Palivizumab (Synagis®)

RSV Prevention

Place of Service
Hospital Administration
Office Administration
Home Infusion Administration
Infusion Center Administration
Outpatient Facility Administration*
[*Prior authorization required – see section (1)]

HCPCS: 90378 per 50 mg

Conditions listed in Policy (*see criteria for details*)

- Prevention of RSV infection

AHFS therapeutic class: Antiviral monoclonal antibody

Mechanism of action: Respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable: ASO/Shared Advantage/HMO (non-direct contract),** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive Synagis injections in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION
MCG™ Care Guidelines, 19th edition, 2015

ADMINISTRATION OF SYNAGIS IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted to support the need for additional clinical monitoring)*

1. **Patient is receiving their first dose or is being re-initiated after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on the medication based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events on the medication based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

Synagis® [Prescribing information]. 11/2021., Pediatrics. 2014;134(2):415-420

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Synagis® (palivizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Prevention of RSV infection and meets one of the following:

1. **Gestational age before 29 weeks** *(i.e., less than 29 weeks and 0 days)* and less than 12 months of age at anticipated start of RSV season *(i.e., <12 months and 0 days)* **OR**
2. **Chronic lung disease (CLD) of prematurity in the FIRST year of life** and both of the following:
    a. Birth at less than 32 weeks, 0 days gestation **AND**
    b. Requirement for more than 21% oxygen for at least 28 days after birth

    OR
3. **CLD of prematurity in the SECOND year of life** and all of the following:
    a. Birth at less than 32 weeks, 0 days gestation, **AND**
    b. Requirement for more than 21% oxygen for at least 28 days after birth, **AND**
    c. Requirement of continued medical support during the 6 month period before the start of the 2nd RSV season (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen)

    OR
4. **Congenital heart disease (CHD) and** all of the following:
    a. Hemodynamically significant CHD, **AND**
    b. Either of the following:
        i. Less than or equal to 12 months or younger, and one of the following:
            1. Acyanotic heart disease receiving medication to control CHF and will require cardiac surgical procedures, OR
            2. Moderate to severe pulmonary hypertension, OR
            3. Cyanotic heart disease if consulted with a pediatric cardiologist

        OR

        ii. Less than 24 months or younger, and one of the following:
            1. Cardiopulmonary bypass or extracorporeal membrane oxygenation and continues to require prophylaxis post-operatively, OR
            2. Cardiac transplant during RSV season

    OR
5. **Cystic fibrosis** and meets one of the following:
    a. Less than or equal to 12 months of age (first year of life), and evidence of chronic lung disease and/or nutritional compromise, OR
    b. More than 12 months of age to less than or equal to 24 months of age (second year of life) and either of the following:

i. 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
ii. Weight for length < 10th percentile

OR

6. **Pulmonary abnormality or neuromuscular disease** and both of the following:
   a. First year of life, **AND**
   b. Inability to clear secretions from upper airway due to medical condition

OR

7. **Immunocompromised** and both of the following:
   a. Less than 24 months of age, **AND**
   b. Infant is profoundly immunocompromised (e.g. solid organ transplant, HSCT, chemotherapy, etc.)

OR

8. **Down syndrome** and meets either point 2, 3, 4, or 7

Covered Doses
15 mg/kg IM once per month during RSV season up to a maximum of 5 doses

Qualifying infants born during the RSV season may require fewer than 5 doses

Synagis is administered once per month (e.g. every 30 days), beginning at the onset of the RSV season, which typically occurs in November.

Synagis should be discontinued in any child who experiences a breakthrough RSV hospitalization. *There is an extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).*

ICD-10:
E86.X (X = any number), P07.21-P07.26, P07.31-P07.35, P22.0, Q32.0-Q32.4, P27.0, P27.1, P27.8, P27.9, Q20.9, Q22.0-Q22.9, Q24.0-Q24.9, G70.2, G70.89, G70.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Synagis® (palivizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

1. Infants and children with hemodynamically insignificant heart disease:
    a. Secundum atrial septal defect
    b. Small ventricular septal defect
    c. Pulmonic stenosis
    d. Uncomplicated aortic stenosis
    e. Mild coarctation of the aorta
    f. Patent ductus arteriosus
2. Infants with lesions adequately corrected by surgery unless they continue to require medication for CHF
3. Infants with mild cardiomyopathy who are not receiving medical therapy
4. Treatment of RSV disease

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:
50 mg, 100 mg (Single-dose preservative-free vials)

Sources for documenting the RSV season has been extended or delayed:
CDC National Respiratory and Enteric Virus Surveillance System (NREVSS)
http://www.cdc.gov/surveillance/nrevss/rsv/state.html
or
DHS
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/Influenza.aspx

BPD = bronchopulmonary dysplasia; now replaced with the term called CLD = chronic lung disease

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- American Academy of Pediatrics Committee on Infectious Diseases, American Academy of Pediatrics Bronchiolitis Guidelines Committee. 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.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Goldstein M, et al. National Perinatal Association 2018 Respiratory Syncytial Virus (RSV) Prevention Clinical Practice Guideline: An Evidence-Based Interdisciplinary Collaboration Peer Reviewed New Guideline. Neonatology Today. 12(10) 1-14.
- Synagis® (palivizumab) [Prescribing information]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; 11/2021.

(7) Policy Update

Date of last review: 4Q2023
Date of next review: 4Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.