A Public Entity
Inland Empire Health Plan

Drug Prior Authorization Criteria
Synagis (palivizumab)

Line of Business: Medicaid
P & T Approval Date: August 21, 2019 **Effective Date:** October 1, 2019

This drug prior authorization criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and was approved by the IEHP Pharmacy and Therapeutics Subcommittee.

CRITERIA:

RSV Season

- To be determined by The National Respiratory and Enteric Virus Surveillance System (NREVSS)
- As defined by the NREVSS: RSV season is over when virology is < 10% for 2 consecutive weeks

Infants with Chronic Lung Disease (CLD) of Prematurity

- Younger than 12 months
- Born less than 32 weeks GA (31 weeks, 6 days or less)
- Requirement for >21% oxygen for at least 28 days after birth
- Maximum of 5 monthly doses may be provided during RSV season
- A second season of palivizumab prophylaxis is recommended for patients with CLD of prematurity who satisfied the above criteria and continue to receive medical therapy (chronic corticosteroid therapy, diuretic therapy or supplemental oxygen) during the 6-month period before the start of the second RSV season

Infants born before 29 weeks GA (28 weeks, 6 days or less)

- Younger than 12 months
- Maximum of 5 monthly doses may be provided during RSV season

Infants with anatomic pulmonary abnormalities of the airway or neuromuscular disorder

- Patients with impaired ability to clear secretions from the upper airway during the first year of life
- Maximum of 5 doses during the first year of life

Infants and children with congenital heart disease

- Children who are 12 months of age or younger with hemodynamically significant acyanotic congenital heart disease:
    - Infants who are receiving medication to control congestive heart failure and will require cardiac surgical procedures
    - Infants with moderate to severe pulmonary hypertension
- Children younger than 2 years who undergo cardiac transplantation during the RSV season
- Maximum of 5 doses may be provided

- For children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab (15mg/kg) should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months

Immunocompromised children

- Children younger than 24 months of age who are profoundly immunocompromised (e.g., severe combined immunodeficiency or advanced acquired immunodeficiency syndrome) during the RSV season
- Maximum of 5 doses may be provided

Patients with cystic fibrosis

- Infants with cystic fibrosis with clinical evidence of CLD and/or who are nutritionally compromised in the first year of life
- Infants with manifestation of severe lung disease in the second year of life (e.g. previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography, chest computed tomography that persist when stable) or weight for length less than 10^{th} percentile
- Maximum of 5 doses may be provided

Other considerations

- Palivizumab prophylaxis should be discontinued for children receiving monthly prophylaxis and experiencing breakthrough RSV hospitalization
- The following groups of infants generally **<u>should not</u>** receive immunoprophylaxis:
    - Children in the second year of life on the basis of a history of prematurity alone
    - Infants and children with hemodynamically insignificant heart disease (e.g. secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
    - Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
    - Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
    - Children with Down syndrome (unless qualifying heart disease, CLD, airway clearance issues, or prematurity less than 29 weeks)
- Hospitalized infants who qualify for prophylaxis during the RSV season should receive the first dose of palivizumab 48 to 72 hours before discharge or promptly after discharge
- RSV is known to be transmitted in the hospital setting and to cause serious disease in high-risk infants. Among hospitalized infants, the major means to reduce RSV transmission is strict observance of infection control practices, including prompt initiation of precautions for RSV-infected infants. If an RSV outbreak occurs in a high-risk unit (e.g. pediatric or neonatal intensive care unit or stem cell transplantation unit), primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use in controlling outbreaks of health care- associated disease, and palivizumab use is not recommended for this purpose
- Palivizumab does not interfere with response to vaccines

References:

1. 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.
2. Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV). Available at: https://www.cdc.gov/surveillance/nrevss/rsv/index.html. Accessed 08/05/2019.
3. California Department of Health Care Services. Palivizumab (Synagis). *N.L.* 13-0914, September 19, 2014. Available at https://www.dhcs.ca.gov/services/ccs/Documents/ccsnl130914.pdf. Accessed 08/05/2019.

Change Control		
Date	**Change**	**Author**
08/21/2019	• Updated RSV season definition to be determined by the NREVSS • Added references section	ND
08/15/2018	• Reformatted document (heading) • Updated RSV season year to 2018-2019 • Renew and no change to criteria	HC