

Medical Policy



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Blue Cross Blue Shield Association

Title: **Synagis (palivizumab)**

➤ **Prime Therapeutics will review Prior Authorization**

Prior Authorization Form:

<http://www.bcbsks.com/CustomService/Forms/pdf/PriorAuth-1302KS-SYNA.pdf>

Link to Drug List (Formulary):

<https://www.bcbsks.com/drugs/>

Professional

Original Effective Date: December 20, 2002
 Revision Date(s): October 31, 2002;
 February 1, 2003; February 1, 2004;
 November 1, 2005; July 1, 2006;
 November 2, 2006; March 22, 2007;
 June 1, 2007; December 7, 2009;
 December 9, 2011; October 26, 2012;
 October 16, 2013; October 9, 2014;
 November 4, 2014; September 1, 2015;
 October 1, 2016; October 25, 2017;
 October 1, 2018
 Current Effective Date: October 1, 2018

Institutional

Original Effective Date: February 1, 2007
 Revision Date(s): March 22, 2007;
 June 1, 2007; December 7, 2009;
 December 9, 2011; October 26, 2012;
 October 16, 2013; October 9, 2014;
 November 4, 2014; September 1, 2015;
 October 1, 2016; October 25, 2017;
 October 1, 2018

Current Effective Date: October 1, 2018

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

DESCRIPTION

The intent of the Synagis (palivizumab) Prior Authorization (PA) program is to ensure that patients prescribed therapy meet the selection requirements defined in product labeling and/or clinical guidelines and/or clinical studies. The PA defines appropriate use as the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV infection as defined by American Academy of Pediatrics (AAP) 2014 guidelines. Length of approvals will be as recommended by the AAP guidelines.

Target Agent

Brand	Generic	Dosage Form
Synagis®	palivizumab	injection

FDA Approved Indications and Dosage¹

Agent	Indication	Dosing and Administration
Synagis® (palivizumab) intramuscular injection	For prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients: <ul style="list-style-type: none"> • with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season • with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season • with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season 	15 mg/kg of body weight administered intramuscularly prior to commencement of the RSV season and remaining doses administered monthly throughout RSV season RSV season typically commences in November and lasts through April

POLICY**Prior Authorization (PA) Criteria for Approval**

Synagis (palivizumab) will be approved when the following are met:

1. The requested agent is being prescribed for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV)
AND
2. The prescriber has provided the patient's RSV season (eg, October to April)
AND
3. The requested agent will be used during the patient's current RSV season
AND
4. The patient has NOT been hospitalized for RSV infection during the current RSV season
AND
5. ONE of the following:
 - A. The patient was a preterm infant with gestational age < 29 weeks, 0 days AND the patient is younger than 12 months of age at the start of RSV season
OR
 - B. The patient has a diagnosis of chronic lung disease of prematurity AND ALL of the following:
 - 1) The patient was a preterm infant with gestational age < 32 weeks, 0 days
AND
 - 2) The patient required >21% supplemental oxygen for at least the first 28 days after birth
AND
 - 3) ONE of the following:
 - a. The patient is younger than 12 months of age at the start of RSV season
OR
 - b. The patient is 12 months to 24 months of age at the start of RSV season AND the patient continues to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of RSV season
 - C. The patient is profoundly immunocompromised during the current RSV season (eg, severe combined immunodeficiency, solid organ/hematopoietic stem cell transplant, undergoing chemotherapy, or advanced acquired immunodeficiency) AND the patient is 24 months of age or younger
OR
 - D. The patient has a diagnosis of cystic fibrosis AND ONE of the following:
 - 1) The patient is younger than 12 months of age at the start of RSV season AND has clinical evidence of chronic lung disease and/or nutritional compromise

- 2) The patient is 12 months to 24 months of age at the start of RSV season AND ONE of the following:
 - a. The patient has manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the patient's 1st year of life, abnormalities on chest radiography, or chest computed tomography that persists when the patient is stable)
OR
 - b. The patient has weight for length less than the 10th percentile
OR
- E. The patient has hemodynamically significant congenital heart disease AND ONE of the following:
 - 1) The patient requires cardiac transplantation during the current RSV season AND the patient is 24 months of age or younger during the start of RSV season
OR
 - 2) The patient is younger than 12 months of age at the start of RSV season AND ONE of the following:
 - a. The patient is an infant with lesions adequately corrected by surgery but still requires medication for congestive heart disease
OR
 - b. The patient has cyanotic heart disease AND is currently receiving medication to control congestive heart failure
OR
 - c. The patient has acyanotic heart disease AND BOTH of the following:
 - i. the patient is currently receiving medication to control congestive heart failure
AND
 - ii. the patient will require a cardiac surgical procedure
OR
 - d. The patient has moderate to severe pulmonary hypertension
OR
- F. The patient has either congenital abnormalities of the airway or a neuromuscular condition that impairs the ability to clear respiratory tract secretions because of an ineffective cough AND the patient is younger than 12 months of age at the start of RSV season
AND
6. The prescriber has provided the number of doses the patient has already received of the requested agent for the current RSV season, if applicable
AND
7. The patient has NOT received more than 5 doses of the requested agent for the current RSV season.

Length of Approval:

Up to 5 doses until the end of the RSV season.

RATIONALE

Respiratory syncytial virus (RSV) causes acute respiratory tract illness in patients of all ages.² Bronchiolitis is the most common viral lower respiratory tract infection and reason infants are hospitalized in the first year of life.^{3,4} The RSV season in the Northern hemisphere is typically November to April.^{2,5} The severity of the RSV season, the time of onset, the peak of activity, and the end of the season cannot be predicted precisely and there may be substantial variation in timing of community outbreaks from year to year in the same community and between communities in the same region.^{2,3,5} These overall variations, however, occur within the overall pattern of RSV outbreaks. Additionally, administration of more than 5 monthly doses is not recommended within the continental United States, which would provide more than 6 months of serum palivizumab concentrations above the desired level for the RSV season.⁵

The American Academy of Pediatrics (AAP) states the benefit from palivizumab is limited and prophylaxis has limited effect on RSV hospitalizations on a population basis, with no measurable effect on mortality and a minimal effect on subsequent wheezing. AAP recommends palivizumab use be restricted to the following populations:⁵

- Infants born before 29 weeks, 0 days' gestation or earlier and are younger than 12 months of age at the start of RSV season, without chronic lung disease (CLD) or congenital heart disease (CHD). Palivizumab prophylaxis is not recommended in the second year of life based on a history of prematurity alone.
- Infants born at 29 weeks, 0 days' gestation or later are not universally recommended to receive palivizumab prophylaxis but may qualify to receive prophylaxis on the basis of congenital heart disease (CHD), chronic lung disease (CLD), or another condition.
- Infants younger than 12 months old during RSV season, who were preterm infants who develop chronic lung disease of prematurity defined as gestational age (birth at) <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth. During the 2nd year (12-24 months) of life who develop chronic lung disease of prematurity defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth AND continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the 2nd RSV season.
- Infants younger than 12 months with hemodynamically significant CHD who are most likely to benefit from immunoprophylaxis include infants with acyanotic heart disease who are receiving medication to control congestive heart failure (CHF) and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension.
 - Infants younger than 12 months with cyanotic heart defects should consult with a pediatric cardiologist for a prophylaxis decision.
 - Infants/children with CHD that should NOT receive immunoprophylaxis are:
 - Those with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus).
 - Infants with lesions adequately corrected by surgery unless medication for CHD is required.
 - Infants with mild cardiomyopathy who are not receiving medical therapy
 - Children in 2nd year of life.
- Children younger than 24 months with hemodynamically significant CHD who are currently receiving prophylaxis and who continue to require it after a surgical procedure, a

post-operative dose should be considered after cardiac bypass or at the conclusion of extra-corporeal membrane oxygenation.

- Children younger than 24 months with hemodynamically significant CHD who are undergoing cardiac transplantation during the RSV season.
- Infants younger than 12 months with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough.
- May be considered in:
 - Children younger than 24 months who are profoundly immunocompromised during the RSV season.
 - Infants younger than 12 months with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise
 - Continuation into the 2nd year for infants with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the 1st 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.

The recommendation for RSV prophylaxis in premature infants without BPD varies upon degree of prematurity. Palivizumab is recommended for preterm infants without BPD⁶:

- ≤28 weeks, 6 days of gestation and are younger than 12 months of age at the start of RSV season.
- Preterm infants born between 29 and 32 weeks gestation, is based off risk factors for severe disease (eg, young age < 4 months during peak RSV season, prevalence of RSV in community, older siblings in home, etc) and out of pocket costs.
- There are no published studies to provide clear threshold of prematurity for which the benefit of palivizumab is definitive. Several population based and cohort studies suggest that the risk of RSV hospitalization among infants born at <29 weeks gestation is two to four times greater than in term infants but the risk of RSV hospitalization among infants born ≥32 weeks gestation is similar to term infants.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

90378 Respiratory syncytial virus, monoclonal antibody recombinant, for intramuscular use, 50 mg, each

REVISIONS

03-22-2007 effective	In "Policy" section 2, b., changed the word 'through' to 'to' and added '(i.e. 32 weeks, 0 days)'.
06-01-2007	In "Policy" section 2, c., changed '33' to '32' and added '(i.e. between 32 weeks, 1 day and 35 weeks, 0 days)'.

12-07-2009	<p>In Header:</p> <ul style="list-style-type: none"> ▪ Title changed to include "Synagis" ▪ Added links to information concerning Prior Authorization information and Prior Authorization forms.
	<p>In Description section:</p> <ul style="list-style-type: none"> ▪ Updated description.
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Updated policy with American Academy of Pediatrics (AAP) 2009 updated criteria for use of Palivizumab for prevention of respiratory syncytial virus infections From: "RSV-Ig is medically necessary and administered once a month during the RSV season (November through April) when the following apply: <ol style="list-style-type: none"> 1. CLD (Bronchopulmonary dysplasia) <ul style="list-style-type: none"> • Children less than two (2) years of age with CLD that have required medical treatment, i.e., oxygen, steroids, bronchodilators, for their CLD within the last six months. 2. Prematurity <ol style="list-style-type: none"> a. Infants born at 28 weeks of gestation or less may receive prophylaxis if less than or equal to 12 months (<12 months) of age at the start of RSV season. b. Infants born at 29 to 32 weeks of gestation (i.e. 32 weeks, 0 days) may receive prophylaxis if less than or equal to 6 months (<6 months) of age at the start of RSV season. c. Infants born at 32 to 35 weeks gestation (i.e. between 32 weeks, 1 day and 35 weeks, 0 days) <ol style="list-style-type: none"> 1) With CLD on medications or treatment (e.g. supplemental oxygen, bronchodilator, diuretic or corticosteroid therapy) within the past six months or 2) Prophylaxis of infants without CLD should be reserved for only those infants who are at the greatest risk of severe infection as defined by two or more of the following risk factors: child care attendance, school-aged siblings, exposure to environmental air pollutants (excluding caregiver smoking), congenital abnormalities of the airways, or severe neuromuscular disease (causing significant respiratory impairment) and less than or equal to six months (<6 months) of age at the start of the RSV season. 3. Heart Disease <ol style="list-style-type: none"> a. Because of the decrease in palivizumab (Synagis®) after the use of cardiopulmonary bypass, a post-operative dose of palivizumab (Synagis®) should be considered. b. Prophylaxis for infants younger than 24 months of age with congenital heart disease is considered medically necessary for an infant (must meet only one of the following): <ol style="list-style-type: none"> 1) Receiving medication to control congestive heart failure, or 2) With moderate to severe pulmonary hypertension, or 3) With cyanotic heart disease. 4. Although specific recommendations for all immunocompromised patients cannot be made, children with severe immunodeficiencies may benefit from RSV-Ig. Providers may consider substituting RSV-Ig during the RSV season for patients receiving IGIV monthly. 5. Treatment for RSV may be administered in the physician's office, outpatient setting, outpatient hospital setting, or a home health visit. <p>Not Medically Necessary</p> <ol style="list-style-type: none"> 1. Prophylaxis is not considered medically necessary for: <ol style="list-style-type: none"> a. An infant with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis,

	<p>uncomplicated aortic stenosis, mild coarctation of the aorta and patent ductus arteriosus),</p> <p>b. An infant with lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure, or</p> <p>c. An infant with mild cardiomyopathy who is not receiving medical therapy.</p> <p>d. Children greater than two years of age."</p> <p>To the current policy language.</p>
	<p>In Rationale section:</p> <ul style="list-style-type: none"> ▪ Rationale section added.
	<p>Coding section deleted.</p>
12-09-2011	<p>Formatting changes to the Policy section.</p>
	<p>Updated Rationale.</p>
	<p>Updated References.</p>
10-26-2012	<p>In the Policy section:</p> <ul style="list-style-type: none"> • In Item #5, moved "(supplemental oxygen, bronchodilator, diuretic, or chronic corticosteroid therapy)" after "medical therapy" to read "Chronological age is less than 24 months at the start of RSV season and the patient has required medical therapy (supplemental oxygen, bronchodilator, diuretic, or chronic corticosteroid therapy)..."
10-16-2013	<p>In Policy Title, removed "(Respiratory Syncytial Virus [RSV]) Prior Authorization Criteria" to read "Synagis".</p>
	<p>Updated Links to Prior Authorization</p>
	<p>Updated Rationale section.</p>
	<p>Added Coding section.</p>
	<p>Updated Reference section.</p>
10-09-2014	<p>Description section updated</p>
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Updated policy with American Academy of Pediatric (AAP) 2014 Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection <p>From:</p> <p>"Synagis will be approved for patients who have not exceeded the maximum recommended doses of palivizumab for the current respiratory syncytial virus (RSV) season (five doses per season EXCEPT for patients born between 32 weeks, 0 days and 34 weeks, 6 days gestation whose age at the beginning of RSV season is less than 3 months. These patients are limited to 3 doses per season.) if ONE of the following is met:</p> <ol style="list-style-type: none"> 1. Gestational age is 28 weeks (28 weeks 6 days) or less and chronological age at the beginning of RSV season is twelve months or less OR 2. Gestational age is greater than 29 weeks (29 weeks, 0 days) but less than 32 weeks (31 weeks, 6 days) and chronological age at the beginning of RSV season will be less than or equal to six months OR 3. Gestational age is 32 weeks or greater (32 weeks, 0 days) but less than 35 weeks (34 weeks, 6 days) and chronological age at the beginning of RSV season is less than 90 days and the patient has at least one of the following two risk factors; 1) child care attendance (defined as a home or facility where care is provided for any number of infants or young toddlers in the child care facility), or 2) one or more siblings or other children younger than 5 years of age live permanently in the same household OR 4. Chronological age is less than 24 months at the start of RSV season and the patient is diagnosed with congenital heart disease, with one of the following factors; requires cardiopulmonary bypass during the current RSV season (one additional dose is allowed if patient has surgery requiring cardiopulmonary bypass during

	<p>prophylaxis therapy), patient is receiving medication to control congestive heart failure, patient has cyanotic heart disease, or patient has moderate to severe pulmonary hypertension OR</p> <p>5. Chronological age is less than 24 months at the start of RSV season and the patient has required medical therapy (supplemental oxygen, bronchodilator, diuretic, or chronic corticosteroid therapy) for chronic lung disease within the six months prior to the beginning of RSV season OR</p> <p>6. Chronological age is less than 24 months at the start of RSV season and the patient has been diagnosed with severe immunodeficiency (e.g., severe combined immunodeficiency or advanced acquired immunodeficiency) OR</p> <p>7. Chronologic age is less than 12 months at the start of RSV season and patient has either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory tract secretions</p> <p>Length of approval: Approvals will be for up to 5 doses until March 31 EXCEPT:</p> <ul style="list-style-type: none"> • Patients whose gestational age at the start of RSV season is 32 weeks or greater (32 weeks, 0 days) but less than 35 weeks (34 weeks, 6 days) and chronological age at the beginning of RSV season is less than 90 days (approval for up to 3 doses until age 90 days) • Patients with CHD requiring surgery involving cardiopulmonary bypass during RSV prophylaxis therapy (approval for one extra dose)" <p>To the current policy language.</p>
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> ▪ CPT coding confirmed
	References updated
11-04-2014	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ In Item #2, A., 7), added, "a) The patient has cyanotic heart disease AND ALL of: i. The patient is receiving medication to control congestive heart failure, AND ii. The prescriber is a pediatric cardiologist or has consulted with a pediatric cardiologist." <p>In Rationale section:</p> <ul style="list-style-type: none"> ▪ Removed the "Table 1. Maximum Number of Synagis (palivisumab) Doses for RSV Prophylaxis of Preterm Infants Without Chronic Lung Disease (CLD), Based on Birth Date and Gestational Age (Shown for Areas Beginning Prophylaxis on November 1st)" table.
09-01-2015	Updated Description section.
10-01-2016	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Added new Item 2 A 7 a, "The patient is an infant with lesions adequately corrected by surgery but still requires medication for congenital heart disease (CHD) AND the following: i. The prescriber is a pediatric cardiologist or has consulted with a pediatric cardiologist". ▪ Re-lettered remaining items in Item 2 A 7. <p>Updated References section.</p>
10-25-2017	Updated Description section.
	Updated References section.
10-01-2018	<p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Removed previous policy language: "Synagis (palivizumab) will be approved for patients who have not exceeded the maximum recommended doses of palivizumab for the current respiratory syncytial virus (RSV) season when the following criteria are met: 1. The patient has not received the maximum recommended doses of Synagis (palivizumab) for the current respiratory syncytial virus (RSV) season AND

	<p>2. ONE of the following</p> <p>A. Patient's chronological age at the start of the RSV season is less than 12 months AND ONE of the following:</p> <ol style="list-style-type: none"> 1) Gestational age is <29 weeks 0 days OR 2) The patient was a preterm infant who developed chronic lung disease of prematurity defined as gestational age (birth at) <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth OR 3) The patient is profoundly immunocompromised during the RSV season (eg, severe combined immunodeficiency, solid organ/hematopoietic stem cell transplant, undergoing chemotherapy, or advanced acquired immunodeficiency) OR 4) The patient has either congenital abnormalities of the airway or a neuromuscular condition that impairs the ability to clear respiratory tract secretions because of an ineffective cough OR 5) The patient has cystic fibrosis (CF) AND clinical evidence of chronic lung disease (CLD) and/or nutritional compromise OR 6) The patient has hemodynamically significant congenital heart disease and requires cardiac transplantation during the current RSV season OR 7) The patient has hemodynamically significant congenital heart disease AND ONE of the following <ol style="list-style-type: none"> a) The patient is an infant with lesions adequately corrected by surgery but still requires medication for congenital heart disease (CHD) AND the following: <ol style="list-style-type: none"> i. The prescriber is a pediatric cardiologist or has consulted with a pediatric cardiologist b) The patient has cyanotic heart disease AND ALL of: <ol style="list-style-type: none"> i. The patient is receiving medication to control congestive heart failure AND ii. The prescriber is a pediatric cardiologist or has consulted with a pediatric cardiologist_OR c) The patient has acyanotic heart disease and the patient is receiving medication to control congestive heart failure AND the patient will require a cardiac surgical procedure OR d) The patient has moderate to severe pulmonary hypertension OR <p>B. Patient's chronological age at the start of the RSV season is 12 months to 24 months AND ONE of the following:</p> <ol style="list-style-type: none"> 1) The patient has hemodynamically significant congenital heart disease and requires cardiac transplantation during the current RSV season OR 2) The patient has chronic lung disease of prematurity (defined as gestational age <32 weeks, 0 days, and a requirement for >21% oxygen for at least the first 28 days after birth) AND continues to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the 2nd RSV season OR 3) The patient is profoundly immunocompromised during the RSV season (eg, severe combined immunodeficiency, solid organ/hematopoietic stem cell transplant, undergoing chemotherapy, or advanced acquired immunodeficiency) OR 4) The patient has cystic fibrosis (CF) AND manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the 1st year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or has weight for length less than the 10th percentile
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	<p>Length of approval: Up to 5 doses until March 31 EXCEPT the following:</p> <ul style="list-style-type: none"> • Patients who have hemodynamically significant congenital heart disease and who will undergo a surgical procedure involving cardiopulmonary bypass or extra-corporeal membrane oxygenation during the RSV season and who will continue to require prophylaxis after the surgical procedure may receive one extra dose of Synagis (palivizumab) after bypass or at the conclusion of the extra-corporeal membrane oxygenation (up to 6 doses per RSV season)." <p>▪ Added current policy language: Synagis (palivizumab) will be approved when the following are met:</p> <ol style="list-style-type: none"> 1. The requested agent is being prescribed for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) AND 2. The prescriber has provided the patient's RSV season (eg, October to April) AND 3. The requested agent will be used during the patient's current RSV season AND 4. The patient has NOT been hospitalized for RSV infection during the current RSV season AND 5. ONE of the following: <ol style="list-style-type: none"> A. The patient was a preterm infant with gestational age < 29 weeks, 0 days AND the patient is younger than 12 months of age at the start of RSV season OR B. The patient has a diagnosis of chronic lung disease of prematurity AND ALL of the following: <ol style="list-style-type: none"> 1) The patient was a preterm infant with gestational age < 32 weeks, 0 days AND 2) The patient required >21% supplemental oxygen for at least the first 28 days after birth AND 3) ONE of the following: <ol style="list-style-type: none"> a. The patient is younger than 12 months of age at the start of RSV season OR b. The patient is 12 months to 24 months of age at the start of RSV season AND the patient continues to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of RSV season OR C. The patient is profoundly immunocompromised during the current RSV season (eg, severe combined immunodeficiency, solid organ/hematopoietic stem cell transplant, undergoing chemotherapy, or advanced acquired immunodeficiency) AND the patient is 24 months of age or younger OR D. The patient has a diagnosis of cystic fibrosis AND ONE of the following: <ol style="list-style-type: none"> 1) The patient is younger than 12 months of age at the start of RSV season AND has clinical evidence of chronic lung disease and/or nutritional compromise 2) The patient is 12 months to 24 months of age at the start of RSV season AND ONE of the following: <ol style="list-style-type: none"> a. The patient has manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the patient's 1st year of life, abnormalities on chest radiography, or chest computed tomography that persists when the patient is stable) OR b. The patient has weight for length less than the 10th percentile OR E. The patient has hemodynamically significant congenital heart disease AND ONE of the following:
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	<ol style="list-style-type: none"> 1) The patient requires cardiac transplantation during the current RSV season AND the patient is 24 months of age or younger during the start of RSV season OR 2) The patient is younger than 12 months of age at the start of RSV season AND ONE of the following: <ol style="list-style-type: none"> a) The patient is an infant with lesions adequately corrected by surgery but still requires medication for congestive heart disease OR b) the patient has cyanotic heart disease AND is currently receiving medication to control congestive heart failure OR c) The patient has acyanotic heart disease AND BOTH of the following: <ol style="list-style-type: none"> i. the patient is currently receiving medication to control congestive heart failure AND ii. the patient will require a cardiac surgical procedure OR d) The patient has moderate to severe pulmonary hypertension OR F. The patient has either congenital abnormalities of the airway or a neuromuscular condition that impairs the ability to clear respiratory tract secretions because of an ineffective cough AND the patient is younger than 12 months of age at the start of RSV season AND 6. The prescriber has provided the number of doses the patient has already received of the requested agent for the current RSV season, if applicable AND 7. The patient has NOT received more than 5 doses of the requested agent for the current RSV season. <p>Length of Approval: Up to 5 doses until the end of the RSV season.”</p>
	Updated Rationale section.
	Updated References section.

REFERENCES

1. Synagis prescribing information. Medimmune, Inc. May 2017.
2. Barr, Frederick E., MD, et al. Respiratory Syncytial Virus Infection: Clinical Features and Diagnosis. UpToDate. Last updated July 2017.
3. Smith, Dustin K, Do, et al. Respiratory Syncytial Virus Bronchiolitis in Children. *American Family Physicians*. January 2017; Vol 95 (2):94-99.
4. Sexton, Sumi, MD, et al. AAP Releases Practice Guideline on Diagnosis, Management, and Prevention of Bronchiolitis. *American Family Physicians*. April 2015. Vol 91 (8): 578-581.
5. The American Academy of Pediatrics. Policy Statement: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics*. August 2014. Vol 134 (2): 415-420.
6. Barr, Frederick E., MD, et al. Respiratory Syncytial Virus Infection: Prevention. UpToDate. Last updated March 2018.

Other References

1. Blue Cross and Blue Shield of Kansas Family Practice Liaison Committee, July 11, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC-03-06).
2. Blue Cross and Blue Shield of Kansas Liaison Pediatric Committee, August 2, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC-03-06).
3. Blue Cross and Blue Shield of Kansas Medical Advisory Committee (MAC) meeting, November 2, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC-03-06).
4. Blue Cross and Blue Shield of Kansas Medical Consultant, Practicing Board Certified Pediatrician (202), December 2005.

5. Blue Cross and Blue Shield of Kansas Family Medicine Liaison Committee, July 2007; July 2009; July 2010; February 2018.
6. Blue Cross and Blue Shield of Kansas Pediatric Liaison Committee, August 2007, August 2008, July 2009, July 2011; July 2015; May 2017.
7. Blue Cross and Blue Shield of Kansas Medical Consultant, Practicing Board Certified Pediatrician (535), January 2009.
8. Blue Cross and Blue Shield of Kansas Family Practice Liaison Committee CB, November 2009.