

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Giese</i>	DATE <i>5-1-12</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>1011422</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>cc: Mr. Teet, Singleton</i> <i>Classed 5/15/12, letter attached.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>5-14-12</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: Jan Polatty
To: Brenda James; Melanie Giese
CC: Annmarie McCanne; Anthony Keck; mburton@aap.net
Date: 5/1/2012 1:09 PM
Subject: Re: Makena (Bren, pls log)

Bren, As we did with other Makena letters, please log to Bz for response. Thanks, Jan.

>>> Dorothy Arnold <dorothyarnold@live.com> 5/1/2012 11:10 AM >>>

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 of chinese origin is questionable

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

Sincerely,

Susan Keeshan MD MI Mostafa MD Orson Ravenell MD Ronni Daniels NP Jill Slice NP

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR**

ACTION REFERRAL

TO <i>Giese</i>	DATE <i>5-1-12</i>
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DIRECTOR'S USE ONLY		ACTION REQUESTED	
1. LOG NUMBER <i>100422</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>5-14-12</i>	
2. DATE SIGNED BY DIRECTOR <i>cc: Mr. Teet, Singleton</i>	<input type="checkbox"/> FOIA DATE DUE _____	<input type="checkbox"/> Necessary Action	

APPROVALS <small>(Only when prepared for director's signature)</small>	APPROVE	* DISAPPROVE <small>(Note reason for disapproval and return to preparer.)</small>	COMMENT
1. <i>[Signature]</i>	<i>✓ 5/19</i>		
2.			
3.			
4.			

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Sincerely,

Susan Keeshan MD/MI Mostafa MD/Orson Ravenell MD/Ronni Daniels NP/Jill Slice NP

May 15, 2012

Susan Keeshan, MD
MI Mostafa, MD
Orson Ravenell, MD
Ronni Daniels, NP
Jill Slice, NP
Greater Columbia OB-GYN
1301 Taylor Street, Suite 3-L
Columbia, South Carolina 29201

Dear Providers:

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-archiv>. 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