



Recommendations for Synagis 2015-2016 Season

The American Academy of Pediatrics (AAP) recommends the use of palivizumab (Synagis), an RSV monoclonal antibody, to prevent serious RSV illness in qualifying high-risk infants.

Who Qualifies for Synagis?

Criteria eligible for coverage through the Alliance

- Infants < 29 weeks, 0 days gestation at birth, and chronological age < 12 months at the start of RSV season (usually beginning in November).

This recommendation is based on the updated guidance from AAP published in July 2014.

Criteria eligible for coverage through CCS

CCS authorizes Synagis requests ONLY from CCS-Special Care Center (SCC) providers, CCS-paneled pediatric subspecialists, or CCS-paneled primary care providers working in conjunction with a child's CCS-Special Care Center. Requests from CCS-paneled primary care pediatricians and family practitioners must be accompanied by medical documentation that the Synagis request is in accordance with the CCS-paneled specialist's recommendation for that child. CCS covers Synagis for:

- Infants < 29 weeks, 0 days gestation at birth, and chronological age < 12 months at the start of RSV season who are open to CCS for treatment of any CCS condition.
- During the first year of life for preterm infants who develop 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.
- During the second year of life for preterm infants who develop chronic lung disease (CLD) of prematurity as defined above and continue to require medical support (corticosteroids, diuretics, bronchodilators, or supplemental oxygen) during the 6-month period before the start of the second RSV season.
- Infants in the first year of life who are born within 12 months of the beginning of RSV season with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and 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.
- Children younger than 2 years who undergo cardiac transplantation during the RSV season.
- 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 post-operative dose of palivizumab (15 mg/kg).
- During the first year of life, infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
- Children younger than 24 months of age who are profoundly immunocompromised during the RSV season, as assessed by a qualified CCS-paneled specialist provider.
- During the first year of life, infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise.
- During the second year of life, infants with cystic fibrosis and manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or persistent abnormalities on chest imaging when clinically stable) or weight for length less than the 10th percentile.

NOTE: CCS does not cover Synagis for infants who are open to CCS for DIAGNOSTIC or High Risk Infant Follow-up services only. Requests for Synagis for these children should be directed to the Alliance.

Authorizations

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 that will administer Synagis in their office, also submit a completed "Statement of Medical Necessity" form.

Alliance Synagis Ordering and Billing Information:

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

Diplomat Contact Information: (P) 877-977-9118 and (F) 800-550-6272.

CCS Authorization: CCS, not the Alliance, authorizes Synagis for children who meet CCS Synagis criteria. Please complete a CCS Synagis Request Form and a SAR Request Form. FAX your request, with medical documentation, to (209) 724-4001. For more information, please contact CCS at 209-381-1114 (main). For billing information, please contact June Contreras at (209) 381-1109.

Please indicate the child's weight on the request, and whether the child has received a previous Synagis dose this RSV season. Medical documentation is not required for premature infants who meet the AAP prematurity criteria at the onset of RSV season.

For other children who are CCS-eligible for Synagis, include the required medical report from the CCS-authorized specialist or CCS pediatrician/family practitioner working in conjunction with the specialist to indicate that Synagis is requested by the specialist.

Administration:

In most seasons, Synagis is given monthly from November through March, the peak RSV months. A dose given in early March will provide protection into April. Specific decisions concerning season duration may be individualized based on local RSV hospitalization data. Updated AAP recommendations for 2014 limit the total number of doses to five (5).

Thank you for caring for young, at risk infants. If you have any questions about the Synagis recommendations, please call Anne Chai, Pharm. D. at (831) 430-5689.

Sincerely,

Dale Bishop, MD
Chief Medical Officer
Central California Alliance for Health



STATEMENT OF MEDICAL NECESSITY

RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLAXIS
Complete form in its entirety and fax to number listed below

1

PATIENT INFORMATION

_____ Last Name			_____ First Name			_____ Middle Initial		
_____ Street Address						_____ City		
_____ County			_____ State			_____ Zip Code		
_____ Date of Birth			_____ CCAH ID Number			_____ Sex		
_____ Parent/Guardian								
_____ Day Telephone (+Area Code)				_____ Night Telephone (+Area Code)				

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PHYSICIAN INFORMATION

_____ Prescriber's Name			_____ Hospital/Clinic			_____ Office Contact		
_____ Street Address				_____ City/State/Zip			_____ Phone (+Area Code)	
_____ Independent Health Provider #			_____ DEA #			_____ Fax (+Area Code)		
_____ Medicaid Provider #			_____ UPIN #			_____ NPI #		
_____ Supervising Physician's Name (If Required for Mid-Level Practitioner)						_____ Independent Health Provider #		

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**Fax Completed Form With TAR Form To (831) 430-5851
OR CALL (831) 430-5507**

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CLINICAL INFORMATION

PRIMARY DIAGNOSIS:
Patient's Gestational Age (GA) _____ Birth Weight ____ kg ____ lbs
Current Weight ____ kg ____ lbs Date Recorded: _____
Gestational Age at Birth Weeks: _____ Days: _____

MEDICAL CRITERIA

Prematurity:
 Gestational age of < 29 weeks, 0 days and <12 months of age at the start of RSV season

Was there a NICU/Hospital Dose Administered? Yes, Date(s) _____ No
EXPECTED DATE OF FIRST/NEXT INJECTION: _____
Injection already given? Yes, Date(s) _____ No
Deliver product to Office Clinic Location: _____

Please submit Synagis requests for CCS-eligible children directly to CCS. CCS covers for:

- Infants < 29 weeks, 0 days gestation at birth, and chronological age < 12 months at the start of RSV season who are open to CCS for treatment of any CCS condition.
- Preterm infants with Chronic Lung Disease (CLD), hemodynamically significant Congenital Heart Disease (CHD), anatomic pulmonary abnormalities or neuromuscular disorders, immunocompromise, or Cystic Fibrosis who meet criteria as specified in CCS Numbered Letter 13-0914.

Synagis® (palivizumab) 50- and/or 100-mg vials

Sig: Inject 15 mg/kg IM one time per month (every 28-30 days)

Sig: _____

Prescriber's Signature: _____

Date: _____