550 N. Meridian Street, Suite 101
Indianapolis, IN 46204

[Date]

[First Name] [Last Name]
[Address 1]
[Address 2]
[City], [State] [ZIP]

Dear Provider,

Enclosed please find the Managed Health Services (MHS) Synagis® Authorization Guidelines for the 2020-2021 RSV season. These guidelines were developed based on recommendations of the American Academy of Pediatrics (AAP) and recently reviewed under the guidance and consultation with key opinion leaders.

MHS will again use our PBM, Envolve Pharmacy Solutions, to process requests for Synagis® for the RSV season. Beginning immediately, all requests for Synagis® should be forwarded to Envolve 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.

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

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 MHS by the specialty pharmacy provider and shipped to your office. Administration charges for the injection should be billed directly to MHS 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 AcariaHealth, requires submission of a claim form using the designated CPT 90378 for Synagis®, with a required NDC and entry of billing units incremental to each 50 mg dose administered (i.e. 100mg = 2 billing units).
To submit your request, fax the completed enrollment form to 1-855-678-6976. For questions, contact the MHS Pharmacy Department at 1-844-798-4814.

Thank you for your cooperation,

MHS Pharmacy Department

Enclosures: 2020-2021 Authorization Guidelines
2020-2021 RSV Prior Authorization Form

Synagis® (Palivizumab)
2020-2021 Authorization Guideline

Respiratory Syncytial Virus (RSV) Prophylaxis *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)*	**Age in Months at RSV Season Onset†**	
	0 to <12	12 to <24
Preterm Infant		
1. Infants with gestational age <29 weeks	✓	
Chronic Lung Disease (CLD) of Prematurity		
2. Infants with CLD of prematurity‡	✓	
3. Infants with both of the following: • CLD of prematurity‡ • Continued requirement for supplemental oxygen, chronic systemic corticosteroid therapy, or diuretic therapy within 6 months of RSV season onset		✓
Congenital Heart Disease (CHD)		
4. Infants with hemodynamically significant CHD - any of the following: • 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 • 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	✓	✓
Anatomic Pulmonary Abnormalities and Neuromuscular Disorders		
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	✓	
Profoundly Immunocompromised during the RSV Season		
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)	✓	✓
Cystic Fibrosis		
9. Infants with cystic fibrosis and clinical evidence of either of the following: • 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: • 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	✓	✓
Alaska Native and Other American Indian Infants		
11. Medical director consultation is required for requests falling outside the above criteria and relating to Alaska Native or other American Indian infants. • 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.

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

1. Synagis Prescribing Information. Gaithersburg, MD: MedImmune, LLC; May 2017. Available at https://www.azpicentral.com/synagis/synagis.pdf#page=1. Accessed February 6, 2020.
2. 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 6, 2020.
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.
6. 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.
7. 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.
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mhs

Phone: 1-855-772-7125 Fax: 1-855-678-6976

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: _____

☐ Preterm birth ☐ Chronic lung disease of prematurity (bronchopulmonary dysplasia) ☐ Congenital heart disease
☐ Anatomic pulmonary abnormalities ☐ Neuromuscular disorder ☐ Profoundly immunocompromised ☐ Cystic fibrosis
☐ Other: _____

Prescription Information

MEDICATION	STRENGTH	DIRECTIONS	QUANTITY	REFILLS
Synagis (palivizumab)				

Clinical Information

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

☐ **INITIAL THERAPY** ☐ **CONTINUATION OF THERAPY;** Therapy start date: _____

1. Has patient had a positive response to the prescribed therapy? ☐ Yes: _____ ☐ No ☐ Not applicable
2. Is Synagis prescribed for prophylaxis of respiratory syncytial virus (RSV)? ☐ Yes ☐ No
3. Has patient received more than 5 doses of Synagis during the current RSV season? ☐ Yes: _____ doses ☐ No
   a. *If yes*, did patient undergo cardio-pulmonary bypass during the current RSV season? ☐ Yes ☐ No
4. If requests for RSV prophylaxis extend beyond the identified season duration for Florida or beyond September through May for the remainder of the U.S., is there medical justification supporting use? ☐ Yes ***Submit documentation*** ☐ No
5. Has patient been hospitalized with RSV disease during the current RSV season? ☐ Yes ☐ No
6. Please document patient's current weight: _____ kg

Complete this section ONLY if the patient is <u>initiating</u> therapy:

7. Is patient an Alaska native or American Indian? ☐ Yes ☐ No
8. 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)? ☐ Yes ☐ No
9. **If preterm birth or chronic lung disease of prematurity**, please document patient's gestational age: _____ weeks _____ days
10. **If chronic lung disease of prematurity,**
    a. Did patient require > 21% oxygen for at least 28 days after birth? ☐ Yes ☐ No
    b. Has patient required any of the following within 6 months of the start of RSV season? ☐ Yes ***Mark all that apply*** ☐ No
       ☐ Supplemental oxygen ☐ Chronic systemic corticosteroid therapy ☐ Diuretic therapy

Please continue to page 2.

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Palivizumab (Synagis)
Prior Authorization Form/Prescription

Date: _____ Date Medication Required: _____
Ship to: ❍ Physician ❍ Patient's Home ❍ Other _____

Patient Name: _____ DOB: _____

11. **If congenital heart disease,** does any of the following apply to patient? ☐Yes ***Mark all that apply*** ☐No
    - ☐Acyanotic heart disease
    - ☐Cyanotic heart defect and RSV prophylaxis is recommended by pediatric cardiologist
    - ☐Medication to control congestive heart failure required
    - ☐Cardiac surgical procedure required
    - ☐Moderate to severe pulmonary hypertension
    - ☐Undergoing cardiac transplantation or cardio-pulmonary bypass during the current RSV season
12. **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
13. **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 < 10th 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 <u>other</u> than those listed above:

14. 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