Synagis (palivizumab)
Policy Number: C6074-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
4/1/2019	9/9/2020	9/9/2021
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
90378-Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use 50mg, ea.	RxPA	Q4 2020 20201028C6074-A

PRODUCTS AFFECTED:
Synagis (palivizumab)

DRUG CLASS:
Antiviral Monoclonal Antibodies

ROUTE OF ADMINISTRATION:
Intramuscular

PLACE OF SERVICE:
Specialty Pharmacy or Buy and Bill
The recommendation is that medications in this policy will be for pharmacy benefit coverage and the IV infusion products administered in a place of service that is a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center).

AVAILABLE DOSAGE FORMS:
Synagis SOLN 50MG/0.5M and 100MG/ML single-dose liquid solution vials

FDA-APPROVED USES:
prevention of serious lower respiratory tract disease caused by RSV in children at high risk of Respiratory Syncytial Virus (RSV) disease. Safety and efficacy of Synagis have not been established for the treatment of RSV disease

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
prevention of Respiratory Syncytial Virus (RSV)

REQUIRED MEDICAL INFORMATION:
PREVENTION OF RSV FOR THE FOLLOWING MEMBER SCENARIOS-
A. CHRONIC LUNG DISEASE OF PREMATURITY:
1. (a_ Infants ≤ 1 year of age at the start of the RSV season must meet the following criteria: The infant was born at < 32 weeks, 0 days gestation; AND 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 must meet the following criteria: The infant was born at < 32 weeks, 0 days gestation AND the infant required > 21% oxygen

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for at least 28 days after birth AND 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

B. HEMODYNAMICALLY SIGNIFICANT CONGENITAL HEART DISEASE:
1. The infant is ≤ 12 months of age at the start of the RSV season with hemodynamically significant congenital heart disease
AND
2. The infant meets one of the following conditions according to the prescribing physician: (a) The infant is considered to have hemodynamically significant cyanotic CHD by a cardiologist recommendation (e.g.,Transposition of the great arteries, Tetralogy of Fallot, etc).; OR (b) The infant has a cyanotic heart disease AND is receiving medication to control heart failure AND will require cardiac surgical procedures; OR (c) The infant has moderate to severe pulmonary hypertension
AND
3. Synagis is prescribed by or in consultation with a cardiologist or intensivist.

C. CONGENTICAL ABNORMALITY OF THE AIRWAY/NEUROMUSCULAR CONDITION:
1. The infant is ≤ 1 year of age at the start of the RSV season
AND
2. Documentation the patient's condition compromises handling of respiratory secretions.

D. PREMATURITY:
1. The infant is ≤ 12 months of age at the start of the RSV season
AND
2. The infant was born before 29 weeks, 0 days gestation (≤ 28 weeks, 6 days gestation) NOTE: Synagis is not recommended in the second year of life on the basis of prematurity alone

E. IMMUNOCOMPROMISED:
1. The child is < 24 months of age at the start of the RSV season
AND
2. Synagis is prescribed by or in consultation with an immunologist or an infectious diseases specialist
AND
3. According to the prescribing physician, the child is/will be profoundly immunocompromised during the RSV season (e.g., chemotherapy or transplant)

F. CARDIAC TRANSPLANT:
1. The child is < 2 years of age at the start of the RSV season
AND
2. The child has undergone or will undergo cardiac transplantation during the current RSV season
AND
3. Synagis is prescribed by or in consultation with a cardiologist, intensivist, or transplant physician.

DURATION OF APPROVAL:
Approve a maximum of 5 months during the RSV season.

QUANTITY:
Per AAP guidelines, up to a maximum of 5 doses (15mg/kg) during RSV season

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(November-April) provides 6 months of RSV prophylaxis.
*Qualifying infants born during the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March or April, depending on the end of the season.

PRESCRIBER REQUIREMENTS:
per RMI if applicable

AGE RESTRICTIONS:
per RMI

CONTINUATION OF THERAPY:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Synagis® will not be approved in the following scenarios: Gestational age greater than or equal to 29 weeks, 0 days (otherwise healthy), Asthma prevention, To reduce wheezing episodes, Down Syndrome (otherwise healthy), Diagnosis of Cystic Fibrosis (otherwise healthy), Healthcare-associated RSV disease, Breakthrough RSV
hospitalization, Hemodynamically insignificant CHD (Secundum atrial septal defect, Small ventricular septal defect, Pulmonic stenosis, Uncomplicated aortic stenosis, Mild coarctation of the aorta, Patent ductus arteriosus), Congenital Heart Disease lesions corrected by surgery (unless Member continue to require CHF meds), Congenital Heart Disease and mild cardiomyopathy not on medical therapy, For patients greater than 12 months of age at the onset of RSV season (Based on prematurity alone), Diagnosis of Chronic Lung Disease of Prematurity without medical support (chronic systemic steroids, diuretic therapy, or supplemental O2), Diagnosis of Congenital Heart Disease and Otherwise healthy children in 2nd year of life.
TREATMENT OF RSV OR TREATMENT OF BREAKTHROUGH RSV is not an indication and will not be approved. The safety and efficacy of Synagis have not been established for treatment of RSV disease
Synagis is NOT recommended for infants with cystic fibrosis or Down syndrome unless other indications are also present.
Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the RSV season to infants who qualify for prophylaxis in the first year of life.
Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.

OTHER SPECIAL CONSIDERATIONS:
For dose requests outside of the RSV season the provider must submit a letter of medical necessity AND current local virology information showing virology >
10% for the most recent two consecutive weeks.

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

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patients with at least one of the following : 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. Additionally, the AAP Red Book was updated in 2018.8 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 seasonality of RSV varies by region, lasting November through March in most areas. 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 Member 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 Member is eligible in July, approve 5 months, if a Member is eligible in August, approve 4 months, etc.

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, Member records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

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