



1100 Circle 75 Parkway
Suite 1100
Atlanta, GA 30339

2015-2016 Respiratory Syncytial Virus (RSV) Season and Synagis® Criteria

September 1, 2015

Dear Provider,

Enclosed please find the Peach State Health Plan Synagis® Authorization Guidelines for the 2015-2016 RSV Season. These guidelines were developed based on recommendations of the American Academy of Pediatrics and local Georgia physicians.

Peach State Health Plan will use our preferred provider of Synagis®, AcariaHealth, for the 2015-2016 RSV Season. Beginning immediately, all requests for Synagis® should be forwarded to Peach State Health Plan for review to determine if the request meets criteria for coverage. A copy of the enrollment form is enclosed. When submitting the request, please include the NICU discharge summary to expedite the review process.

AcariaHealth will be responsible for the delivery of the injectable product and the overall coordination of the drug distribution process. All injectable products will be billed directly to Peach State Health Plan by AcariaHealth and shipped to your office. Administration charges for the injection should be billed directly to Peach State Health Plan on a (HCFA) CMS 1500 claim form using CPT code 96372 and the diagnosis code for RSV prophylaxis (V04.82). You may also bill an appropriate evaluation and management office visit code (99212 – 99215) in conjunction with CPT code 96372 when medically necessary.

AcariaHealth is one of the nation's leading comprehensive specialty pharmacy companies, offering healthcare solutions through a unique brand of specialty pharmacy services. With AcariaHealth, patients and their parents, have ready access to patient-centered care and support to help simplify the complexities of RSV. AcariaHealth is a dedicated partner with years of clinical expertise providing:

- ✓ Dedicated, multilingual team available 24/7 to meet the unique needs of each patient
- ✓ Disease-specific product education and training
- ✓ Customized treatment programs and compliance monitoring
- ✓ Prior authorization support and enrollment forms that minimize pharmacy callbacks
- ✓ Timely delivery to your office or the patient's home, as requested
- ✓ Confirmation of weight-based patient dose to ensure timely and accurate refills
- ✓ Coordination of care with Peach State Health Plan to ensure medication compliance

To submit your request, fax the completed enrollment form to 866-374-1579. For questions, contact the Peach State Health Plan Pharmacy Department at 800-514-0083, option 2.

Thank you for your cooperation,

Dean Greeson, MD, MBA
Sr. VP Medical Affairs, Peach State Health Plan

Enclosures: 2015-2016 Administration Policy
2015-2016 Authorization Guidelines
2015-2016 Enrollment Form



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Peach State Health Plan Synagis[®] Administration Policy 2015-2016

Peach State Health Plan strongly encourages Synagis[®] administration in the physician's office. The Synagis[®] season in Georgia is expected to run from October 1, 2015 through February 29, 2016. In the event, the Centers for Disease Control (CDC) reports that Respiratory Syncytial Virus RSV is being detected earlier than October 1, 2015 or the incidence is remaining high after February 29, 2016, Peach State Health Plan would consider extending the season beyond the dates noted. Requests for home administration will only be approved if:

1. Child is homebound and unable to travel
2. Child is immune compromised and may be endangered by contact with other children in the physician's office.

Peach State Health Plan will pay for the office administration fee for the injection when billed on a (HCFA) CMS 1500 claim form using CPT code 96372 and the diagnosis code for RSV prophylaxis (V04.82). You may also bill the appropriate evaluation and management office visit code (99212 – 99215) in conjunction with CPT code 96372 when medically necessary.

If an alternate venue for Synagis[®] administration is necessary, the physician's office may contact our Pharmacy Department for assistance at 1-800-514-0083 option #2.



Synagis[®] 2015-2016 Authorization Guideline



Condition	Max Number of Doses	Age (in months) at Onset of RSV Season	
		0 to < 12	12 to < 24
Premature infants <29 weeks 0 days gestational age	5	Yes	No
Infants with a neuromuscular condition or congenital anomaly of the airway that impairs the ability to clear secretions from the upper airway because of ineffective cough	5	Yes	No
Infants <32 weeks 0 days gestational age with chronic lung disease (CLD) defined as a requirement for >21% oxygen for at least the first 28 days after birth	5	Yes	No
Infants/children in the second year of life who continue to require treatment for CLD during the 6-month period before start of the second RSV season with one of the following: <ul style="list-style-type: none"> • Supplemental Oxygen; or • Diuretic; or • Chronic corticosteroid therapy 	5	N/A	Yes
Hemodynamically significant congenital heart disease (CHD) <ul style="list-style-type: none"> • Infants/children with acyanotic heart disease requiring medication to control congestive heart failure (CHF) and will require cardiac surgical procedures • Infants/children with moderate to severe pulmonary hypertension • Infants/children with cyanotic heart disease when decision made in consultation with a pediatric cardiologist 	5	Yes	No
Infants with cystic fibrosis with clinical evidence of CLD (defined as birth at <32 weeks 0 days gestational age and a requirement for >21% oxygen for at least 28 days after birth) and/or nutritional compromise in the first year of life.	5	Yes	No
Infants in the second year of life with cystic fibrosis with <p>1) Manifestations of severe lung disease – e.g.,</p> <ul style="list-style-type: none"> • Previous hospitalization for pulmonary exacerbation in the first year of life; or • Abnormalities on chest radiography or chest computed tomography that persists when stable <p>OR</p> <p>2) Weight for length <10th percentile</p>	5	N/A	Yes

Additional Notes:

1. If an infant receiving Synagis has a breakthrough RSV hospitalization, Synagis administration should not be continued;
2. High-risk CHD patients receiving Synagis who undergo heart surgery with the use of cardio-pulmonary bypass should receive a dose of Synagis post-op as soon as medically stable.
3. Patients with CHD who are NOT candidates for Synagis include:
 - Hemodynamically insignificant heart disease
 - Secundum ASD
 - Small VSD
 - Pulmonic stenosis
 - Uncomplicated aortic stenosis
 - Mild coarctation of the aorta
 - Patent ductus arteriosus (PDA)
 - Infants with corrected surgical lesions unless they continue to require medication for CHF
 - Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
 - Children in the second year of life (see above for exceptions)
4. CLD can develop in preterm neonates treated with oxygen and positive pressure ventilation. Many cases are seen in infants who previously had respiratory distress syndrome (RDS). CLD is not asthma, croup, recurrent upper respiratory infections, chronic bronchitis, bronchiolitis, or a history of a previous RSV infection.
5. Generally, congenital conditions of the upper airway, such as laryngomalacia or cleft palate, while making a cough somewhat less effective, would not, by themselves, qualify the patient for Synagis administration.
6. Once an infant qualifies for initiation of prophylaxis at the start of the RSV season, administration should continue throughout the season and should not stop when the infant reaches 12 or 24 months of age.

7. **All high-risk infants and their contacts should be immunized against influenza beginning at 6 months of age.**
8. Prophylaxis with Synagis is not recommended for primary asthma prevention or to reduce subsequent episodes of wheezing.

Bibliography

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2. Bresee, MD, J.S., Shay, MD, D.K., Smith, PhD, N.M., et. al. *MMWR Prevention and Control of Influenza - Recommendations of the Advisory Committee on Immunization Practices (ACIP)* July 28, 2006/55/(RR10):1-42 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm?s_cid=rr5510a1_e
3. Errata: RSV Policy Statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *American Academy of Pediatrics. Pediatrics* 2014;134(2):415–420.
4. Facts and Comparisons, on-line. <http://online.factsandcomparisons.com/MonoDisp.aspx?monoID=fandc-hcp11580&inProdGen=true&quick=Synagis>
5. *MMWR Prevention and Control of Influenza - Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 2008. <http://www.cdc.gov/mmwr/pdf/rr/rr5707.pdf>
6. Policy Statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *American Academy of Pediatrics. Pediatrics*, August 2014;134(2):415-420.
7. Synagis[®] [package insert]. MedImmune, LLC., Gaithersburg, MD. March 2014 http://www.medimmune.com/pdf/products/synagis_pi.pdf.

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Telephone: (800) 514 - 0083
 Fax: (866) 374 - 1579

**Respiratory Syncytial Virus
 Prior Authorization Form/ Prescription**

Date: _____	Date Medication Required: _____
Ship to: <input type="radio"/> Physician <input type="radio"/> Patient's Home <input type="radio"/> Other _____	

Patient Information

Last Name:	First Name:	Middle:	DOB: ___/___/___
Address:		City:	State: Zip:
Daytime Phone:	Evening Phone:	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	

Insurance Information (Attach Copies of cards)

Primary Insurance:		Secondary Insurance:	
ID #	Group #	ID #	Group #
City:	State:	City:	State:

Physician Information

Name:	Specialty:	NPI:
Address:		City: State: Zip:
Phone # ()	Secure Fax #: ()	Office contact:

Primary Diagnosis

ICD-9/ICD-10 Code: _____

<input type="checkbox"/> Congenital Heart Disease	<input type="checkbox"/> Chronic Respiratory disease arising in the perinatal period	<input type="checkbox"/> Congenital Abnormality of Respiratory System	<input type="checkbox"/> Cystic Fibrosis
<input type="checkbox"/> < 24 weeks of gestation	<input type="checkbox"/> 24 weeks gestation	<input type="checkbox"/> 25-26 weeks of gestation	<input type="checkbox"/> 27-28 weeks of gestation
<input type="checkbox"/> 29-30 weeks of gestation	<input type="checkbox"/> 31-32 weeks of gestation	<input type="checkbox"/> 33-34 weeks of gestation	<input type="checkbox"/> 35-36 weeks of gestation
<input type="checkbox"/> 37+ weeks of gestation	<input type="checkbox"/> Other _____		

Clinical Information

***** Please submit supporting clinical documentation *****

Patient's gestational age (Required): _____ weeks _____ days Birth Weight: _____ g/kg/lbs Current Weight: _____ g/kg/lbs Date Recorded: _____

Did the patient spend time in the NICU? Yes No *If yes, provide NICU name and attach discharge summary:* _____

Was this season's first Synagis dose given in the NICU? Yes No *If yes, provide date(s):* _____ Expected date of first/next injection: _____

Patient Evaluation (Check all that apply and submit clinical documentation):

Hospitalization for RSV infection this season?

Diagnosis of hemodynamically significant Congenital Heart Disease (CHD) and < 12 months of age at start of RSV Season and patient has the following conditions (Check all that apply):

- Moderate-Severe Pulmonary Hypertension
- Cyanotic Heart Disease (if consulted with a pediatric cardiologist)
- Acyanotic heart disease medications to control CHF (list medications): _____ Last Date Received: _____ **AND** require cardiac surgical procedures

Diagnosis of Chronic Lung Disease* and less than 12 months at start of RSV Season

*CLD is generally defined as: **Infants <32 weeks, 0 days** with oxygen requirement > 21% for at least the first 28 days of birth. CLD is NOT defined as asthma, croup, recurrent upper respiratory infections, chronic bronchitis, bronchiolitis, or a history of a previous RSV infection

Diagnosis of Chronic Lung Disease* and between 12 to less than 24 months at start of RSV Season and receiving treatment of (check all that apply and provide last date received):

- Supplemental oxygen, Date: _____
- Chronic corticosteroid therapy, Date: _____
- Diuretic therapy, Date: _____

Diagnosis of Cystic Fibrosis and less than 12 months of age at start of RSV season?

- Clinical evidence of CLD
- Nutritional compromise: Explain: _____

Diagnosis of Cystic Fibrosis and between 12 to less than 24 months of age at start of RSV season

- Manifestations of severe lung disease (hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or CT that persists when stable)
- Weight for length less than 10th percentile

Diagnosis of condition that impairs the ability to clear secretions from the upper airway because of ineffective cough **AND** less than 12 months at the start of RSV season

- Congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
- Neuromuscular condition

Please list other medical history and/or risk factors: _____

Home Health Coordination

Please note, separate authorization is required for injection training/home health visit. Call Utilization Management at 800-704-1483 for prior authorization

Specialty Pharmacy to coordinate injection to coordinate injection training/home health nurse visit as necessary. Please list Agency of choice: _____

Prescription Information

MEDICATION	STRENGTH	DIRECTIONS	QUANTITY	REFILLS
Synagis	<input type="checkbox"/> 50mg <input type="checkbox"/> 100mg	Inject 15 mg/kg IM one time per month		
Epinephrine	1:1000 amp	Inject 0.01 mg/kg subcutaneously as directed		

Prescriber has counseled parent/guardian on Synagis therapy and the specialty pharmacy may contact parent/guardian

Physician's Signature _____ **Date:** _____ DAW