Synagis® (Palivizumab) 2020-2021 Authorization Guidelines

September 3, 2020

Respiratory Syncytial Virus (RSV) can cause a variety of respiratory illness in infants and young children. It most commonly causes a cold like illness but can also cause lower respiratory infections like bronchitis and pneumonia.

Synagis® (Palivizumab) is a monoclonal antibody recommended by the American Academy of Pediatrics (AAP) to be administered to high-risk infants and young children likely to benefit from immunoprophylaxis for RSV, based on gestational age and certain underlying conditions. Palivizumab 15mg/kg is administered intramuscularly once per month for a maximum of five doses from November through March, the peak RSV months. Palivizumab is not effective for the treatment of RSV disease.

The Alliance's utilization criteria listed in Synagis policy 403-1120 follows the current AAP recommendations. The Alliance will cover Synagis for members who meet Conditions of Usage outlined in the Alliance's Synagis policy.

For providers who wish to administer Synagis in their office, the Statement of Medical Necessity form is required to be submitted along with the prior authorization request.

These guidelines follow American Academy of Pediatrics (AAP) recommendations.

DIAGNOSIS	
Age 0-12 months at RSV season onset ☐ Infant born < 29 weeks, 0 days gestation at birth. ☐ Preterm infant with Chronic Lung Disease (CLD) of prematurity defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth. ☐ Infant with hemodynamically significant Congenital Heart Disease (CHD) such as infants with acyanotic heart disease who are receiving medication to control Congestive Heart Failure and will require cardiac surgical procedure and infants with moderate to severe pulmonary hypertension.	**Age 12 - <24 months at RSV season onset** ☐ Preterm Infant with Chronic Lung Disease (CLD) of prematurity, who continued to require supplemental oxygen, chronic systemic corticosteroids or diuretic therapy during the 6-months period before to the start of second RSV season. ☐ Child who undergo cardiac transplantation during the RSV Season ☐ Profound immunocompromised during the RSV season. ☐ Infant with Cystic Fibrosis and manifestations of severe lung disease or weight for length <10th percentile

☐ Infant with cyanotic heart defects if deemed warranted by the infant's pediatric cardiologist. ☐ Infant who undergo cardiac transplantation during the RSV Season. ☐ Infant with neuromuscular disease, significant respiratory disease or congenital anomaly that impairs the ability to clear secretions from the upper airway due to ineffective cough. ☐ Profound immunocompromised during the RSV season. ☐ Infant with Cystic Fibrosis and clinical evidence of Chronic Lung Disease of prematurity and/or Nutritional compromise.	

DOSING

☐ Was a NICU/Hospital Dose Administered to the patient? Yes_____ No _____

☐ Expected Date of First/Next Injection_____

Synagis 15mg/kg IM every month Nov through March: Dose based on current weight _____

Alliance Authorization

Submit Alliance prior authorization forms by fax to (831) 430-5851. A single form is required for the series. Please indicate infant weight on the form. For providers administering Synagis in their office, also submit a completed "Statement of Medical Necessity" form found on the Alliance website, Pharmacy Page: http://www.ccah-alliance.org/pharmacy.html.

Alliance Synagis Ordering and Billing Information

For providers that administer Synagis in their office, the Alliance specialty pharmacy, US Bioservices, must be used. CCAH staff will notify US Bioservices when Synagis has been authorized.

US Bioservices contact Information: Phone (888) 518-7246 and Fax (888) 418-7246. Thank you for caring for young, at risk infants.

If you have any questions about the Synagis recommendations, please call Yasuno Sato, Pharm D., Clinical Pharmacy Manager at (831) 430-5952.


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