

Title: SYNAGIS (palivizumab)	Division: Medical Management Department: Pharmacy
Approval Date: 9/1/2021	LOB: Medicaid, Medicare, HIV SNP, CHP, HARP, MetroPlus Gold, Goldcare I&II, EP, QHP
Effective Date: 9/1/2021	Policy Number: UM-MP323
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1. POLICY DESCRIPTION

Anti-Infective Agent, Antiviral, Synagis (Rx)

2. RESPONSIBLE PARTIES

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. DEFINITIONS

Palivizumab is a humanized monoclonal antibody directed against the fusion protein of respiratory syncytial virus (RSV). Passive immunity is provided via blockage of the membrane fusion process. Cell-to-cell fusion of RSV-infected cells is also prevented.

4. POLICY

Synagis used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) will be covered with prior authorization when ANY of the following criteria is met. Approval is up to 5 doses (15mg/kg of body weight per dose) and Synagis Season will be from October 15th to March 31st.

1. PREMATURITY

- a. Patient's gestational age is < 29 weeks, 0 days **AND**
- b. Patient's chronological age at the start of RSV season is \leq 12 months **AND**
- c. Patient has not previously experienced a hypersensitivity reaction to Synagis

2. CHRONIC LUNG DISEASE (CLD) OF PREMATURITY/ BRONCHOPULMONARY DYSPLASIA (BPD)

- a. Patient's gestational age is < 32 weeks, 0 days **AND**
- b. Patient required > 21% oxygen for at least the first 28 days after birth **AND**
- c. Patient meets either of the following:
 - i. Patient's chronological age at the start of their first RSV season is \leq 12 months
 - ii. Patient's chronological age at the start of the subsequent RSV season is \leq 24 months and the patient continues to require medical support

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(e.g., chronic corticosteroids, diuretic therapy, supplemental oxygen) during the 6-month period prior to the start of the RSV season

3. CONGENITAL HEART DISEASE (CHD)

- a. Patient has congenital heart disease (CHD) as defined by Appendix B **AND**
- b. CHD is hemodynamically significant **AND**
- c. Patient meets either of the following:
 - i. Patient's chronological age at the start of RSV season is < 12 months
 - ii. Patient's chronological age at the start of RSV season is between 12 to 24 months and the patient will be undergoing cardiac transplantation during the RSV season

4. CONGENITAL AIRWAY ABNORMALITY OR NEUROMUSCULAR CONDITION

- a. Patient's chronological age at the start of RSV season is < 12 months **AND**
- b. The condition impairs the ability to swallow/cough/clear secretions from the airways

5. IMMUNOCOMPROMISED CHILDREN

- a. Patient's chronological age at the start of RSV season is < 24 months **AND**
- b. Patient is profoundly immunocompromised during the RSV season (e.g., SCID, stem cell transplant, bone marrow transplant)

6. CYSTIC FIBROSIS (CF)

- a. Patient has a confirmed diagnosis consistent with cystic fibrosis, as defined by the following*:
 - i. Clinical symptoms consistent with CF in at least one organ system, **OR** positive newborn screen, **OR** having a sibling with CF **AND**
 - ii. Evidence of cystic fibrosis transmembrane conductance regulator (CFTR) dysfunction by any of the following:
 1. Elevated sweat chloride ≥ 60 mmol/L
 2. Presence of two disease-causing mutations in the CFTR gene, one from each parental allele

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3. Abnormal nasal potential difference (NPD) **AND**
 - b. Patient meets either of the following criteria:
 - i. Patient's chronological age at the start of the RSV season is < 12 months and the patient has evidence of CLD or nutritional compromise **OR**
 - ii. Patient's chronological age at the start of RSV season is between 12 to 24 months and the patient has manifestations of lung disease (e.g., hospitalizations for pulmonary exacerbations) or weight less than the 10th percentile

Documentation, including chart notes and lab results, MUST be submitted for approval

7. OFF SEASON REQUESTS

For all off-season Synagis requests, authorization of 1 dose per request may be granted if the RSV activity for the requested region is $\geq 10\%$ within 2 weeks of the intended dose according to the CDC National Respiratory and Enteric Virus Surveillance System (NREVSS). The local health department or the CDC NREVSS will be consulted to assess the RSV activity for that region (<http://www.cdc.gov/surveillance/nrevss/rsv/index.html>).

B. APPENDICES

APPENDIX A – RECOMMENDED USE OF SYNAGIS FOR PREVENTION OF RSV INFECTION

Recommendations from the American Academy of Pediatrics for the prevention of RSV infection with Synagis are summarized in Table below. Synagis should be administered intramuscularly at a dose of 15 mg/kg once per month beginning prior to the onset of the RSV season, which typically occurs in November. Because 5 monthly doses of Synagis will provide more than 6 months of serum Synagis concentrations above the desired serum concentration for most infants, administration of more than 5 monthly doses is not recommended within the continental United States.

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Prematurity	<ul style="list-style-type: none"> • Preterm infants born < 29 weeks, 0 days of gestation who are younger than 12 months at the start of the RSV season
Congenital Heart Disease	<ul style="list-style-type: none"> • Infants and children < 12 months of age with hemodynamically significant CHD • Those most likely to benefit from prophylaxis include: <ul style="list-style-type: none"> ○ Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures ○ Infants with moderate to severe pulmonary hypertension • Infants and children < 24 months of age who undergo cardiac transplantation during the RSV season
Chronic Lung Disease of Prematurity	<ul style="list-style-type: none"> • For the first RSV season during the first year of life: Preterm infants who develop CLD of prematurity defined as: <ul style="list-style-type: none"> ○ Gestational age < 32 weeks, 0 days <u>AND</u> ○ Requirement for > 21% oxygen for at least the first 28 days after birth • For the second RSV season during the second year of life: Preterm infants who: <ul style="list-style-type: none"> ○ Satisfy the above definition of CLD of prematurity <u>AND</u> ○ Continue to require medical support* for CLD during the 6-month period prior to the start of the second RSV season
Congenital Abnormality of the Airway/ Neuromuscular Condition	<ul style="list-style-type: none"> • Infants who have either a significant congenital abnormality of the airway or a neuromuscular condition that compromises handling of respiratory secretions for the first year of life
Immunocompromised children	<ul style="list-style-type: none"> • Children younger than 24 months of age who are profoundly immunocompromised during the RSV season

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Cystic Fibrosis	<ul style="list-style-type: none"> • For the first year of life, children with clinical evidence of CLD and/or nutritional compromise • For the second year of life, children with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) OR weight for length less than the 10th percentile.
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Abbreviations: CHD = congenital heart disease; CLD = chronic lung disease (formerly bronchopulmonary dysplasia); RSV = respiratory syncytial virus.

* Medical support includes supplemental oxygen, diuretic therapy, or chronic corticosteroid therapy.

Appendix B: Examples of Congenital Heart Anomalies*

- Atrial or ventricular septal defect
- Patent ductus arteriosus
- Coarctation of aorta
- Tetralogy of Fallot
- Pulmonary or aortic valve stenosis
- D-Transposition of great arteries
- Hypoplastic left/right ventricle
- Truncus arteriosus
- Total anomalous pulmonary venous return
- Tricuspid atresia
- Ebstein's anomaly
- Pulmonary atresia
- Single ventricle
- Double-outlet right ventricle

*Must be hemodynamically significant. See Table above for examples of infants and children who are most likely to benefit from Synagis

5. LIMITATIONS/EXCLUSIONS

- a. The safety and efficacy of Synagis have not been established for treatment of RSV disease.

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6. APPLICABLE PROCEDURE CODES

CPT	Description
90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each
S9562	Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

7. REFERENCES

- a. Synagis [package insert]. Gaithersburg, MD: MedImmune, LLC; May 2017.
- b. American Academy of Pediatrics. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):415-20.
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- d. Bernstein D. Epidemiology and Genetic Basis of Congenital Heart Disease. In: Kliegman RM, St. Geme J. Nelson Textbook of Pediatrics, Edition 21. Chap. 451. Philadelphia, PA: Elsevier; 2020. Accessed May 26, 2020.
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REVISION LOG:

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Approved:

Date:

Approved:

Date:

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Senior Medical Director

Sanjiv Shah, MD
Chief Medical Officer

Medical Guideline Disclaimer:

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