

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

ACTION REFERRAL

TO <i>Myers</i>	DATE <i>8-29-08</i>
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DIRECTOR'S USE ONLY		ACTION REQUESTED	
1. LOG NUMBER <i>100126</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>9-10-08</i> <input type="checkbox"/> FOIA DATE DUE _____ <input type="checkbox"/> Necessary Action		
2. DATE SIGNED BY DIRECTOR <i>cc: Ms. Farkner, Dr. Burton Cleared 8/29/08, letters attached.</i>			

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>Dr. Beutman, Dr. Daniel Brown, Dr. Givum, Dr. David Brown, & Dr. Vella-Daniel</i>		
2.			
3.			
4.			



State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Emma Portner
Director

August 29, 2008

C. Michael Bowman, MD
MUSC Children's Hospital
Pediatric Pulmonology, Allergy and Immunology
135 Rutledge Avenue, Suite 279
PO Box 250291
Charleston, SC 29425

Re: Palivizumab [Synagis] prophylaxis for pulmonary patients

Dear Dr. Bowman.:

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Thank you again for this timely and thoughtful correspondence.

Sincerely,

A handwritten signature in dark ink, appearing to read "Marion Burton". The signature is fluid and cursive, with the first name "Marion" and the last name "Burton" clearly distinguishable.

O. Marion Burton, MD
Medical Director

OMB/mk



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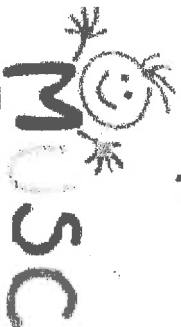
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O. Marion Burton, MD
Medical Director

OMB/mk



Children's Hospital

Pediatric Pulmonology,
Allergy and Immunology

135 Rutledge Avenue

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PO Box 250291

Charleston, SC 29425

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C. Michael Bowman PhD, MD

Division Director

Patrick A. Flume, MD
Director, CF Center

Isabel Vreila-Léwell, MD
Director, Pediatric CF Center

Cheryl E. Kerrigan, MSN, RN, CPNP
Pediatric Nurse Practitioner
Pulmonary Nurse Specialist

Laura Carsti, MSN, RN, CPNP
Pediatric Nurse Practitioner
Pulmonary Nurse Specialist

Jessica Donahue, RN
Pediatric CF Center Coordinator



Aimee Tiller, RN
Asthma Nurse Educator

July 2, 2008

Dr. O. Marion Burton
Medical Director
PO Box 8206
Columbia, SC 29202-8206


Dear Dr. Burton,

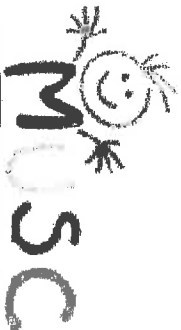
We feel strongly that our state needs a consensus statement regarding which pulmonology patients should be considered for Synagis prophylaxis. While the guidelines for premature infants are well detailed, these for children with "chronic lung disease" are less specific. We have decided to work together to better define which disorders should be included in the chronic lung disease category and receive RSV prophylaxis. The American Academy of Pediatrics (AAP) guidelines state clearly (Redbook 2006) that infants with "chronic lung disease" should receive synagis.

We are enclosing an article that is titled, "Chronic lung disease after premature birth," (New England Journal of Medicine 2007; 357: 1946-55)  which details the differences in "old" and "new" bronchopulmonary dysplasia and defines chronic lung disease as any pulmonary disease resulting from a neonatal respiratory disorder. We believe that children meeting the criteria for BPD should receive RSV prophylaxis. Other patients that we support receiving Synagis include those with any of the disorders listed in Table 1 of the attached article: infants with cystic fibrosis, chronic pneumonitis of infancy, interstitial lung disease, as well as those infants requiring tracheostomy or who are ventilator dependent. 

In addition to lung disease that presents in the neonatal period, there are conditions/situations that arise in the first year of life that put young children at greater risk of having severe complications with RSV infection. These include ECMO (any length), conventional ventilator (>1 week), tracheostomy, and a dependence on systemic steroids for a chronic pulmonary condition.

There are also multiple other diagnoses in the realm of the neuromuscular and immunodeficient categories that should qualify a child for Synagis as they are unable to clear secretions effectively and demonstrate resultant respiratory insufficiency. 

We ask that you give appropriate consideration to allowing the above patient populations to receive Synagis prophylaxis if they are less than 2 years of age at season onset, and for the entire duration of that season. We also request that any child recommended for synagis by pediatric pulmonologists in the state be automatically approved. In exchange, we would be happy to review any questionable request for synagis for children we do not normally follow in our clinics. We understand that the cost of Synagis continues to be problematic. We would however like to prevent the long-term sequelae from 



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Pediatric CF Center Coordinator

Aimee Tiller, RN
Asthma Nurse Educator

an RSV infection in our already-compromised patients. Prevention is, by far, less costly, than hospitalizations and long term therapy. We appreciate your time and consideration to this matter.

Sincerely,

Jane V. Gwin, MD (Children's Respiratory Center, Greenville)
Board Certified, Pediatric Pulmonology

David Frey Brown, MD (USC Division of Pediatric Pulmonology)
Board Certified, Pediatric Pulmonology

Daniel C. Brown, MD (USC Division of Pediatric Pulmonology)
Board Certified, Pediatric Pulmonology

C. Michael Bowman, MD (MUSC Division of Pediatric Pulmonology)
Board Certified, Pediatric Pulmonology

Isabel Virella-Lowell, MD (MUSC Division of Pediatric Pulmonology)
Board Certified, Pediatric Pulmonology

From: Marion Burton <Marion.Burton@uscmed.sc.edu>
To: Margarete Keller <Keller@scdhhs.gov>
Date: 8/29/2008 12:04 PM
Subject: addresses Gwinn, Brown and Brown

Marga, for info.

58 BEAR DR
GREENVILLE, SC 29605-4458

Name: JANE VANCE GWINN

Profession:
MD<javascript:spec2_window%20=%20window.open('med_profession.aspx','%20'spec2_window','%20'width=500,%20height=400,%20left=15,%20top=15,%20scrollbars=yes');spec2_window.focus()>

Office Phone: (864) 220-8000

Basis: NB
82<javascript:spec2_window%20=%20window.open('med_basis.aspx','%20'spec2_window','%20'width=700,%20height=400,%20left=15,%20top=15,%20scrollbars=yes');spec2_window.focus()>

School:
SC<javascript:spec2_window%20=%20window.open('med_schools.htm','%20'spec2_window','%20'width=700,%20height=400,%20left=15,%20top=15,%20scrollbars=yes');spec2_window.focus()>

Graduation: 01/01/1981

License No: 11118

Date Issued: 08/30/1982

Expiration: 09/30/2009

Specialty: PDP* PD*
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Trey Brown
University Pediatrics
9 Medical Park Ste. 200A
Columbia, SC 29203

Name: David Eugene Brown III

Profession:
MD<javascript:spec2_window%20=%20window.open('med_profession.aspx','%20'spec2_window','%20'width=500,%20height=400,%20left=15,%20top=15,%20scrollbars=yes');spec2_window.focus()>

Office Phone: 803-434-7950

Basis: US

00<javascript:spec2_window%20=%20window.open('med_basis.aspx','%20'spec2_window','%20'width=700,%20height=400,%20left=15,%20top=15,%20scrollbars=yes');spec2_window.focus()

School:

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Graduation: 05/05/2000

License No: 22532

Date Issued: 08/20/2001

Expiration: 09/30/2009

Specialty: PD

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Primary Source Verification of Graduation Certified

Hospital Affiliation (s):

PALMETTO HEALTH RICHLAND
MCLEOD REGIONAL MEDICAL CTR OF THE PEE DEE

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Sincerely,

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O. Marion Burton, MD
Medical Director

OMB/mk



State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Emma Fortner
Director

August 29, 2008

David 'Trey' Brown, MD
University Pediatrics
9 Medical Park Ste. 200A
Columbia, SC 29203

Re: Palivizumab [Synagis] prophylaxis for pulmonary patients

Dear Dr. Brown.:

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O. Marion Burton, MD
Medical Director

OMB/mk



State of South Carolina
Department of Health and Human Services

Mark Sanford
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Emma Forkner
Director

August 29, 2008

Isabel Virella-Lowell, MD
MUSC Children's Hospital
Pediatric Pulmonology, Allergy and Immunology
135 Rutledge Avenue, Suite 279
PO Box 250291
Charleston, SC 29425

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

Don
PHD

ACTION REFERRAL

TO <i>Myers</i>	DATE <i>8-29-08</i>
--------------------	------------------------

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>100126</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>cc: Ms. Forlmer, Dr. Burton</i> <i>Cleared 8/29/08, letter</i> <i>attached.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>9-10-08</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.			



Children's Hospital

Pediatric Pulmonology,
Allergy and Immunology

135 Rutledge Avenue

Suite 279

PO Box 250291

Charleston, SC 29425

Phone (843) 792-8157

Fax (843) 792-5011

C. Michael Bowman PhD, MD

Division Director

Patrick A Flume, MD

Director, CF Center

Isabel Virella-Lowell, MD
Director, Pediatric CF Center

Cheryl E. Kerrigan, MSN, RN, CPNP

Pediatric Nurse Practitioner

Pulmonary Nurse Specialist

Laura Caristi, MSN, RN, CPNP

Pediatric Nurse Practitioner

Pulmonary Nurse Specialist

Jessica Donahue, RN

Pediatric CF Center Coordinator

Aimee Tiller, RN

Assistant Nurse Educator

July 2, 2008

Dr. O. Marion Burton

Medical Director

PO Box 8206

Columbia, SC 29202-8206

Dear Dr. Burton,

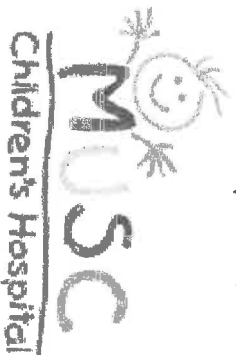
We feel strongly that our state needs a consensus statement regarding which pulmonology patients should be considered for Synagis prophylaxis. While the guidelines for premature infants are well detailed, those for children with "chronic lung disease" are less specific. We have decided to work together to better define which disorders should be included in the chronic lung disease category and receive RSV prophylaxis. The American Academy of Pediatrics (AAP) guidelines state clearly (Redbook 2006) that infants with "chronic lung disease" should receive synagis.

We are enclosing an article that is titled, "Chronic lung disease after premature birth," (New England Journal of Medicine 2007; 357: 1946-55) which details the differences in "old" and "new" bronchopulmonary dysplasia and defines chronic lung disease as any pulmonary disease resulting from a neonatal respiratory disorder. We believe that children meeting the criteria for BPD should receive RSV prophylaxis. Other patients that we support receiving Synagis include those with any of the disorders listed in Table 1 of the attached article: infants with cystic fibrosis, chronic pneumonitis of infancy, interstitial lung disease, as well as those infants requiring tracheostomy or who are ventilator dependent.

In addition to lung disease that presents in the neonatal period, there are conditions/situations that arise in the first year of life that put young children at greater risk of having severe complications with RSV infection. These include ECMO (any length), conventional ventilator (>1 week), tracheostomy, and a dependence on systemic steroids for a chronic pulmonary condition.

There are also multiple other diagnoses in the realm of the neuromuscular and immunodeficient categories that should qualify a child for Synagis as they are unable to clear secretions effectively and demonstrate resultant respiratory insufficiency.

We ask that you give appropriate consideration to allowing the above patient populations to receive Synagis prophylaxis if they are less than 2 years of age at season onset, and for the entire duration of that season. We also request that any child recommended for synagis by pediatric pulmonologists in the state be automatically approved. In exchange, we would be happy to review any questionable request for synagis for children we do not normally follow in our clinics. We understand that the cost of Synagis continues to be problematic. We would however like to prevent the long-term sequelae from



an RSV infection in our already-compromised patients. Prevention is, by far, less costly, than hospitalizations and long term therapy. We appreciate your time and consideration to this matter.

Sincerely,

**Pediatric Pulmonology,
Allergy and Immunology**

135 Rutledge Avenue

Suite 279

PO Box 250291

Charleston, SC 29425

Phone (843) 792-8157

Fax (843) 792-5011

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Board Certified, Pediatric Pulmonology

From: Marion Burton <Marion.Burton@uscmed.sc.edu>
To: Margarete Keller <Keller@scdhs.gov>
Date: 8/29/2008 12:04 PM
Subject: addresses Gwinn, Brown and Brown

Marga, for info.

58 BEAR DR
GREENVILLE, SC 29605-4458

Name: JANE VANCE GWINN

Profession:

MD<javascript:spec2_window%20=%20window.open('med_profession.aspx','%20'spec2_window','%20'width=500,%20height=400,%20left=15,%20top=15,%20scrollbars=yes');spec2_window.focus()>

Office Phone: (864) 220-8000

Basis: NB

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School:

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Graduation: 01/01/1981

License No: 11118

Date Issued: 08/30/1982

Expiration: 09/30/2009

Specialty: PDP* PD*

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Trey Brown
University Pediatrics
9 Medical Park Ste. 200A
Columbia, SC 29203

Name: David Eugene Brown III

Profession:

MD<javascript:spec2_window%20=%20window.open('med_profession.aspx','%20'spec2_window','%20'width=500,%20height=400,%20left=15,%20top=15,%20scrollbars=yes');spec2_window.focus()>

Office Phone: 803-434-7950

Basis: US

00<javascript:spec2_window%20=%20window.open('med_basis.aspx','%20'spec2_window','%20'width=700,%20height=400,%20left=15,%20top=15,%20scrollbars=yes');spec2_window.focus(>

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Graduation: 05/05/2000

License No: 22532

Date Issued: 08/20/2001

Expiration: 09/30/2009

Specialty: PD

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Primary Source Verification of Graduation Certified

Hospital Affiliation (s):
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August 29, 2008

Jane V. Gwinn, MD
58 Bear Drive
Greenville, SC 29605-4458

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Re: Palivizumab [Synagis] prophylaxis for pulmonary patients

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Thank you for the recent correspondence relating to SC Medicaid coverage for palivizumab for infants with pulmonary conditions. The NEJM article is quite interesting and clearly describes children with "new bronchopulmonary dysplasia" resulting from reduced alveolar development, etc. Table 1 of the article did not print in the copy I received, but I assume the conditions of concern are noted in your letter. The studies that led to the approval of Synagis for the prophylaxis of RSV infection in infants less than two years of age were predominantly focused on children with bronchopulmonary dysplasia, profound prematurity and risk factors. This prophylaxis has been shown to reduce hospitalizations but I have not found substantive literature that it prevents deaths or chronic lung disease later in life. As noted, prevention of RSV disease in infancy has not been substantiated to lessen or prevent or decrease severity of asthma in later life. Further, RSV prophylaxis programs have not proven cost effective.

American Academy of Pediatrics guidelines support RSV prophylaxis in very premature gestation infants without chronic lung disease for the first six or twelve months of life depending on gestational age and older prematures with certain defined risk factors. Infants with uncorrected hemodynamically significant congenital heart disease were added to the recommendations more recently. The AAP Committee on Infectious Diseases routinely reviews these recommendations, and with the exception of the congenital heart disease indication, have not revised their current guidelines. Periodically, I talk with members of this Committee and, to date, they have not found enough evidenced-based medicine to include cystic fibrosis in the recommendations. We will continue to monitor this.

C. Michael Bowman, MD
August 29, 2008
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As you may know, reviews of Synagis uses are now partially the responsibility of the South Carolina Department of Health and Human Services [SCDHHS] Pharmacy Program. I believe that they are following the AAP guidelines but if there are concerns about specific approvals, please let me know. There are also other SCDHHS staff colleagues who review the physician purchased [bill and buy] products. Similarly, if you are having some difficulty with approvals in this area, please inform me of this. I am aware that there have been requests for children with chronic lung disease, including those who are ventilator dependent or have a tracheotomy, who are older than 2 years of age. These children, in most cases, should have been exposed to RSV sufficiently to have immunity similar to what Synagis would afford at this age. There are also numerous requests for coverage relating to infants under 2 years of age with reactive airway disease but with no history of chronic lung disease. I cannot find literature that supports the use of Synagis in these infants.

We would be most appreciative of further dialogue regarding this issue. Certainly, any support, oversight or review that the State's pediatric pulmonologists can provide would be most welcomed. State Medicaid programs must make coverage decisions based on evidenced based medicine. I am confident that your group can bring those "best practices" items to a forum for us to discuss. In that regard, please let me know if you would be willing to meet either by conference call or in person to discuss this further.

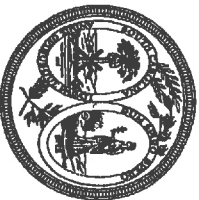
Thank you again for this timely and thoughtful correspondence.

Sincerely,

A handwritten signature in dark ink, appearing to read "O. Marion Burton". The signature is fluid and cursive, with the first name "O." being small and the last name "Burton" being larger and more prominent.

O. Marion Burton, MD
Medical Director

OMB/mk



State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Emma Forkner
Director

August 29, 2008

Isabel Virella-Lowell, MD
MUSC Children's Hospital
Pediatric Pulmonology, Allergy and Immunology
135 Rutledge Avenue, Suite 279
PO Box 250291
Charleston, SC 29425

Re: Palivizumab [Synagis] prophylaxis for pulmonary patients

Dear Dr. Virella-Lowell:

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Medical Director

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Isabel Virella-Lowell, MD

August 29, 2008

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O. Marion Burton, MD
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