Medical Policy:

Synagis (Palivizumab)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.18	January 3, 2024	March 2016

Definitions

Synagis is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the preservation of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.

Guideline

Up to a maximum of 5 monthly doses of Synagis (15 mg/kg body weight per dose) are considered medically necessary during the RSV season and the last dose is in March. Coverage of Synagis is contingent on the member meeting one of the following criteria:

1. Early Preterm Infants:
    a. Infants born before 29 weeks, 0 days' gestation who are ≤ 12months of age at the start of RSV season
2. Preterm Infants with Chronic Lung Disease of Prematurity (CLD)/Bronchopulmonary dysplasia (BPD):
    a. </= 12 months of age:

        - Preterm infants who develop CLD/BPD of prematurity (defined as gestational age <32 weeks, 0 days and a requirement for > 21% of oxygen for at least the first 28 days after birth)
    b. 12 – 24 months of age:
        - Preterm infants who develop CLD/BPD of prematurity **and** continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season
3. Infants with hemodynamically significant Congenital Heart Disease (CHD):
    a. < 12 months of age:
        - Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures
        - Infants with cyanotic heart defects
        - Infants with moderate to severe pulmonary hypertension
    b. < 24 months of age:
        - Children who undergo cardiac transplantation during RSV season
4. Children with Anatomic Pulmonary Abnomalities or Neuromuscular Discorder:
    a. Children < 12 months of age with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
5. Immunocompromised children:
    a. Children < 24 months of age who are profoundly immunocompromised during the RSV season
        - Examples of severe immunodeficiencies are:
            - Severe combined immunodeficiency
            - Severe acquired immunodeficiency syndrome
            - Acute myeloid leukemia / acute lymphoblastic leukemia
            - Hematopoietic stem cell transplant recipients
6. Cystic Fibrosis:
    a. < 12 months of age:
        - Infants with cystic fibrosis with clinical evidence of CLD/BPD and/or nutritional compromise
    b. 12–24 months of age:
        - Children with cystic fibrosis who have 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 < the 10th percentile

Note: For infants and children < 24 months of age who are receiving Synagis prophylaxis and continue to require prophylaxis after a surgical procedure, a postoperative dose of 15 mg/kg should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation.

Limitations/Exclusions

Synagis is not considered medically necessary when any of the following are applicable due to insufficient evidence or therapeutic value:

1. Infants with cardiac lesions adequately corrected by surgery (unless pharmacological management is required for CHF)
2. Infants with CLD not requiring medical support in the 2nd year of life
3. Infants with mild cardiomyopathy, which does not require pharmacotherapy
4. Synagis use as routine prophylaxis for any of the following conditions
    a. Cystic fibrosis (unless Guideline indications present)
    b. Down syndrome (unless qualifying heart disease, CLD/BPD, airway clearance issues or prematurity [<29 weeks, 0 day's gestation] is present)

c. Nosocomial disease prevention
a. Primary asthma prevention (or for reduction of subsequent wheezing episodes) in infants and children

5. Synagis use as prophylaxis in any of the following scenarios:
    d. Outside of RSV “season”
    e. Dosing > necessary to provide protection in RSV “season”
    f. In excess of 5 doses per single RSV “season”
    g. Monthly Synagis administration as prophylaxis post breakthrough RSV hospitalization during the current season (if child had met criteria for palivizumab).
6. Treatment of symptomatic RSV disease
7. Use in a Patient who has Received Beyfortus (nirsevimab-alip intramuscular injection) in the Same RSV Season.

Applicable Procedure Codes

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

Applicable NDCs

Code	Description
6658-0230-01	Palivizumab 50mg/0.5mL
60574-4114-01	Palivizumab 50mg/0.5mL
66658-0231-01	Palivizumab 100mg/1mL
60574-4113-01	Palivizumab 100mg/1mL

ICD-10 Diagnoses

Code	Description
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.8	Other immunodeficiencies with predominantly antibody defects
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
P07.21	Extreme immaturity of newborn, gestational age less than 23 completed weeks
P07.22	Extreme immaturity of newborn, gestational age 23 completed weeks
P07.23	Extreme immaturity of newborn, gestational age 24 completed weeks
P07.24	Extreme immaturity of newborn, gestational age 25 completed weeks
P07.25	Extreme immaturity of newborn, gestational age 26 completed weeks
P07.26	Extreme immaturity of newborn, gestational age 27 completed weeks
P07.31	Preterm newborn, gestational age 28 completed weeks

P07.32	Preterm newborn, gestational age 29 completed weeks
P07.33	Preterm newborn, gestational age 30 completed weeks
P07.34	Preterm newborn, gestational age 31 completed weeks
P07.35	Preterm newborn, gestational age 32 completed weeks
P07.36	Preterm newborn, gestational age 33 completed weeks
P07.37	Preterm newborn, gestational age 34 completed weeks
P27.1	Bronchopulmonary dysplasia originating in the perinatal period
P27.8	Other chronic respiratory diseases originating in the perinatal period
P27.9	Unspecified chronic respiratory disease originating in the perinatal period
P29.30	Pulmonary hypertension of newborn (Eff. 10/01/2017)
P29.38	Other persistent fetal circulation (Eff. 10/01/2017)
Q20.0	Common arterial trunk
Q20.1	Double outlet right ventricle
Q20.2	Double outlet left ventricle
Q20.3	Discordant ventriculoarterial connection
Q20.4	Double inlet ventricle
Q20.5	Discordant atrioventricular connection
Q20.6	Isomerism of atrial appendages
Q20.8	Other congenital malformations of cardiac chambers and connections
Q20.9	Congenital malformation of cardiac chambers and connections, unspecified
Q21.0	Ventricular septal defect
Q21.1	Atrial septal defect
Q21.2	Atrioventricular septal defect
Q21.3	Tetralogy of Fallot
Q21.4	Aortopulmonary septal defect
Q21.8	Other congenital malformations of cardiac septa
Q21.9	Congenital malformation of cardiac septum, unspecified
Q22.0	Pulmonary valve atresia
Q22.1	Congenital pulmonary valve stenosis
Q22.2	Congenital pulmonary valve insufficiency
Q22.3	Other congenital malformations of pulmonary valve
Q22.4	Congenital tricuspid stenosis
Q22.5	Ebstein's anomaly
Q22.6	Hypoplastic right heart syndrome
Q22.8	Other congenital malformations of tricuspid valve
Q22.9	Congenital malformation of tricuspid valve, unspecified
Q23.0	Congenital stenosis of aortic valve
Q23.1	Congenital insufficiency of aortic valve
Q23.2	Congenital mitral stenosis
Q23.3	Congenital mitral insufficiency
Q23.4	Hypoplastic left heart syndrome
Q23.8	Other congenital malformations of aortic and mitral valves
Q23.9	Congenital malformation of aortic and mitral valves, unspecified
Q24.0	Dextrocardia
Q24.1	Levocardia
Q24.2	Cor triatriatum

Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis
Q24.5	Malformation of coronary vessels
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
Q24.9	Congenital malformation of heart, unspecified
Q25.0	Patent ductus arteriosus
Q25.1	Coarctation of aorta
Q25.21	Interruption of aortic arch
Q25.29	Other atresia of aorta
Q25.3	Supravalvular aortic stenosis
Q25.40	Congenital malformation of aorta unspecified
Q25.41	Absence and aplasia of aorta
Q25.42	Hypoplasia of aorta
Q25.43	Congenital aneurysm of aorta
Q25.44	Congenital dilation of aorta
Q25.45	Double aortic arch
Q25.46	Tortuous aortic arch
Q25.47	Right aortic arch
Q25.48	Anomalous origin of subclavian artery
Q25.49	Other congenital malformations of aorta
Q25.5	Atresia of pulmonary artery
Q25.6	Stenosis of pulmonary artery
Q25.71	Coarctation of pulmonary artery
Q25.72	Congenital pulmonary arteriovenous malformation
Q25.79	Other congenital malformations of pulmonary artery
Q25.8	Other congenital malformations of other great arteries
Q25.9	Congenital malformation of great arteries, unspecified
Q26.0	Congenital stenosis of vena cava
Q26.1	Persistent left superior vena cava
Q26.2	Total anomalous pulmonary venous connection
Q26.3	Partial anomalous pulmonary venous connection
Q26.4	Anomalous pulmonary venous connection, unspecified
Q26.8	Other congenital malformations of great veins
Q26.9	Congenital malformation of great vein, unspecified
Q33.0	Congenital cystic lung
Q33.1	Accessory lobe of lung
Q33.2	Sequestration of lung
Q33.4	Agenesis of lung
Q33.5	Ectopic tissue in lung
Q33.6	Congenital hypoplasia and dysplasia of lung
Q33.8	Other congenital malformations of lung
Q33.9	Congenital malformation of lung, unspecified
Z23	Encounter for immunization

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/3/2024	Annual Review: Limitations and Exclusions: Added: Use in a Patient who has Received Beyfortus (nirsevimab-alip intramuscular injection) in the Same RSV Season."
EmblemHealth & ConnectiCare	4/27/2023	Annual Review- no criteria changes
EmblemHealth & ConnectiCare	1/13/2023	Transfer to New Template
EmblemHealth & ConnectiCare	12/30/2020	Annual review: no policy changes
EmblemHealth & ConnectiCare	9/30/2019	Guidelines – under Preterm infants with chronic lung disease, section a, added - </= 12 months of age. Additionally, under guidelines #2 - Preterm infants with bronchopulmonary dysplasia per FDA insert
EmblemHealth & ConnectiCare	10/14/2016	Prior authorization criteria updated based on the 2014 AAP updates guidance on use of palivizumab for RSV prophylaxis.

References

1. Groothuis JR, Simoes EA, Levin MJ, et al. Prophylactic administration of respiratory syncytial virus immune globulin to high-risk infants and young children. *N Engl J Med*. 1993;329(21):1524-30.
2. Wegzyn C, Toh, LK, Notario G, et al. Safety and Effectiveness of Palivizumab in Children at High Risk of Serious Disease Due to Respiratory Syncytial Virus Infection: A Systematic Review. *Infect Dis Ther*. 2014 Dec; 3(2): 133–158.
3. Centers for Disease Control and Prevention. Respiratory Syncytial Virus Activity - United States, July 2012-January 2014. MMWR. December 5, 2014 / 63(48);1133-1136.
4. Hall CB, Weinberg GA, Iwane MK, et al. The Burden of Respiratory Syncytial Virus Infection in Young Children. *N Eng J Med*. 2009;360(6):588-98.
5. Simoes E, Groothuis JR, Carbonell-Estrany X, et al. Palivizumab prophylaxis, respiratory syncytial virus, and subsequent recurrent wheezing. *J Pediatr*. 2007;151(1):34-42, 42.e1.
6. Robinson KA, Odelola OA, Saldanha IJ. Palivizumab for prophylaxis against respiratory syncytial virus infection in children with cystic fibrosis. Cochrane Database Syst Rev. 2014 May 22;5:CD007743.
7. Synagis [prescribing information]. Gaithersburg, MD: Medimmune, LLC. November 2020.
8. AAP updates guidance on use of palivizumab for RSV prophylaxis (Policy Statement). AAP News 2014; 35:8 1.
9. AAP updates guidance on use of palivizumab for RSV prophylaxis (Technical Report) AAP News 2014; 35:8 1.
10. Panozzo CA, Stockman LJ, Curns AT, et al. Use of respiratory syncytial virus surveillance data to optimize the timing of immunoprophylaxis. *Pediatrics*. 2010 Jul;126(1):e116-23.