

SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-800-750-9692.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization may be delayed.**

Drug Requested: SYNAGIS® (palivizumab)

If approved, an authorization will be given for a specific number of injections, to be **ORDERED between October 1st and March 31st.** RSV season for Virginia (as well as West Virginia, Maryland, DC, Delaware, and Pennsylvania) begins in late October and ends in April. **Typically, RSV season begins November and ends in March. However, the duration of the Synagis season remains 5 consecutive months for all geographic areas in the United States.

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code: _____

Weight: _____ Date: _____

Infant/Child Weight: _____ Date Recorded: _____

Gestational Age at Birth: _____ Weeks: _____ Days: _____

Synagis® (palivizumab) is a humanized monoclonal antibody produced by recombinant DNA technology indicated for the **prevention** of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV)

Recommended Dosing: Synagis® will be authorized according to the FDA recommended dose: Infants and Children <24 months - 15 mg/kg IM once monthly

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- Dosing Allowance: Synagis® is available in 50 mg and 100 mg vials. Due to the potential for significant waste, the following table should be utilized to determine the permitted dose (within 5% of calculated dose due to vial overflow) and vials to dispense. Any dosage increase must have corresponding weight charts and/or progress notes with current weight.
- Current Weight (kg): _____
- Synagis® has been administered in an inpatient setting: Yes, date of last dose _____ No

<u>Weight-based Dose</u>	<u>Dosage</u>	<u>Dispense Units</u>
0 – 3.5 kg	≤ 53 mg	1 vial of 50 mg/0.5mL
3.6 – 7 kg	54 – 105 mg	1 vial of 100 mg/1ml
7.1 – 10.3 kg	106.5 – 154.5 mg	1 vial of 50 mg/0.5mL and 1 vial of 100 mg/1mL
10.4 – 13.6 kg	156 – 205 mg	2 vials of 100 mg/1mL
13.7 – 16.93 g	205.5 – 254 mg	1 vial of 50 mg/0.5mL and 2 vials of 100 mg/1mL
17 – 20.3 kg	255 – 305 mg	3 vials of 100 mg/1mL

- If Beyfortus™ has been administered, please provide date & dose of administration: _____
- If Beyfortus™ (nirsevimab) is administered, Synagis® (palivizumab) should **NOT** be administered later that season.
- If Enflonia™ has been administered, please provide date & dose of administration: _____

Quantity Limit: 1 vial (50 mg/0.5 mL or 100 mg/1 mL) per 28 days

- Approval will be given for the current dosage and vial size(s). Throughout the RSV season, weight changes should be submitted on the Synagis request form when a different vial size(s) is/are required.
- Requests for doses exceeding the five (5) dose maximum or beyond the season end date will be **DENIED**.
- As defined by The National Respiratory and Enteric Virus Surveillance System (NREVSS): RSV season is over when virology is < 10% for 2 consecutive weeks.
- Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Diagnosis: Preterm Infants without Chronic Lung Disease (CLD) of Prematurity or Congenital Heart Disease (CHD)

Please select ONE of the following:

- Infants without CLD or CHD born <28 weeks, 6 days and member’s current age <12 months
- Infants without CLD or CHD born between ≥ 29 weeks to 31 weeks, 6 days and member’s current age ≤ 6 months at start of (RSV) season

Provider please note: Infants without CLD or CHD born ≥ 32 weeks, 0 days’ gestation: Synagis® is NOT RECOMMENDED.

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❑ Diagnosis: Preterm Infants with Chronic Lung Disease (CLD)

Please select ONE of the following:

- Infants with CLD <12 months (first year life) born <32 weeks, 0 days' gestation and require >21% supplemental O² for at least 28 days after birth
- Infants with CLD <24 months and >12 months (second year life) born <32 weeks, 0 days' gestation with CLD of prematurity **AND** continued to require medical support during the 6-month period before the start of the second RSV season (**must be verified by pharmacy paid claims and/or submitted chart notes**):
 - Chronic systemic corticosteroid therapy: date of last use: _____
 - Diuretic therapy: date of last use: _____
 - Supplemental oxygen: date of last use: _____

❑ Diagnosis: Infants with Hemodynamically Significant Congenital Heart Disease (CHD)

Please select ONE of the following:

- Infants < 12 months old at the start of RSV season with hemodynamically significant heart disease defined by **ONE** of the following:
 - Acyanotic CHD, receiving treatment for congestive heart failure (CHF) and requires cardiac surgery
 - Moderate to severe pulmonary hypertension (PH, PAH)
 - Cyanotic CHD and Synagis is recommended by a pediatric cardiologist
- Infants in the first year or second year of life who are undergoing cardiac transplant or cardiac bypass **DURING** the RSV season

Provider please note: For children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of Synagis should be considered after cardiac bypass or at the conclusion of extra-corporeal membrane oxygenation for infants and children younger than 24 months

EXAMPLES OF SIGNIFICANT AND APPROVABLE CARDIAC CONDITIONS

Examples of significant hemodynamic cyanotic congenital heart disease:

Tetralogy of Fallot, Transposition of the great vessels, Ebstein's anomaly, Tricuspid atresia, Total anomalous pulmonary venous return, Truncus arteriosus, Hypoplastic left heart syndrome

NON-APPROVABLE CARDIAC CONDITIONS

Insignificant hemodynamic heart disease (and therefore are NOT approvable indications):

Secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus

Indications in which patients are NOT at an increased risk for RSV (and therefore are NOT approvable indications)

- Lesions adequately corrected by surgery (unless the patient continues to require medications for CHF)
- Mild cardiomyopathy who are NOT receiving medical therapy

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❑ Diagnosis: Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder

- ❑ Infants <12 months old (first year life) with a neuromuscular disorder(s) or congenital pulmonary anomaly that impairs the ability to clear secretions from upper airway
- ❑ Provider has submitted name and ICD-10 code for anatomic pulmonary abnormality or neuromuscular disorder: _____
- ❑ Member must have **ONE** of the following:
 - ❑ pulmonary malformations
 - ❑ tracheoesophageal fistula
 - ❑ upper airway conditions
 - ❑ requires tracheostomy

❑ Diagnosis: Immunocompromised Children

- ❑ Infants and children <24 months of age who are severely immunocompromised DURING the RSV season (i.e., receiving chemotherapy, undergoing solid organ or hematopoietic stem cell transplantation)

EXAMPLES OF SEVERE IMMUNODEFICIENCIES/IMMUNOSUPPRESSION:

Advanced Acquired Immunodeficiency Syndrome (AIDS), Transplant, Chemotherapy, Severe Combined Immunodeficiency (SCID)

❑ Diagnosis: Children with Cystic Fibrosis

Please select ONE of the following:

- ❑ Infants < 12 months old (first year of life) with Cystic Fibrosis with clinical evidence of CLD and/or nutritional compromise (e.g., requires total parenteral nutrition)
- ❑ Infants with Cystic Fibrosis <24 months and >12 months (second year life) with manifestations of severe lung disease (e.g., previous history of hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest x-ray or CT scan that persist when stable or patient weight for length is less than the 10th percentile)

- ❑ **Authorization Criteria for additional dose(s) of Synagis.** Check below all that apply. All criteria must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

NOTE: For all requests received after March 31st – If all below conditions are met, the request will be approved for an additional 1-month duration. **For all requests received prior to November 1st** – For members born between 32 to less than 35 weeks of gestation (without any significant medical conditions), if all below conditions are met, the request will only be approved for a maximum quantity of up to 3 doses. All other members will be approved for a quantity of 5 doses. If all the criteria below is **NOT** met, then the request will be referred to a Medical Director for medical necessity review.

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- For requests to initiate treatment of Synagis prior to November 1st:
 - Local virology data supplied from the National Respiratory & Enteric Virus Surveillance System (NREVSS) RSV Surveillance website OR recent surveillance data from a local/regional hospital (dated within < 14 days prior to the member's appointment) indicates an incidence of RSV greater than 10% (percent positive total antigen detection tests greater than 10%) for that locality
 - Member meets the above stated criteria for their chronological and/or gestational age
- For requests to administer an additional dose of Synagis after March 31st:
 - Member has **NOT** already received the maximum approvable five (5) doses of Synagis according to the member's chronological age, gestational age, and/or clinical situation
 - Local virology data supplied from the National Respiratory & Enteric Virus Surveillance System (NREVSS): RSV Surveillance website OR recent surveillance data from a local/regional hospital (dated within < 14 days prior to the member's appointment) indicates an incidence of RSV greater than 10% (percent positive total antigen detection tests greater than 10%) for that locality

Medication being provided by (check box below that applies):

- Physician's office **OR** Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****