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Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	**Date Approved:** 12/06/2023
Pharmacy Clinical Policy Document: Synagis Prior Authorization	**Replaces Effective Policy Dated:** 12/07/2022
Reference #: PC/S005	**Page:** 1 of 4

PURPOSE:
The intent of the Synagis Prior Authorization Pharmacy Clinical Policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria – Must satisfy all of the following: I and II

I. Indications – must satisfy any of the following: A - F

A. Member born before 29 weeks, 0 days' gestation who is less than 12 months of age at the beginning of the RSV season; or

B. Member diagnosed with *Chronic Lung Disease (CLD) of prematurity* – must satisfy: 1, and either 2 or 3
1. Born before 32 weeks, 0 days' gestation; and

2. Less than or equal to 12 months of age during the RSV season and required greater than 21% oxygen for at least the first 28 days after birth; or

3. Between 13 to less than 24 months of age – must meet both of the following: a and b
a. The member required greater than 21% oxygen for at least the first 28 days after birth; and
b. The member still requires medical support (eg, chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

C. Member diagnosed with hemodynamically significant congenital heart disease (CHD) – must satisfy any of the following: 1 or 2
1. Initial request - less than or equal to 12 months of age, born within 12 months of onset of the RSV season – must satisfy any of the following: a - c

a. *Acyanotic heart defect* – must meet both of the following: i and ii
i. The member is receiving medication to control congestive heart failure; and
ii. The member will require cardiac surgical procedures.

b. Moderate to severe *pulmonary hypertension*; or

c. *Cyanotic heart defect* in the first year of life with documentation of decision for prophylaxis made in consultation with a pediatric cardiologist.

2. Additional dose request - less than 24 months of age and the prescriber is requesting one additional postoperative dose of Synagis for prophylaxis – must meet any of the following: a or b
   a. The member has undergone cardiac transplantation during the RSV season; or
   b. The member has undergone cardiac bypass or after extracorporeal membrane oxygenation during the RSV season.

   [Note: One additional dose will be approved if medically necessary.]

D. Member diagnosed with anatomic pulmonary abnormalities or neuromuscular disorders – must satisfy both of the following: 1 and 2
   1. Less than 12 months of age; and

   2. The member's anatomic pulmonary abnormalities (eg, pulmonary malformations, tracheoesophageal fistula, conditions requiring tracheostomy) or neuromuscular disorders (eg, cerebral palsy) impair the member's ability to clear secretions from the upper airway because of ineffective cough.

E. Member is profoundly immunocompromised (eg, solid organ transplantation, hematopoietic stem cell transplantation, severe combined immunodeficiency syndrome) and is less than 24 months of age during the RSV season.

F. Member diagnosed with cystic fibrosis – must satisfy either of the following: 1 or 2
   1. Less than 12 months of age with evidence of CLD and/or nutritional compromise; or

   2. Between 12 to 24 months of age – must meet either of the following: a or b
      a. Manifestations of severe lung disease (ie, 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
      b. Weight for length is less than the 10th percentile on the pediatric growth chart.

II. Dosing – Allowed dose must follow the Dosing Allowance policy (see Attachment A).

III. Duration - Approve up to 5 monthly injections during the RSV season, typically November 1 to March 31, or determined in real time by identifying the first week of two consecutive weeks that RSV RT-PCR test positivity is greater than or equal to 3% or antigen detection positivity is greater than or equal to 10% (according to CDC RSV Surveillance for a particular member's state of residence).

DEFINITIONS:

Acyanotic heart defect:
An acyanotic heart defect, also known as non-cyanotic heart defect, is a class of congenital heart disease. In these, blood is shunted (flows) from the left side of the heart to the right side of the heart due to a structural defect (hole) in the septum. People often retain normal levels of oxyhemoglobin saturation in systemic circulation. Examples include atrial septal defect (ASD), patent ductus arteriosus (PDA), and ventricular septal defect (VSD).

Chronic Lung Disease of prematurity:
Requiring supplemental oxygen for at least 28 days after birth

Cyanotic heart defect:
A group-type of congenital heart defect that occurs due to deoxygenated blood bypassing the lungs and entering the systemic circulation or a mixture of oxygenated and unoxygenated blood entering the systemic circulation. It is caused by structural defects of the heart (i.e.: right-to-left, bidirectional shunting, malposition of the great arteries), or any condition which increases pulmonary vascular resistance with the result being the development of collateral circulation. Examples include coarctation of the aorta, hypoplastic left heart, pulmonary atresia, Tetralogy of Fallot, transposition of the great arteries, tricuspid valve abnormalities, truncus arteriosus, and total anomalous pulmonary venous connection.

Pulmonary hypertension:
It is an increase in pulmonary artery pressure. In congenital heart disease it is caused by pulmonary over circulation, pulmonary vasoconstriction, and pulmonary vascular disease, either alone in combination. Grading is based on pulmonary artery pressures (PAP) and functional limitations. Moderate to severe pulmonary hypertension is a PA systolic pressure greater than or equal to 70 mm/Hg; diastolic pressure greater than or equal to 26 mm/Hg; and/or a mean pressure of greater than 40 mm/Hg.

BACKGROUND:
Synagis (palivizumab) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. The American Academy of Pediatrics (AAP) has issued an updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for RSV.

This clinical policy is based on U.S. Food and Drug Administration (FDA) approved indications, expert consensus opinion and/or available reliable evidence.

Prior Authorization: Yes, per network provider agreement - Approve 1 injection monthly during the defined RSV season up until March 31. Extended durations beyond March will be determined by that particular RSV season as defined above.

[Note: Initiation of Synagis prophylaxis after the start of a typical RSV season will not require all 5 doses.]

Coverage is subject to the member's contract benefits.

Form: Synagis (palivizumab) Authorization Form

CODING:
CPT/HCPCS
90378 Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each

REFERENCES:
1. Medical Management Process Manual UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines

3. Pharmacy Clinical Policy: PP/T002 Therapeutic Equivalence
4. American Academy of Pediatrics (AAP). Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics* 2014;134(2): 415-420. Retrieved from https://pediatrics.aappublications.org/content/134/2/415?ijkey=f5605e522dffca37d900343e5b875e07d577cb2f&keytype2=tf_ipsecsha. Reaffirmed February 2019. Accessed 10-14-2023.
5. Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV) [website]. 2020. Retrieved from https://www.cdc.gov/rsv/index.html. Accessed 10-14-2023.
6. Synagis [package insert] Gaithersburg, MD; MedImmune, LLC 2021.

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Attachment A

Dosing Allowance

The calculated dose of Synagis is 15 mg/kg. Because this drug is available only in 50 mg and 100 mg vials, and costs approximately $1,000 per 50 mg, there is the potential for significant waste. Follow the table below, which shows a 10% difference in allowed dose from the calculated dose.

Weight	Calculated dose (max wt.) (15 mg/kg)	Allowed Dose	Dispense
0 to 3.6 kg	54 mg	50 mg	One 50 mg vial
3.7 to 7.3 kg	110 mg	100 mg	One 100 mg vial
7.4 to 11.1 kg	166.5 mg	150 mg	One 100 mg and one 50 mg vials
11.2 to 14.6 kg	220 mg	200 mg	Two 100 mg vials
14.7 to 18.1 kg	271.5 mg	250 mg	Two 100 mg and one 50 mg vials

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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