, MD; Triz V. Smith, MD; Murrell Smith, MD; Cecil Collins, MD; Samuel M. Riddle, MD; John J. Britton, MD.

Judy Russell  
Practice Manager  
Sumter OB-GYN

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2. DATE SIGNED BY DIRECTOR <i>cc: Mr. Tyeet, Singleton,</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>5-15-12</i>
	<input type="checkbox"/> FOIA DATE DUE _____
	<input type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1. <i>JR Davis</i>	<i>✓ 5/9</i>		
2.			
3.			
4.			

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Judy Russell  
Practice Manager  
Sumter OB-GYN

May 15, 2012

Ms. Judy Russell  
Sumter OB-GYN  
115 North Sumter Street  
Suite 200  
Sumter, South Carolina 29150

Dear Ms. Russell:

Thank you for your letter regarding South Carolina Medicaid providing access to the drug, Makena®. We welcome the opportunity to be of assistance.

The South Carolina Department of Health and Human Services (SCDHHS) currently covers both 17 Alpha Hydroxyprogesterone Caproate (17-P) and Makena® which have the same clinical indications. The reimbursement rate per 250mg injection for compounded 17-P is \$20.00 per unit, while Makena® is approximately 25 times more expensive at \$248.08 per unit after rebates. A bulletin was issued on May 18, 2012 outlining the policy and procedures for both products. For your convenience we have included a link, <http://www2.scdhhs.gov/press-release/may-2011-bulletin-archive>. This bulletin implemented a prior authorization process for the Makena® product which requires clinical justification and documentation of medical necessity.

The SCDHHS has not been provided any official documentation that compounded 17-P is unsafe or clinically less effective than Makena®. We recognize that the FDA is conducting reviews of its hydroxyprogesterone caproate polices and may revise their guidance. However, absent of any official notification addressing compounded 17-P as unsafe or inferior to Makena®, SCDHHS will continue offering both forms of the medication to assure the best health outcomes for our beneficiaries.

We greatly appreciate your continued support of the South Carolina Medicaid program, as we all strive to provide the best healthcare to the citizens of the State. If you have any questions or concerns please contact Mr. William Feagin, Division Director, Office of Physicians, Pharmacy and Enhanced Care Services at 803-898-3079.

Sincerely,



Melanie "BZ" Giese, RN  
Deputy Director

MG/m