

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Giese</i>	DATE <i>7-20-12</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>100032</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>CC: Mr. Keck, Singleton, Kest, Roberts, Dr. Burton</i> <i>cleared 8/2/12, letter attached.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>7-31-12</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.			
2.			
3.			
4.			

## Brenda James

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**From:** Valeria Williams  
**Sent:** Friday, July 20, 2012 11:07 AM  
**To:** Brenda James  
**Cc:** Melanie Giese  
**Subject:** FW: Makena

**RECEIVED**

JUL 20 2012

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

Please log this email for response. Val

---

**From:** Correll, Lisa B. [<mailto:LBCorrell@magellanhealth.com>]  
**Sent:** Friday, July 20, 2012 9:53 AM  
**To:** Marion Burton; James Assey; Valeria Williams  
**Cc:** Roberts, Mary  
**Subject:** RE: Makena

Good Morning Dr. Burton,

Conferred with Janet Giles regarding any letter for Makena. Apparently, this is the first "issue" (documented).

There will have to be a letter drafted by the State to respond to this Physician, in the interim a PA (Physician side) can be used to procure the medication to assist the Physicians patients.

Thank you,

Lisa

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**From:** Marion Burton [<mailto:Marion.Burton@uscmed.sc.edu>]  
**Sent:** Thursday, July 19, 2012 6:21 PM  
**To:** James Assey; Correll, Lisa B.; Valeria Williams  
**Subject:** Fwd: Makena

Do we have a copy of the letter we have sent to prior inquirers?

Sent from my iPhone

Begin forwarded message:

**From:** Anthony Keck <[KECK@scdhhs.gov](mailto:KECK@scdhhs.gov)>  
**Date:** July 18, 2012 1:27:06 PM EDT  
**To:** Marion Burton <[Marion.Burton@uscmed.sc.edu](mailto:Marion.Burton@uscmed.sc.edu)>  
**Cc:** Byron Roberts <[Robertsb@scdhhs.gov](mailto:Robertsb@scdhhs.gov)>, Deirdra Singleton <[Singled@scdhhs.gov](mailto:Singled@scdhhs.gov)>  
**Subject:** Fw: Makena

Please respond with our standard letter emphasizing it is available through pa. Please have legal look at it before though to make sure there are no problems aka our pending lawsuit

---

**From:** Sharon Eden  
**Sent:** Wednesday, July 18, 2012 1:24:05 PM  
**To:** Anthony Keck  
**Cc:** Greta Harper; [Polatty@scdhhs.gov](mailto:Polatty@scdhhs.gov); [mburton@aap.net](mailto:mburton@aap.net); Patty Kline  
**Subject:** Makena

Dear Director Keck:

As a obstetrician/gynecologist in the state of South Carolina, I am requesting the approval of Makena branded product for use of preterm labor prophylaxis. You should be well aware of the statistics regarding preterm births and associated morbidity and mortality. Our state has been fighting this battle for many decades. Discovery of using hydroxyprogesterone caproate beginning in the sixteenth week of gestation has significantly improved the outcomes for these high risk pregnancies.

Makena is currently the only branded product for this situation. Compounded hydroxyprogesterone is NOT an acceptable substitute. Compounded products cannot provide the same accuracy, safety or efficacy. The US FDA has issued statements to this effect. Makena would provide approved and standardized therapy for our patients. Not all "generic" products are considered safe nor efficacious. The benefits/costs of using Makena would far outweigh the ultimate risks.

Let us keep striving to improve health care in South Carolina, not backslide!

Sincerely,

*Sharon I Eden, MD FACOG  
PH-Women Physicians Associates OB/GYN  
9 Medical Park, Suite 620  
Columbia, SC 29203  
(803) 779-6776--Office  
(803)779-7346--Fax*

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APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1. <i>Valerie Williams</i>	<i>7-28-12</i>		
2. <i>Don O'R</i>	<i>7/31/12</i>		
3.			
4.			

**Brenda James**

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9 Medical Park, Suite 620  
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August 2, 2012

Sharon I Eden, MD FACOG  
PH-Women Physicians Associates OB/GYN  
9 Medical Park, Suite 620  
Columbia, South Carolina 29203

Dear Dr. Eden:

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. A bulletin was issued on May 18, 2011 outlining the policy and procedures for both products. For your convenience we have included the link, <http://www.scdhhs.gov/Internet/pdf/17AlphaHydroxyprogesteroneCaproate.pdf>. This bulletin implemented a prior authorization process for the Makena® product which requires clinical justification and documentation of medical necessity.

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 Policy Administration at (803)-898-3079.

Sincerely,

Melanie "BZ" Giese, RN  
Deputy Director

MG/rw