SENTARA COMMUNITY PLAN
(MEDICAID)

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 the information provided is not complete, correct, or legible, the authorization process can 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, if applicable:** _____

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 overfill) 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

Weight-based Dose	Dosage	Dispense Units
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.

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 O^2 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, Transportation of the great vessels, Ebstein's anomally, 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):	**Indications in which patients are NOT at an increased risk for RSV (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	• 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 Immunodeficieny 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**

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****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.****

***Approved by Pharmacy and Therapeutics Committee:** ~~8/1/2018; 9/26/2022;~~ **9/21/2023**
REVISED/UPDATED: ~~6/3/2011; 9/12/11; 4/24/2012; 10/1/2012; 8/29/13; 2/26/2014; 8/13/2014; 8/15/14; 8/21/2014; 8/26/2014; 10/31/2014; 4/3/2015; 5/23/2015; 12/30/2015; 1/29/2016; 9/22/2016; 12/11/2016; 2/2/2017; 7/24/2017; (Rev 3/23/2019); (Reformatted) 7/8/2019; 9/24/2019; 10/9/2019; 10/25/2019; 9/23/2021;10/25/2019; 9/23/2021 11/12/2021; 11/22/2021; 10/4/2022;~~ **10/17/2023**