



2021-2022 RSV SEASON - Synagis®

9/29/21

Dear Care1st Providers and Staff:

Care1st has been closely monitoring Respiratory Syncytial Virus (RSV) activity in Arizona and has taken the necessary steps to ensure patients who are at high risk for RSV infection can continue to receive appropriate care. Passive prophylactic immunization with Synagis® continues to be the standard of care for RSV in children at risk for infection.

As RSV season approaches, please find enclosed the Care1st Synagis® authorization guidelines for the 2021-2022 RSV season and the Care1st RSV (Synagis®) Enrollment Form. All requests for Synagis® should be submitted using the Enrollment form as this form will serve as the prior authorization form. All Synagis® requests require prior authorization and will be approved for a maximum of 5 doses. Synagis® is available through a limited distribution network as established by the manufacturer. To obtain prior authorization:

- Please complete the Care1st RSV (Synagis®) Enrollment Form (available on the Care1st website www.care1staz.com > Provider > Forms) and fax it to 602.778.8387 with progress notes &/or NICU discharge summary. We will review and process your request as quickly as possible.
- For all counties serviced by Care1st, the following pharmacies are available to dispense Synagis® which will be shipped directly to the provider's office* to be administered to the member. FAX the same RSV Enrollment Form to one of the specialty pharmacies below to initiate the prescription once the PA has been approved.
 - Acaria Health (FAX: 1-877-252-2444) OR
 - CVS Specialty Pharmacies (FAX: 1-800-323-2445)
*if a member requires an alternate site of administration or in-home administration, please request Synagis from CVS Specialty who can help make arrangements for the member.

Prior Authorization Form/ Prescription

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

- Providers should bill administration charges (CPT codes) for Synagis® directly to Care1st.

Please contact the *Care1st Pharmacy Department at 602.778.1800 or 1.866.560.4042 (Options 5, 5)* if you have any questions

Thank you!

Care1st Network Management
Ph 602.778.1800/866.560.4042 (Options in order: 5, 7)
Fax 602.778.1875/E-mail SM_AZ_PNO@Care1stAZ.com
Visit our website at www.care1staz.com

Looking for your assigned Provider Network Rep? On our website go to Providers > Provider Rep Contact Info

Synagis® (Palivizumab)

2021-2022 Authorization Guideline

Respiratory Syncytial Virus (RSV) Prophylaxis <i>Covered Conditions per the American Academy of Pediatrics, reaffirmed February, 2019 Synagis doses per RSV Season: 5 at 15 mg/kg per dose (6 doses if cardio-pulmonary bypass)</i>	Age in Months at RSV Season Onset†	
	0 to <12	12 to <24
<i>Preterm Infant</i>		
1. Infants with gestational age <29 weeks	✓	
<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"> • CLD of prematurity‡ • Continued requirement for supplemental oxygen, chronic systemic corticosteroid therapy, or diuretic therapy within 6 months of RSV season onset 		✓
<i>Congenital Heart Disease (CHD)</i>		
4. Infants with hemodynamically significant CHD - any of the following: <ul style="list-style-type: none"> • 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 • Acyanotic heart disease with moderate to severe pulmonary hypertension • Cyanotic heart defect if RSV prophylaxis is recommended by a pediatric cardiologist 	✓	
5. Infants undergoing cardiac transplantation or cardio-pulmonary bypass during the current RSV season, and <ul style="list-style-type: none"> • 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. 	✓	✓
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"> • Chronic lung disease (CLD) of prematurity‡ • Nutritional compromise 	✓	
10. Infants with cystic fibrosis who have either CLD of prematurity‡ or nutritional compromise, and either of the following: <ul style="list-style-type: none"> • 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) • Weight for length less than the 10th percentile 	✓	✓
<i>Alaska Native and Other American Indian Infants</i>		
11. Medical director consultation is required for requests falling outside the above criteria and relating to Alaska Native or other American Indian infants. <ul style="list-style-type: none"> • Alaska Native infants: Prophylaxis eligibility may differ from the remainder of the U.S. based on RSV epidemiology in Alaska, particularly in remote regions where RSV disease burden 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. No matter the season duration, only 5 doses are recommended; < 5 if middle of season.

‡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.

Synagis® 2021-2022 Authorization Guideline

The American Academy of Pediatrics does not recommend Synagis for the following uses:

- Treatment of RSV disease
- RSV prophylaxis post hospitalization for RSV disease during the current RSV 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, or 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 and 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, is not used in the production of Synagis. Synagis cannot be stored once opened.

Bibliography

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3. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. *MMWR Morb Mortal Wkly Rep* 2018;67:71–76. DOI: <http://dx.doi.org/10.15585/mmwr.mm6702a4>.
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5. 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. Reaffirmed February 2019. Available online at <https://pediatrics.aappublications.org/content/134/2/415.full#sec-13>.
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Phone: 1-602-778-1800 (Options 5,5)
Fax: 1-602-778-8387

Respiratory Syncytial Virus
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-9/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
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 (888) 788-4408 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. Rows include Synagis and Epinephrine.

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

Physician's Signature _____ Date: _____ DAW