

September 17, 2018

## 2018-2019 Respiratory Syncytial Virus (RSV) Season and Synagis® Criteria

Dear Provider,

Enclosed you will find the Peach State Health Plan Synagis® Authorization Guidelines for the 2018-2019 RSV Season. These guidelines were developed based on the 2014 recommendations of the American Academy of Pediatrics and recently reviewed under the guidance and consultation with key opinion leaders.

Peach State Health Plan will use our preferred provider of Synagis®, AcariaHealth, for the 2018-2019 RSV Season. Beginning immediately, all requests for Synagis® should be forwarded to Peach State Health Plan for initial screening 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 (Administration) and the diagnosis code for vaccine administration (Z23). You can also bill for an appropriate office visit for each administration of the drug 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,

Steve Dziabis, MD  
Sr. VP Medical Affairs, Peach State Health Plan

Enclosures: 2018-2019 Administration Policy  
2018-2019 Authorization Guidelines  
2018-2019 RSV Referral Form

## Synagis® (Palivizumab) 2018-2019 Authorization Guideline

Respiratory Syncytial Virus (RSV) Prophylaxis: Conditions Covered <i>(Follows American Academy of Pediatrics Recommendations)</i> Maximum Monthly Synagis Doses per RSV Season = 5 at 15 mg/kg per dose	Age in Months at RSV Season Onset†	
	0 to <12	12 to <24
<i>Preterm Birth</i>		
1. Infants born before 29 weeks, 0 days' gestation.	✓	
<i>Chronic Lung Disease (CLD) of Prematurity</i>		
2. Infants with CLD of prematurity‡.	✓	
3. Infants with both of the following: <ul style="list-style-type: none"> <li>• CLD of prematurity‡;</li> <li>• Continued requirement for supplemental oxygen, chronic systemic corticosteroid therapy, or diuretic therapy within 6 months of RSV season onset.</li> </ul>		✓
<i>Congenital Heart Disease (CHD)</i>		
4. Infants with hemodynamically significant CHD - any of the following: <ul style="list-style-type: none"> <li>• Acyanotic heart disease if receiving medication to control congestive heart failure and will require a cardiac surgical procedure or if continues to need medication for congestive heart failure despite surgery;</li> <li>• Acyanotic heart disease with moderate to severe pulmonary hypertension;</li> <li>• Cyanotic heart defect if RSV prophylaxis is recommended by a pediatric cardiologist.</li> </ul>	✓	
5. Infants undergoing cardiac transplantation or cardio-pulmonary bypass during the current RSV season, and <ul style="list-style-type: none"> <li>• Infants who continue to require RSV prophylaxis after cardio-pulmonary bypass should receive an additional Synagis dose as soon as possible after the procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled.</li> </ul>	✓	✓
6. Infants who undergo cardiac transplantation during the RSV season.	✓	✓
<i>Anatomic Pulmonary Abnormalities and Neuromuscular Disorders</i>		
7. Infants with an anatomic pulmonary anomaly or neuromuscular disorder that impairs the ability to clear secretions from the upper airway due to ineffective cough.	✓	
<i>Profoundly Immunocompromised during the RSV Season</i>		
8. Infants who will be profoundly immunocompromised during the RSV season (e.g., solid organ or hematopoietic stem cell transplantation, chemotherapy, severe combined immunodeficiency, chronic granulomatous disease).	✓	✓
<i>Cystic Fibrosis</i>		
9. Infants with cystic fibrosis and clinical evidence of either of the following: <ul style="list-style-type: none"> <li>• Chronic lung disease (CLD) of prematurity‡;</li> <li>• Nutritional compromise.</li> </ul>	✓	
10. Infants with cystic fibrosis who have either of the following in addition to CLD of prematurity‡ or nutritional compromise: <ul style="list-style-type: none"> <li>• Manifestations of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography/computed tomography that persist when stable);</li> <li>• Weight for length less than the 10th percentile.</li> </ul>	✓	✓
<i>Alaska Native and Other American Indian Infants</i>		
11. Medical director consultation is required for requests relating to Alaska Native and other American Indian infants that fall outside the criteria outlined above: <ul style="list-style-type: none"> <li>• Alaska Native infants: Eligibility for prophylaxis may differ from the remainder of the U.S. on the basis of epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than in the general U.S. population,</li> <li>• Other American Indian infants: Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.</li> </ul>		

†RSV Season Onset: The RSV season typically commences in November and continues through April but may begin earlier or persist later in certain states. See <http://www.cdc.gov/rsv/research/us-surveillance.html>. Synagis ideally is initiated prior to the RSV season onset.

‡CLD of prematurity (also known as bronchopulmonary dysplasia or BPD) is defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth.

## Additional Notes

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*Synagis is not Recommended for the Following Uses per the American Academy of Pediatrics:*

- Treatment of RSV disease;
- Continued RSV prophylaxis after hospitalization for RSV disease during the current season;
- Routine RSV prophylaxis for:
  - Infants with hemodynamically insignificant congenital heart disease (CHD) (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus);
  - Infants with Down syndrome unless criteria in the above table are met;
  - Prevention of health care-associated RSV disease;
  - Primary asthma prevention or to reduce subsequent episodes of wheezing.

*Synagis Contraindications:*

Hypersensitivity to Synagis (e.g., anaphylaxis, anaphylactic shock, urticaria, pruritus, angioedema, dyspnea, respiratory failure, cyanosis, hypotonia, hypotension, unresponsiveness).

*Synagis Description/Mechanism of Action:*

Synagis (palivizumab), a recombinant humanized mouse immunoglobulin (IgG1) monoclonal antibody, provides passive immunity against RSV by binding the RSV envelope fusion protein (RSV F) on the surface of the virus and blocking a critical step in the membrane fusion process. Palivizumab also prevents cell-to-cell fusion of RSV-infected cells.

*Synagis Formulations:*

Sterile, preservative-free liquid solution (100 mg/mL) for intramuscular injection\*

- 1 mL single-dose vial containing 100 mg palivizumab
- 0.5 mL single-dose vial containing 50 mg palivizumab

*\*Thimerosal or other mercury-containing salts are not used in the production of Synagis. Synagis cannot be stored once opened.*

### Bibliography

1. Synagis Prescribing Information. Gaithersburg, MD: MedImmune, LLC; May 2017. Available at <https://www.azpicentral.com/synagis/synagis.pdf#page=1>. Accessed January 2018.
2. 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 Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. *Pediatrics*. August 2014; 134(2): e415-20. doi: 10.1542/peds.2014-1665.
3. Technical Report: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. *Pediatrics*. August 2014; 134(2): e620-38. doi: 10.1542/peds.2014-1666.
4. 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*. December 2014; 134(6): 1221.
5. Respiratory syncytial virus infection (RSV): Trends and surveillance. Centers for Disease Control and Prevention website. Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases. Available at <http://www.cdc.gov/rsv/research/us-surveillance.html>. Page last reviewed: March 7, 2017. Accessed January 2018.

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## **Peach State Health Plan Synagis® Administration Policy 2018-2019**

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, 2018 through March 4, 2019. In the event, the Centers for Disease Control (CDC) reports that Respiratory Syncytial Virus RSV is being detected earlier than October 1, 2018 or the incidence is remaining high after March 4, 2019, 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 Vaccine Administration (Z23). 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 800-514-0083 option #2.



Telephone: (800) 514-0083 option 2

Fax: (866) 374-1579

Palivizumab (Synagis)

Prior Authorization Form/ Prescription

Date: \_\_\_\_\_ Date Medication Required: \_\_\_\_\_
Ship to: Physician Patient's Home Other \_\_\_\_\_

Patient Information

Last Name: First Name: Middle: DOB: \_\_\_/\_\_\_/\_\_\_
Address: City: State: Zip:
Daytime Phone: Evening Phone: Sex: Male 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-10 Code:
Congenital Heart Disease Chronic Respiratory disease arising in the perinatal period Congenital Abnormality of Respiratory System Cystic Fibrosis
< 24 weeks of gestation 24 weeks gestation 25-26 weeks of gestation 27-28 weeks of gestation
29-30 weeks of gestation 31-32 weeks of gestation 33-34 weeks of gestation 35-36 weeks of gestation
37+ weeks of gestation 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
Patient be profoundly immunocompromised during the RSV season (e.g., due to solid organ or hematopoietic stem cell transplantation, chemotherapy, severe combined immunodeficiency, chronic granulomatous disease). If yes, provide chart notes documenting care plan
Patient is an Alaska native or American Indian.

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 (866) 296-8731 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

Table with 5 columns: MEDICATION, STRENGTH, DIRECTIONS, QUANTITY, REFILLS. Row 1: Synagis, 50mg 100mg, Inject 15 mg/kg IM one time per month, ,

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

Physician's Signature \_\_\_\_\_ Date: \_\_\_\_\_ DAW