Update to Synagis (palivizumab) Protocol
Approved January 2024

Background:

Respiratory Syncytial Virus (RSV) is a common respiratory virus that usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can be serious. Infants and older adults are more likely to develop severe RSV and require hospitalization.

Synagis (palivizumab) is a respiratory syncytial virus F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients

Synagis is authorized during New Jersey's RSV season. Consideration will be given for requests received outside New Jersey's normal RSV season.

Updates includes expanded eligibility for 4 classes of patients, and exclusion for Beyfortus.

1. Impaired ability to clear secretions
2. Cystic fibrosis
3. Severe immunodeficiencies
4. Cardiac transplant

Criteria for Approval:

A. Prematurity

1. Patient is < 12 months of age at the start of the RSV season
2. Patient's gestational age is less than 29 weeks, 0 days

B. Chronic Lung Disease (CLD) of Prematurity

1. Patient is < 12 months of age at the start of the RSV season and has ALL the following:
    a. Diagnosis of CLD; **AND**
    b. Gestational age < 32 weeks, 0 days; **AND**
    c. Required greater than 21 percent oxygen for the first 28 days of life; **OR**
2. Patient is < 24 months of age at the start of the RSV season and has ALL the following:
    a. Diagnosis of CLD; **AND**
    b. Gestational age < 32 weeks, 0 days; **AND**
    c. Required greater than 21 percent oxygen for the first 28 days of life; **AND**
    d. Required medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6 months period before the start of the current RSV season

C. Hemodynamically Significant Congenital Heart Disease (CHD)

1. Patient is < 12 months of age at the start of the RSV season and has ALL the following:
2. Diagnosis of hemodynamically significant CHD including the following:
    a. Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures
    b. Infants with moderate to severe pulmonary hypertension

D. Impaired ability to clear secretions

1. Patient is < 12 months of age at the start of the RSV season and has either congenital abnormalities of the airway or a neuromuscular condition that impairs the ability to clear secretions from the upper airway.

E. Cystic fibrosis

1. Patients is < 12 months of age at the start of the RSV season and meets the following:
    a. Clinical evidence of CLD **OR**
    b. Nutritional compromise (defined as weight is at or below the 10th percentile based on growth charts)
2. Patients is < 24 months of age at the start of the RSV season and meets the following:
    a. 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**
    b. Nutritional compromise (defined as weight is at or below the 10th percentile based on growth charts)

F. Severe Immunodeficiencies

1. Patient is < 24 months of age at the start of the RSV season and has severe immunodeficiencies (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, receiving chemotherapy).

G. Cardiac Transplant

1. Patient is < 24 months of age at the start of the RSV season and has had cardiac transplantation

Exclusions

1. Patient has received Beyfortus (nirsevimab) in the current RSV season
2. Patient must not have experienced breakthrough RSV hospitalization during the current RSV season

Approval Duration and Quantity Restrictions:
Durations are variable; will typically run until the end of the RSV season and for a maximum of 5 doses

References:

1. Synagis [package insert]. Sobi Inc. Waltham, MA. November 2021
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically
3. Caserta MT, O'Leary ST, Munoz FM, et al; Committee on Infectious Diseases. Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Pediatrics. 2023;152(1):e2023061803
4. CDC Health Alert Network. Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season. October 2023. 5. American Academy of Pediatrics. Policy statement – updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014; 134(2):415-20.
5. American Academy of Pediatrics. Errata - RSV policy statement – updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014;134(6):1221
6. American Academy of Pediatrics News and Journals. RSV recommendations unchanged after review of new data. Available at https://www.aappublications.org/news/2017/10/19/RSV101917. October 2017. Accessed July 16, 2019.
7. American Academy of Pediatrics. Policy statement – modified recommendations use of Palivizumab for prevention of respiratory syncytial virus infections. Pediatrics. 2009;124:1694-1701.