Medical Policy

Synagis® (palivizumab)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-059
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Synagis® (palivizumab) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

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* with the last dose given in March.

Synagis is approved for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients who meet **at least one** of the following criteria:

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1. Early Preterm Infants
    a. Infants born before 29 weeks, 0 days' gestation and younger than 12 months of age at the start of RSV season

2. Chronic Lung Disease of Prematurity (CLD)/Bronchopulmonary dysplasia (BPD)
    a. Infants younger than 12 months of age at the start of RSV season:
        i. 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. Infants between 12 – 24 months of age at the start of RSV season:
        i. 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) AND continue to require medical intervention (e.g., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) within the 6-month period before the start of the child's second RSV season

3. Hemodynamically significant Congenital Heart Disease (CHD)
    a. Infants younger than 24 months of age at the start of RSV season with **one** of the following:
        i. Acyanotic heart disease who are receiving medication to control congestive heart failure (CHF) AND will require cardiac surgical procedures
        ii. Cyanotic heart defects
        iii. Moderate to severe pulmonary hypertension
        iv. Will undergo cardiac transplantation during RSV season

4. Anatomic Pulmonary Abnormalities or Neuromuscular Disorder
    a. Infants younger than 12 months of age at the start of RSV season with a neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough/swallow

5. Immunocompromised status
    a. Infants younger than 24 months of age at the start of RSV season and are profoundly immunocompromised during the RSV season
        i. Examples of severe immunodeficiencies are:
            1. Severe combined immunodeficiency
            2. Severe acquired immunodeficiency syndrome
            3. Acute myeloid leukemia / acute lymphoblastic leukemia
            4. Chemotherapy
            5. Solid organ or hematopoietic stem cell transplant recipients

6. Cystic Fibrosis:
    a. Infants younger than 12 months of age at the start of RSV season:
        i. With clinical evidence of CLD/BPD and/or nutritional compromise
    b. Infants between 12–24 months of age at the start of RSV season:

i. For second year treatment, infant has manifestations of severe lung disease including one of the following:
    1. Previous hospitalization for pulmonary exacerbation in the first year of life
    2. Abnormalities on chest radiography or chest computed tomography that persist when stable
    3. Weight for length less than the 10th percentile on a pediatric growth chart

*In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of Synagis administration.9 Despite varied onsets, the RSV "season" is of the same duration (5 months) in the different regions of Florida. For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% and RSV "season" offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is ≥ 10%. Use of specimens to determine the start of the RSV "season" requires that the number of specimens tested be statistically significant.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Infants with cardiac lesions adequately corrected by surgery (unless pharmacological management is required for CHF)
3. Infants with CLD not requiring medical support in the 2nd year of life
4. Infants with mild cardiomyopathy, which does not require pharmacotherapy
5. 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 [less than 29 weeks, 0 day's gestation] is present)
    c. Nosocomial disease prevention
    d. Primary asthma prevention (or for reduction of subsequent wheezing episodes) in infants and children
6. Synagis use as prophylaxis in any of the following scenarios:
    a. Outside of RSV "season" as defined by Centers for Disease and Prevention (CDC) surveillance reports or state or local health departments
    b. Dosing in excess of 5 doses per single RSV "season" as defined by Centers for Disease and Prevention (CDC) surveillance reports or state or local health departments

c. Monthly Synagis administration as prophylaxis post breakthrough RSV hospitalization during the current season (if child had met criteria for palivizumab)

7. Treatment of symptomatic RSV disease

BACKGROUND

Synagis (palivizumab) 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 pediatric patients at high risk of RSV disease.

DEFINITIONS

1. SYNAGIS (palivizumab) injection, for intramuscular use. Initial U.S. Approval: 1998
   a. Synagis is supplied in single-dose vials as a preservative-free, sterile liquid solution at 100 mg per mL for intramuscular injection.
   b. The 50 mg vial contains 50 mg Synagis in 0.5 mL.
   c. The 100 mg vial contains 100 mg Synagis in 1 mL.
   d. The rubber stopper used for sealing vials of Synagis is not made with natural rubber latex.

CODING

Applicable NDC Codes	
60574-4114-01	Synagis 50 mg/0.5 mL Intramuscular vial (0.5 mL)
60574-4113-01	Synagis 100 mg/1 mL Intramuscular vial (1 mL)

Applicable Procedure Code	
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

Applicable ICD-10 Codes	
PREMATURITY (≤35 WEEKS GA)	
P07.21	Extreme immaturity of newborn, GA <23 completed weeks
P07.22	Extreme immaturity of newborn, GA 23 completed weeks
P07.23	Extreme immaturity of newborn, GA 24 completed weeks
P07.24	Extreme immaturity of newborn, GA 25 completed weeks
P07.25	Extreme immaturity of newborn, GA 26 completed weeks
P07.26	Extreme immaturity of newborn, GA 27 completed weeks
P07.31	Preterm newborn, GA 28 completed weeks
P07.32	Preterm newborn, GA 29 completed weeks
P07.33	Preterm newborn, GA 30 completed weeks
P07.34	Preterm newborn, GA 31 completed weeks
P07.35	Preterm newborn, GA 32 completed weeks

P07.36	Preterm newborn, GA 33 completed weeks
P07.37	Preterm newborn, GA 34 completed weeks
P07.38	Preterm newborn, GA 35 completed weeks
BRONCHOPULMONARY DYSPLASIA/CHRONIC LUNG DISEASE OF PREMATURITY	
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
HEMODYNAMICALLY SIGNIFICANT CONGENITAL HEART DISEASE	
I42.9	Cardiomyopathy, unspecified
I50.9	Heart failure, unspecified
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
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
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
Q24.1	Levocardia
Q24.2	Cor triatriatum
Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis
Q24.5	Malformation of coronary vessels
Q24.8	Other specified congenital malformations of heart

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
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
PATIENT HISTORY	
Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)

EVIDENCE BASED REFERENCES

1. Product Information: SYNAGIS(R) intramuscular injection, palivizumab intramuscular injection. MedImmune, LLC (per FDA), Gaithersburg, MD, 2017.

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. November 8, 2022: Annual review – no changes made. March 1, 2023: Adopted by MA UM Committee – no changes made. January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 11/8/2022