Department:	Pharmacy Management	**Original Approval:**	11/10/2014
Policy #:	PM109	**Last Approval:**	12/12/2018
Title:	Palivizumab (Synagis®)		
Approved By:	UM Committee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Palivizumab (Synagis): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Age -Weight -Dosing and duration requested -Labs/diagnostics -Prescribed by or in consultation with a cardiologist, intensivist, immunologist, transplant physician or infectious disease specialist as indicated.

BACKGROUND

Synagis is a humanized monoclonal antibody (IgG1K) that has neutralizing and fusion-inhibitory activity against respiratory syncytial virus (RSV). It is approved by the Food and Drug Administration (FDA) for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease:

- bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are ≤ 24 months of age at the beginning of the RSV season;
- history of premature birth (≤ 35 weeks gestational age) and who are ≤ 6 months of age at the beginning of the RSV season;
- hemodynamically significant congenital heart disease (CHD) who are ≤ 24 months of age at the beginning of the RSV season.

The American Academy of Pediatrics (AAP) revised their policy statement and modified their recommendations for use of Synagis for prevention of RSV infections in 2014.[2] A maximum of 5 monthly doses for all geographic locations is recommended regardless of the month when prophylaxis is started for CHD, chronic lung disease of prematurity (CLD), and premature infants/children born before 29 weeks' 0 days gestation. In the updated recommendations the only group of children who qualify for Synagis prophylaxis in the second year of life are those born < 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth and who continue to require supplemental oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of the start of the second RSV season.

The Centers for Disease Control and Prevention (CDC) published a report on RSV activity in the US from July 2012 to June 2014.[3] For the 2012/2013 season, RSV onset occurred the weeks ending October 27, 2012 and lasted 23 weeks until the week ending March 30, 2013. With Florida excluded, the national onset occurred 2 weeks after (November 10, 2012), and the season duration decreased by 2 weeks

compared with the national onset calculated with Florida data included. For the 2013/2014 season, RSV onset occurred the week ending November 9, 2013 and lasted 21 weeks until the week ending March 29, 2014. The season peak occurred the week ending December 28, 2013. Excluding Florida, the national onset occurred 1 week later (November 16, 2013), and the season duration decreased by 1 week compared with the national onset, including Florida. The national and regional RSV onsets for the 2013-2014 season were similar to patterns previously reported. Florida's season onset for the 2012/2013 season occurred 3 weeks earlier than in the 2011/2012 season and the 2013/2014 season onset occurred 2 weeks before the 2012/2013 season. Florida's earlier onset has been well documented, as have differences in activity from year-to-year in the same geographic location.

Synagis is available as preservative-free liquid in single-dose vials containing 50 mg in 0.5 mL or 100 mg in 1 mL.[1] Synagis is given by intramuscular (IM) injection preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. The dose per month is 15 mg per kg. If the injection volume is over 1 mL, the dose should be divided.

Guidelines

Below is a summary of recommendations from the AAP Policy Statement and Red Book.[2,8] **Groups recommended for a maximum of five monthly doses (5 months):**

Preterm Infants with CLD

- Prophylaxis may be considered during the RSV season during the first year of life for preterm infants who develop CLD of prematurity defined as < 32 weeks' gestation (≤ 31 weeks, 6 days) AND required > 21% oxygen for at least the first 28 days after birth.
- In the second year of life, prophylaxis is recommended only for infants who satisfy the above definition of CLD AND who continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

Preterm infants born before 29 weeks' gestation (≤ 28 weeks, 6 days)

- Synagis prophylaxis may be administered to infants born **≤** 28 weeks, 6 days' gestation who are < 12 months at the start of the RSV season. For infants born during the RSV season, fewer than 5 monthly doses will be needed.

Infants with anatomic pulmonary abnormalities or a neuromuscular disease

- Infants with a congenital anomaly or neuromuscular disease that impairs the ability to clear secretions from the upper airway because of ineffective cough may be considered for Synagis prophylaxis during the first year of life.

Infants with CHD

- Infants **≤** 12 months of age with hemodynamically significant CHD may benefit from prophylaxis with Synagis.
- Infants with CHD who are most likely to benefit from Synagis include: 1) infants with acynaotic heart disease who are receiving medication to control CHF and will require cardiac surgical

procedures; and 2) infants with moderate to severe pulmonary hypertension. Decisions regarding prophylaxis with Synagis for infants with cyanotic heart disease may be made in consultation with a pediatric cardiologist.

- The following group of infants are not at increased RSV risk and should generally not receive prophylaxis: 1) infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus); 2) infants with lesions adequately corrected by surgery, unless they continue to require heart failure medication; 3) infants with mild cardiomyopathy who are not receiving medical therapy for the condition; and 4) children in their second year of life.
- Following cardiopulmonary bypass or at the conclusion of extracorporeal membrane oxygenation, in children who are receiving Synagis prophylaxis, a postoperative dose (15 mg/kg) should be considered for infants and children < 24 months of age.
- Children < 2 years of age who undergo cardiac transplantation during RSV season may be considered for Synagis prophylaxis.

Immunocompromised children

- Prophylaxis may be considered for children < 24 months of age who are profoundly immunocompromised during the RSV season (e.g., receiving chemotherapy, transplantation).

Policy Statement

This policy involves the use of Synagis. Prior authorization is recommended for medical benefit coverage of Synagis. Coverage is recommended for those who meet the conditions of coverage in the **Criteria** and **Dosing. Waste Management** applies for all covered conditions. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. All approvals for initial therapy are provided for the initial approval duration noted below.

The seasonality of RSV varies by region, lasting November through March in most areas.[2,3] Because five monthly doses of Synagis at 15 mg/kg per dose will provide more than 6 months of serum Synagis concentrations for most infants, administration of more than five monthly doses is not recommended within the continental US.[8] Children who qualify for five monthly doses of Synagis should receive the first dose at the time of onset of the RSV season. For qualifying infants born during the RSV season, fewer than five monthly doses will be needed to provide protection until the RSV season ends in their region. For example, in regions where the season begins in November, if the child meets criteria in November, approve for 5 months; if patient meets criteria in December, approve for 4 months, etc. The RSV season in some areas of the US commences earlier than November, such as in Florida, where the onset may be as early as July. Despite varying onset and end dates of the RSV season in different regions of Florida, a maximum of five monthly doses of Synagis will be adequate for qualifying infants for most RSV seasons in Florida. Therefore, if a patient is eligible in July, approve 5 months, if a patient is eligible in August, approve 4 months, etc.

DEFINITIONS

None.

INDICATIONS/CRITERIA

Medicaid Members	***Continue to criteria for approval below.***
Medicare Members	***Step-utilization of Part D drugs not required.***

Coverage of Synagis for *prevention* of respiratory syncytial virus (RSV) is recommended in those who meet one of the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. Prevention of RSV Infection in an Infant With Chronic Lung Disease (CLD).

Criteria: *The patient must meet the one of the following conditions (a OR b)*:

A) Infants ≤ 1 year of age at the start of the RSV season.
- **i.** The infant was born at < 32 weeks, 0 days gestation; AND
- **ii.** The infant required > 21% oxygen for at least 28 days after birth.

OR

B) Infants ≤ 2 years of age at the start of the RSV season.
- **i.** The infant was born at < 32 weeks, 0 days gestation; AND
- **ii.** The infant required > 21% oxygen for at least 28 days after birth; AND
- **iii.** The child has required medical therapy (i.e., supplemental oxygen, diuretic therapy, or chronic corticosteroid therapy) during the 6 months before the start of the second RSV season.[2]

Dosing in Infants with CLD. *Dosing must meet the following:* 15 mg per kg once monthly given IM during the RSV season.[1]

The FDA-approved dose is 15 mg per kg once monthly during the RSV season.

Most children who are hospitalized with RSV are ≤ 1 year of age and < 20% of all pediatric RSV hospitalizations occur during the second year of life.[2] Regardless of the presence of absence of comorbidities, RSV hospitalization rates decline during the second RSV season for all children.

Initial Approval/Extended Approval.

Initial Approval: Approve a maximum of 5 months during the RSV season.

Extended Approval: Not applicable; administration of more than five monthly doses is not recommended.

Duration of Therapy in Infants with CLD. Up to 5 months.

Labs/Diagnostics. None required.

2. Prevention of RSV Infection in an Infant with Congenital Heart Disease (CHD).

Criteria. *The patient must meet the following criteria (a, b, AND c):*

- **A)** The infant is ≤ 1 year of age at the start of the RSV season;[1] AND
- **B)** The infant meets one of the following conditions (i, ii, iii, OR iv) according to the prescribing physician:
  - **i.** The infant is considered to have hemodynamically significant cyanotic CHD; OR
  - **ii.** The infant has acyanotic heart disease AND is receiving medication to control heart failure AND will require cardiac surgical procedures; OR
  - **iii.** The infant has moderate to severe pulmonary hypertension; OR
  - **iv.** The infant has lesions that have been adequately corrected by surgery AND continues to require medication for congestive heart failure; AND
- **C)** Synagis is prescribed by or in consultation with a cardiologist or intensivist

Dosing in Infants With CHD. *Dosing must meet the following:* 15 mg per kg once monthly given IM during the RSV season.[1]

The FDA-approved dose is 15 mg per kg once monthly during the RSV season.

Initial Approval/Extended Approval.
Approve a maximum of 5 months during the RSV season (lasting November through March in most areas).[2-3] [Example: If the child meets criteria in November, approve for 5 months; if patient meets criteria in December, approve for 4 months etc.] The RSV season in some areas of the US commences earlier than November, such as in Florida, where the onset may be as early as July.

Duration of Therapy in Infants With CHD.
Initial Approval: Approve a maximum of 5 months during the RSV season.
Extended Approval: Not applicable; administration of more than five monthly doses is not recommended.

A retrospective analysis of children aged < 3 years in the Tennessee Medicaid program revealed that the RSV hospitalization rate for children with CHD in the second year of life (18.2/1,000) was less than half the hospitalization rate for low-risk infants in the first 5 months after birth (44.1/1,000), a group for whom Synagis prophylaxis is not recommended. Therefore, prophylaxis is not recommended during the second year of life.

Labs/Diagnostics. None required.

3. Prevention of RSV in an Infant Born Prematurely.

Criteria. *The patient must meet the following criterion a.*

- **A)** The infant is ≤ 12 months of age at the start of the RSV season AND

B) The infant was born before 29 weeks, 0 days gestation (≤ 28 weeks, 6 days gestation).[2]

Dosing in an Infant Born Prematurely. *Dosing must meet the following*: 15 mg per kg once monthly given IM during the RSV season.[1]

Available data for infants born at 29 weeks, 0 days gestation or later do not identify clear gestational age cutoff for which the benefits of prophylaxis with Synagis are clear.[2] For this reason, infants born at 29 weeks, 0 days gestation or later are not universally recommended to receive Synagis unless they meet other conditions of coverage (e.g., CHD or CLD). Synagis is not recommended in the second year of life on the basis of prematurity alone.

Initial Approval/Extended Approval.

Initial Approval: Approve a maximum of 5 months during the RSV season.

Extended Approval: Not applicable; administration of more than five monthly doses is not recommended.

Duration of Therapy in an Infant Born Prematurely.

Prevention of RSV in a child ≤ 12 months of age and born at 28 weeks 6 days gestation or earlier: up to 5 months.

Labs/Diagnostics. None required.

Other Uses with Supportive Evidence

4. Prevention of RSV in an Infant with Congenital Anatomic Pulmonary Abnormalities or a Neuromuscular Disorder.

Criteria. *The patient must meet the following criteria (a AND b):*

A) Infant is ≤ 1 year of age at the start of the RSV season;[2] AND

B) According to the prescribing physician, the patient's condition compromises handling of respiratory secretions.

Dosing in an Infant with Congenital Anatomic Pulmonary Abnormalities or a Neuromuscular Disorder. *Dosing must meet the following:* 15 mg per kg once monthly given IM during the RSV season.[1]

The risk for hospitalization is not well defined in children with neuromuscular disorders that impair the ability to clear secretions from the upper airway because of ineffective cough, recurrent gastroesophageal tract reflux, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy.[2] Infants with neuromuscular disease or congenital anomaly that impairs the ability to clear airway secretions from the upper airway because of ineffective cough are known to be at risk for a prolonged hospitalization related to lower respiratory tract infection, and, therefore, may be considered for prophylaxis during the first year of life.

In the professional opinion of specialized physicians reviewing the data, children ≤ 1 year of age with an underlying condition that predisposes to respiratory complications are considered high-risk in the clinical practice setting and should receive Synagis.

Initial Approval/Extended Approval.

Initial Approval: Approve a maximum of 5 months during the RSV season.

Extended Approval: Not applicable; administration of more than five monthly doses is not recommended.

Duration of Therapy in an Infant with Congenital Anatomic Pulmonary Abnormalities or a Neuromuscular Disorder. Up to 5 months.

Labs/Diagnostics. None required.

5. Prevention of RSV in an Immunocompromised Child.

Criteria. *The patient must meet the following criteria (a, b, AND c)*:

- **A)** The child is < 24 months of age at the start of the RSV season; AND
- **B)** Synagis is prescribed by or in consultation with an immunologist or an infectious diseases specialist; AND
- **C)** According to the prescribing physician, the child is/will be profoundly immunocompromised during the RSV season (e.g., chemotherapy or transplant).

Guidelines note that that there are no population-based data on the incidence of RSV hospitalization in children who undergo solid organ transplantation.[2] Severe and even fatal disease attributed to RSV is recognized in children receiving chemotherapy because of other conditions, but the efficacy of prophylaxis in this cohort is not known. Prophylaxis may be considered for children < 24 months of age who are profoundly immunocompromised during the RSV season.

In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion.

Dosing in an Immunocompromised Child. *Dosing must meet the following:* 15 mg per kg once monthly given IM during the RSV season.

The FDA-approved dose is 15 mg per kg once monthly during the RSV season.

Initial Approval/Extended Approval.

Initial Approval: Approve a maximum of 5 months during the RSV season.

Extended Approval: Not applicable; administration of more than five monthly doses is not recommended.

Duration of Therapy in Severely Immunocompromised Children. Up to 5 months.

Labs/Diagnostics. None required.

6. Prevention of RSV in a Child with Cardiac Transplant.

Criteria. *The patient must meet the following criteria (a, b, AND c)*:

- **A)** The child is < 2 years of age at the start of the RSV season; AND
- **B)** The child has undergone or will undergo cardiac transplantation during the current RSV season; AND
- **C)** Synagis is prescribed by or in consultation with a cardiologist, intensivist, or transplant physician.

Note: Children with cardiac transplant may also be immunocompromised. In children who do not meet criteria for cardiac transplant below, please see criterion 5 above (Prevention of RSV in an Immunocompromised Child).

The AAP guidelines note that in children < 2 years of age who undergo cardiac transplantation during the RSV season may be considered for Synagis prophylaxis.[2]

Dosing in a Child with Cardiac Transplant. *Dosing must meet the following:* 15 mg per kg once monthly given IM during the RSV season.

Initial Approval/Extended Approval.

Initial Approval: Approve a maximum of 5 months during the RSV season.

Extended Approval: Not applicable; administration of more than five monthly doses is not recommended.

Duration of Therapy in a Child with Cardiac Transplant. Up to 5 months.

Labs/Diagnostics. None required.

Waste Management for All Indications.

The dose is 15 mg per kg with the dose being adjusted each month as the child's weight changes. The dose should be calculated and the number of vials needed assessed.

Conditions Not Recommended for Approval

Synagis has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. ***Treatment* of RSV Disease.** There are limited data investigating Synagis for the treatment of established RSV infections.[1-2,4] Passive antibody administration is not effective in treatment of RSV disease and is not approved or recommended for this indication.[2] If any infant or young child receiving monthly Synagis prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization (< 0.5%).

2. **Prevention of RSV in a Patient with Hematopoietic Stem Cell Transplant (Bone Marrow Transplant [BMT], Peripheral Blood, Placental or Cord Blood) Who Does Not Meet Any of the Approval Criteria Above.** Phase I studies in a total of 21 patients have evaluated Synagis in BMT patients.[5] Guidelines (2009) cosponsored by the Center for International Blood and Marrow Transplant Research (CIBMTR), National Marrow Donor Program (NMDP), European Blood and Marrow Transplant Group (EBMT), American Society for Blood and Marrow Transplant (ASBMT), Canadian Blood and Marrow Transplant Group (CBMTG), Infectious Diseases Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), Association of Medical Microbiology and Infectious Diseases (AMMI), the CDC, and the Health Resources and Services Administration address RSV prevention in patients with hematopoietic stem cell transplant.[6] These guidelines state preemptive aerosolized ribavirin is recommended by some for patients with RSV upper respiratory infection (URI), especially those with lymphopenia (during the first 3 months after hematopoietic stem cell transplant), and preexisting obstructive lung disease (late after hematopoietic stem cell transplant). The recommendation is based on retrospective studies as well as a prospective trial with inadequate accrual. Although a definitive, uniformly effective preemptive therapy for RSV infection among hematopoietic stem cell transplant recipients has not been identified, certain other strategies have been proposed, including systemic ribavirin, RSV antibodies (i.e., passive immunization with high RSV-titer intravenous immune globulin [IVIG], RSV immunoglobulin) in combination with aerosolized ribavirin, and RSV monoclonal antibody (mAb [e.g., Synagis]). No randomized trial has been completed to test the efficacy of these strategies; therefore, no specific recommendation regarding any of these strategies can be given at this time.

3. **Prevention of RSV in a Patient with Cystic Fibrosis (CF) Who Does Not Meet Any of the Approval Criteria Above.** The AAP guidelines for RSV (2014) note that routine use of Synagis prophylaxis in patients with CF, including neonates diagnosed with CF by newborn screening, is not recommended unless other indications are present.[2] An infant with CF with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for infants 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. A Cochrane Review identified one trial (presented in poster/abstract form) eligible for their review of Synagis prophylaxis in children with cystic fibrosis.[7] In this prospective, double-blind, placebo-controlled, multi-center study, 14.1% vs. 14.9% of Synagis and placebo-treated patients, respectively were hospitalized within the first 6 months, and only one patient in each group was identified with RSV infection. The authors calculated a risk ratio (RR) and found no significant difference between the two groups (RR 1.02; 95% confidence interval [CI]: 0.06, 16.09). There were no deaths in either group of participants during the first 6 months of follow-up; this outcome was not reported at 12 months follow-up.

4. **Prevention of RSV in a Patient with Down Syndrome Who Does Not Meet Any of the Approval Criteria Above.** Limited data suggest a slight increase in RSV hospitalization rates among children with Down syndrome.[2] However, data are insufficient to justify a recommendation for routine use of prophylaxis in children with Down syndrome unless qualifying heart disease, CLD, airway clearance issues, or prematurity is present. Multiple logistic-regression analyses of data from a 4-

year population-based prospective study revealed of the evaluated risk factors (male gender, child care attendance, smoke exposure, lack of breastfeeding, and other children in the house), only preterm birth and young chronologic age independently correlated with more severe RSV disease after adjusting for other covariates. In the professional opinion of specialized physicians reviewing the data, we have adopted this criterion.

5. **Wheezing, Prevention in Patients Who Do Not Meet Any of the Approval Criteria Above.** Prophylaxis with Synagis is not recommended for primary asthma prevention or to reduce subsequent episodes of wheezing.[2,4] In the professional opinion of specialized physicians reviewing the data, we have adopted this criterion.

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References	1. Synagis® injection [prescribing information]. Gaithersburg, MD: MedImmune LLC; May 2017. 2. Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants

and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics.* 134(2):415-420.
3. Centers for Disease Control and Prevention. Respiratory syncytial virus activity – United States, July 2012-June 2014. *MMWR*. 2015;63(48):1133-1136 Available at: http://www.cdc.gov/surveillance/nrevss/rsv/reports.html. Accessed on September 18, 2018.
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5. Boeckh M, Berrey MM, Bowden RA, et al. Phase 1 evaluation of the respiratory syncytial virus-specific monoclonal antibody palivizumab in recipients of hematopoietic stem cell transplants. *J Infect Dis.* 2001;184:350-354.
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OTHER REFERENCES UTILIZED

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Contract Citation	☐ WAH	
	☐ IMC	
	☐ MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
11/03/2014	Original	Kate Brostoff
11/10/2014	Approval	MMLT
10/29/2015	Updated to reflect American Academy of Pediatrics (AAP) policy revised in 2014.	Kelly Force; Kate Brostoff, MD
02/01/2016	Renumbered from UM235 to UM117	Compliance
02/02/2016	Approval	MMLT
04/10/2017	Updated format and references, reviewed content for accuracy and no updates made	Sophia Yun, PharmD
04/18/2017	Approval	MMLT
03/09/2018	Reassigned from UM to PM	Cindy Bush
04/25/2018	Transferred to new template	Cindy Bush
05/22/18	Policy review	Jennifer Farley, PharmD
06/14/2018	Approval	UM Committee
11/20/2018	Policy update due to ESI annual policy update	Jennifer Farley, PharmD
12/12/2018	Approval	UM Committee