



## 2019 - 2020 Respiratory Syncytial Virus (RSV) Season and Synagis® Criteria

Dear Provider,

Below please find the Synagis® Authorization Guidelines for the 2019 - 2020 Respiratory Syncytial Virus (RSV) season for NextLevel Health. These guidelines were developed in 2014 based on recommendations of the American Academy of Pediatrics.

NextLevel Health will use our PBM, Envolve Pharmacy Solutions, to process requests for Synagis®. Requests for Synagis® should be forwarded to Envolve Pharmacy Solutions for initial screening in efforts of determining whether the request meets criteria for coverage. Additionally, enclosed, you can find a copy of the prior authorization form. When submitting the request, please include the Neonatal, Intensive Care Unit (NICU) discharge summary to expedite the review process.

Synagis® is available through a limited distribution network as established by the manufacturer.

Your specialty pharmacy of choice will be responsible for delivery of the injectable product and overall coordination of the drug distribution process. Synagis® can be billed directly to NextLevel Health by the specialty pharmacy provider and shipped to your office. Administration charges for the injection should be billed directly to NextLevel Health on a (HCFA) CMS 1500 claim form using CPT code 96372 (Administration) and CPT code 90378 (Medicine.) You can also bill for an appropriate office visit for each administration of the drug.

Billing and payment for pre-approved Synagis® administration, outside of your specialty pharmacy provider. Administration charges for the synagis injection should be billed on a (HCFA) CMS 1500 claim form, using CPT code 96372. Providers can also bill for an appropriate office visit for each administration of the drug.

Synagis® prescriptions can be sent to AcariaHealth®, a dedicated specialty pharmacy with years of clinical expertise. AcariaHealth® can be responsible for the delivery of the injectable product and overall coordination of the drug distribution process. With AcariaHealth®, Members and their parents, have ready access to patient-centered care and support to help simplify the complexities of RSV. In addition, AcariaHealth® provides prior authorization support and enrollment forms that will help to minimize pharmacy callbacks. To learn more about their services call 855-422-2742, their multilingual team is available 24/7.

Thank you for your cooperation,

NextLevel Health

**Synagis® (Palivizumab)**  
**2019-2020 Authorization Guideline**

Respiratory Syncytial Virus (RSV) Prophylaxis: Conditions Covered (Follows American Academy of Pediatrics Recommendations) 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
<b>Preterm Birth</b>		
1. Infants born before 29 weeks, 0 days' gestation.	<input type="checkbox"/>	<input type="checkbox"/>
<b>Chronic Lung Disease (CLD) of Prematurity</b>		
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>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<b>Congenital Heart Disease (CHD)</b>		
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 Member continues to need medication for congestive heart failure despite any 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>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5. Infants undergoing cardiac transplantation or cardio-pulmonary bypass during the current RSV season: <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, following his or her procedure. Even if sooner than a month from the previous dose. Thereafter, doses should be administered monthly as scheduled.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
6. Infants who undergo cardiac transplantation during the RSV season.	<input type="checkbox"/>	<input type="checkbox"/>
<b>Anatomic Pulmonary Abnormalities and Neuromuscular Disorders</b>		
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.	<input type="checkbox"/>	<input type="checkbox"/>
<b>Profoundly Immunocompromised during the RSV season</b>		
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.)	<input type="checkbox"/>	<input type="checkbox"/>
<b>Cystic Fibrosis</b>		
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>	<input type="checkbox"/>	<input type="checkbox"/>
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>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

### **Alaska Native and other American Indian Infants**

11. Medical Director consultation is required for requests related to Alaska Native and other American Indian infants that fall outside the criteria outlined above:

- Alaska Native infants: Eligibility for prophylaxis may differ from the remainder of the U.S. based on 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.
- 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.

RSV Season Onset: The RSV season may commence as early as September and continue through May. In Florida, the RSV season may begin at any time throughout the year.

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**

**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 February 8, 2019.
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: June 26, 2018. Accessed February 8, 2019.



# Palivizumab (Synagis) Prior Authorization Form

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: <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-10 Code: _____				
<input type="checkbox"/> Preterm birth <input type="checkbox"/> Chronic lung disease of prematurity (Bronchopulmonary dysplasia) <input type="checkbox"/> Congenital heart disease <input type="checkbox"/> Anatomic pulmonary abnormalities <input type="checkbox"/> Neuromuscular disorder <input type="checkbox"/> Profoundly immunocompromised <input type="checkbox"/> Cystic fibrosis <input type="checkbox"/> Other: _____				
Prescription Information				
MEDICATION	STRENGTH	DIRECTIONS	QUANTITY	REFILLS
Synagis (palivizumab)				
Clinical Information <span style="float: right;">***** Please submit supporting clinical documentation *****</span>				
<input type="checkbox"/> INITIAL THERAPY <input type="checkbox"/> CONTINUATION OF THERAPY - therapy start date: _____				
1. Has patient had a positive response to the prescribed therapy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable 2. Is Synagis prescribed for prophylaxis of respiratory syncytial virus (RSV)? <input type="checkbox"/> Yes <input type="checkbox"/> No 3. Has patient received more than 5 doses of Synagis during the current RSV season? <input type="checkbox"/> Yes <input type="checkbox"/> No a. <b>If yes</b> , did patient undergo cardio-pulmonary bypass during the current RSV season? <input type="checkbox"/> Yes <input type="checkbox"/> No 4. Has patient been hospitalized with RSV disease during the current RSV season? <input type="checkbox"/> Yes <input type="checkbox"/> No 5. Please document patient's current weight: _____ kg  <b>Complete this section ONLY if the patient is initiating therapy:</b> 6. Is patient an Alaska native or American Indian? <input type="checkbox"/> Yes <input type="checkbox"/> No 7. Will 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)? <input type="checkbox"/> Yes <input type="checkbox"/> No 8. <b>If preterm birth or chronic lung disease of prematurity</b> , please document patient's gestational age: _____ weeks _____ days 9. <b>If chronic lung disease of prematurity</b> , a. Did patient require > 21% oxygen for at least 28 days after birth? <input type="checkbox"/> Yes <input type="checkbox"/> No b. Has patient required any of the following within 6 months of the start of RSV season? <b>**Mark all that apply**</b> <input type="checkbox"/> Supplemental oxygen <input type="checkbox"/> Chronic systemic corticosteroid therapy <input type="checkbox"/> Diuretic therapy 10. <b>If congenital heart disease</b> , does any of the following apply to patient? <input type="checkbox"/> Acyanotic heart disease <input type="checkbox"/> Cyanotic heart defect and RSV prophylaxis is recommended by pediatric cardiologist <input type="checkbox"/> Medication to control congestive heart failure required <input type="checkbox"/> Cardiac surgical procedure required <input type="checkbox"/> Moderate to severe pulmonary hypertension <input type="checkbox"/> Undergoing cardiac transplantation or cardio-pulmonary bypass during the current RSV season				

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

**Patient Name:** \_\_\_\_\_ **DOB:** \_\_\_\_\_

11. **If anatomic pulmonary abnormalities or neuromuscular disorder**, does patient have impaired ability to clear secretions from the upper airways (e.g., due to ineffective cough)?  Yes  No

12. **If cystic fibrosis**,

a. Does patient have manifestations of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable?)  
 Yes  No

b. Is patient's weight for length < 10<sup>th</sup> percentile?  Yes  No

c. Is there clinical evidence of nutritional compromise?  Yes  No

d. Has patient been diagnosed with chronic lung disease of prematurity?  Yes  No

**Complete this section ONLY for indications other than those listed above:**

13. Has patient tried and failed, or is contraindicated to, accepted standards of care?  Yes  No

*If yes, submit documentation and answer the following:*

a. Please list all previous therapies:

b. Was patient adherent to previously tried therapies?  Yes  No  No-patient intolerant to drug

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

Submit completed Prior Authorization request to:

**Involve Pharmacy Solutions**  
**Phone: 866-399-0928 Fax: 866-399-0929**