

**RECOMMENDATIONS  
FOR SYNAGIS  
2018-2019  
CPT Code 96372**

The American Academy of Pediatrics (AAP) recommends the use of palivizumab (Synagis), an RSV monoclonal antibody vaccine, to prevent serious RSV illness in qualifying high-risk infants. The 2014 AAP recommendations (Red Book 29<sup>th</sup> edition) as well as the 2014 CCS Synagis Guidelines (NL: 13-0914) are incorporated into the following HPSJ Synagis Qualification Criteria:

**Who Qualifies for Synagis Prophylaxis?**

**Criteria eligible for coverage through HPSJ:**

| <b>Patients meeting one of the following criteria during RSV season (Nov 1<sup>st</sup> – Mar 31<sup>st</sup>)</b>   |                       |
|--|-----------------------|
| • Infant born before 29 weeks gestation and less than 12 months of age at start of RSV season.   | Up to 5 doses         |
| • Infant born at before 32 weeks gestation with Chronic Lung Disease (CLD) and require >21% oxygen for at least 28 days after birth  | Up to 5 doses         |
| • Infants <12 months born with hemodynamically significant heart disease (i.e. acyanotic heart disease requiring cardiac surgery and receiving medication(s) to control congestive heart failure or moderate-severe pulmonary hypertension)                  | Up to 5 doses         |
| • Infants <12 months with pulmonary disorders or neuromuscular disease that lead to impaired clearing of upper respiratory secretions may be considered for prophylaxis.   | Up to 5 doses         |
| • Children <24 months requiring oxygen for at least 28 days after birth and continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic) during 6-month period prior to RSV season may be considered for prophylaxis. | Up to 5 doses         |
| • Children <24 months who are profoundly immunocompromised during RSV season may be considered for prophylaxis.  | Up to 5 doses         |
| • Children <24 months who undergone cardiac transplant during RSV season may be considered for prophylaxis.  | Up to 5 doses         |
| • Children <24 months who were receiving RSV prophylaxis and will continue to require RSV prophylaxis after cardiopulmonary bypass should be given a post-operative Synagis dose at the conclusion of the surgery.   | 1 post-operative dose |

***For infants less than 29 weeks estimated gestational age, prophylaxis should be administered as 15mg/kg monthly doses throughout the season to maximum of 5 doses. Prophylaxis occurs for between November to March. (This will provide protection until April.) Synagis should not be administered more frequently than monthly (every 28-30 days). Infants experiencing breakthrough RSV hospitalization while receiving prophylaxis should discontinue Synagis because a second RSV hospitalization in the same season is extremely unlikely (<0.05%).***

**Criteria eligible for coverage through CCS (CCS preauthorization is required).**

Children with any CCS qualifying diagnosis should be referred to CCS for ongoing case management and Synagis authorization should be obtained through CCS. Please refer to CCS NL: 13-0914 for complete details (available at <http://www.dhcs.ca.gov/services/ccs/Documents/ccsnl130914.pdf>). CCS requires separate authorizations for outpatient administration. For inpatient administration, a separate authorization is not needed.

Palivizumab is a benefit for CCS clients, regardless of the eligible medical condition, who meet at least one of the following criteria:

| <b>Patients meeting one of the following criteria during RSV season (Nov 1<sup>st</sup> – Mar 31<sup>st</sup>):</b>   |
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| <ul style="list-style-type: none"><li>• Children who meet the above criteria and have a CCS condition.<ol style="list-style-type: none"><li>1. <b>Preterm infants without Chronic Lung Disease of Prematurity or Congenital Heart Disease.</b> The RSV prophylaxis may be administered to infants born at 29 0/7 weeks' gestation or less, who are less than 12 months of age at the start of RSV season. Infants <b>born during</b> the RSV season do not require five monthly doses. For example, infants born in January would receive their last dose in March.</li><li>2. <b>Preterm infants with Chronic Lung Disease (CLD).</b> CLD of prematurity is defined as gestational age 0.21 for at least the first 28 days after birth. The RSV prophylaxis may be administered to infants with CLD during the first year of life. The RSV prophylaxis may be administered to infants with CLD during the second year of life only for such infants who continue to require corticosteroids, diuretics, bronchodilators, or supplemental O2 during the 6-month period before the start of the second RSV season.</li><li>3. <b>Infants with hemodynamically significant Congenital Heart Disease (CHD).</b> For infants in the first year of life who are born within 12 months of the beginning of RSV season, Palivizumab prophylaxis is authorized for infants with acyanotic heart disease who receives medication to manage congestive heart failure and will require cardiac surgery, and for infants with moderate to severe pulmonary hypertension. Infants with cyanotic heart defects in the first year of life may receive Palivizumab prophylaxis if deemed warranted by the infant's pediatric cardiologist.<ol style="list-style-type: none"><li>a. An infant younger than 24 months receiving prophylaxis who undergoes cardiopulmonary bypass or extracorporeal membrane oxygenation and continues to require prophylaxis post-operatively may receive a postoperative dose of palivizumab (15 mg/kg).</li><li>b. Children younger than 24 months who receive a cardiac transplant during RSV season may qualify for palivizumab prophylaxis.</li></ol></li><li>4. <b>Anatomic pulmonary abnormalities or neuromuscular disorder.</b> Immunoprophylaxis may be considered <b>during the first year of life</b> for infants who have impaired ability to clear respiratory secretions from the upper airway because of ineffective cough. Infants and young children in this category should receive a maximum of five doses of palivizumab.</li><li>5. <b>Immunocompromised.</b> Prophylaxis may be considered for children younger than 24 months of age who are profoundly immunocompromised during RSV season. See section IV.A. for details.</li><li>6. <b>Down syndrome.</b> Prophylaxis is authorized only if qualifying heart disease, CLD, airway clearance issues, or qualifying prematurity are present.</li></ol></li></ul> |

7. **Cystic Fibrosis.** Prophylaxis may be considered only if clinical heart disease and/or nutritional compromise are present in the first year of life. Prophylaxis in the second year of life may be considered for infants with severe lung disease evidenced by previous hospitalization for pulmonary exacerbation in the first year of life, persistent abnormalities on chest imaging when clinically stable, or weight for length < 10 percentile.

Please note: Premature infants who are currently only eligible for diagnostic services through the high-risk infant follow-up program are not eligible for authorization of Palivizumab through CCS and should be authorized through HPSJ.

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## **How do I Obtain Authorization and Medication?**

### **Authorization:**

Obtain the Synagis Authorization/Order Form on DRE or the website and submit by fax to (209) 762-4704 or (209) 942-6302. A single authorization is required for the series.

If approved, this authorization will be good for a maximum of 3 to 5 monthly (every 30 day) injections between November 1, 2018 and March 31, 2019 depending on the criteria met (listed above). The approval and order will be faxed by HPSJ to Diplomat Specialty Pharmacy to initiate the procurement process.

*\* If prophylaxis was initiated in December or if credible epidemiological evidence indicating new RSV infections extend into April 2019 exists, consideration will be given to add an April dose. Such determination will be made by March 31, 2019. Infants born during RSV season (i.e. January) will not require all 5 doses.*

### **Procurement:**

Synagis is provided through Diplomat Specialty Pharmacy. Once authorized by HPSJ, Diplomat Specialty Pharmacy will then contact your office to arrange/coordinate delivery of the approved medications to your office.

### **Administration Billing:**

When billing for the Synagis injection please bill with the **CPT Code 96372**.

### **Ordering Synagis:**

Diplomat Specialty Pharmacy, the Specialty Pharmacy serving members of Health Plan of San Joaquin (HPSJ) provides Synagis.

Diplomat Specialty Pharmacy has many positive features for you and your patients, including:

- Delivery of medications directly to your infusion center or office within 24 business hours of approval
- Reduced inventory management responsibility for your office
- Refills and renewals coordinated by Diplomat Specialty Pharmacy, lessening the burden on your staff

- Coordinated monthly scheduling of deliveries
- Phone access to pharmacists, nurses, and trained staff to assist HPSJ members
- Patient monitoring and education program to improve adherence to prescribed regimens

Any questions regarding scheduling of the patients' order should be directed to the Diplomat Specialty Pharmacy Customer service Monday through Friday 9:00 am until 11:00 pm, and Saturday 9:00 am until 5:00 pm (EST) at (877)-319-6337.

**Administration:**

Synagis is to be given monthly from November through March, the peak RSV months, for a maximum total five doses for infants less than 29 weeks or for infants less than 32 weeks with CLD requiring >21% oxygen supplementation for at least the first 28 days after birth. A dose given in early March will provide protection into April.

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Thank you for caring for young, at risk infants. If you have any questions about the Synagis recommendations, please feel free to call HPSJ Utilization Management Department at (209) 942-6350.