

1600 Green Hills Road, Suite 101 • Scotts Valley, CA 95066-4981 • (831) 430-5500  
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530 West 16th Street, Suite B • Merced, CA 95340-4710 • (209) 381-5300

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DATE: October 11, 2012  
FROM: Provider Services Department  
RE: Recommendation for Synagis 2012-2013

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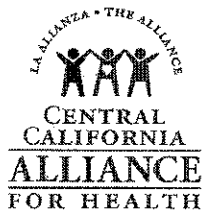
**Please find enclosed the following important information:**

- **Recommendations for Synagis 2012 – 2013 Season**
- **Synagis TAR Information Form 2012–2013**
- **Statement of Medical Necessity Form**

For providers that will be administering Synagis to CCAH children both a completed TAR and “Statement of Medical Necessity Form” must be submitted.

For providers that will have Synagis administered at a “Synagis Clinic” for a CCAH child a completed TAR and “Alliance Synagis Information Form” both must be submitted.

For questions concerning Synagis, contact Rich Johnson, Pharm. D. at (831) 430-5553



# Recommendations for Synagis 2012-2013 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 (Use Alliance TAR form)

1. Infants < 28 weeks, 6 days gestation at birth, and chronological age < 12 months on 11/1/12
2. Infants 29 weeks, 0 days through 31 weeks, 6 days gestation at birth, and chronological age < 6 months on 11/1/12
3. Infants 32 weeks, 0 days through 34 weeks, 6 days gestation at birth, and < 3 months on 11/1/12 (or born during RSV season) with either of the following risk factors will be considered on an individual basis:
  - child care attendance
  - sibling younger than 5 years of age

### Criteria eligible for coverage through CCS

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

- **Ex-premature infants open to CCS for treatment of an ongoing CCS condition:** Ex-premature infants who meet the AAP prematurity criteria (listed above) at the onset of RSV season who are open to CCS for TREATMENT of any CCS condition.
- **Chronic Lung Disease:** Children with Chronic Lung Disease who are younger than 24 months at the onset of RSV season who have required medical treatment for CLD in the 6 months prior to RSV season. Synagis is requested by the CCS pulmonologist or the CCS pediatrician/family practitioner authorized in conjunction with the pulmonologist.
- **Congenital Heart Disease:** Children with CHD who are younger than 24 months at the onset of RSV season. Synagis is requested by the CCS cardiologist or the CCS pediatrician/family practitioner authorized in conjunction with the cardiologist.
- **Immunodeficiency:** Children with immunodeficiency who are younger than 24 months at the onset of RSV season. Synagis is requested by the CCS specialist (Infectious Diseases, Immunologist, Transplant Service, Hematologist, Oncologist) or the CCS pediatrician/family practitioner authorized in conjunction with the CCS specialist.
- **CCS Condition that may be severely complicated by RSV:** Children who are at high risk of developing severe complications due to RSV infection. Synagis is requested by the CCS specialist who is authorized to treat the child's CCS eligible condition, or the CCS pediatrician/family practitioner authorized in conjunction with the specialist.

**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 TARs by fax to (831) 430-5851. A single TAR is required for the series. Please indicate infant weight on the TAR. For infants 32 weeks, 0 days through 34 weeks, 6 days, indicate which risk factors are present on the TAR. Or, if you prefer, indicate the risk factors on the supplemental "Synagis TAR Information" form and submit it with the TAR.

### 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: Phone 877-977-9118 and Fax 800-550-6272.

**CCS Authorization:** CCS, not Alliance, authorizes Synagis for children who meet CCS Synagis criteria. 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 ex-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.

In Santa Cruz County, please complete a CCS Synagis Request Form and a SAR Request Form. FAX, with medical documentation, to (831) 763-8410.

Monterey County: For more information, please contact Kathy McCoy, P.H.N, at (831) 796-1384.

### 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 2009 now limit the total number of doses to five (5) for infants < 32 weeks gestation and no more than three (3) doses up to 3 months of age for infants 32 weeks, 0 days through 34 weeks, 6 days gestation with a qualifying risk factor (please refer to the chart).

### Synagis Clinics:

Many providers prefer to refer members to a Synagis Clinic for administration of the Synagis series.

#### Synagis Clinics

Dominican Synagis Clinic

#### Contacts

Janie King (457-7041)

Dr. Magarian (462-7675)

Fax (457-7195)

Natividad Pediatric Synagis Clinic

Pat Butcher, RN

(769-8683)

Fax (755-5583)

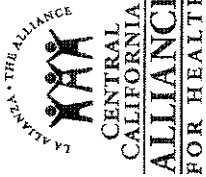
Month of Birth	Maximum No. of Doses for Season Beginning November 1		
	≤28 Weeks, 6 Days of Gestation and <12 Months of Age at Start of Season	29 Weeks, 0 Days Through 31 Weeks, 6 Days of Gestation and <6 Months of Age at Start of Season	32 Weeks, 0 Days Through 34 Weeks, 6 Days of Gestation and With Risk Factor <sup>b</sup>
November 1– March 31 of previous RSV season	5 <sup>c</sup>	0 <sup>d</sup>	0 <sup>e</sup>
April	5	0 <sup>d</sup>	0 <sup>e</sup>
May	5	5	0 <sup>e</sup>
June	5	5	0 <sup>e</sup>
July	5	5	0 <sup>e</sup>
August	5	5	1 <sup>f</sup>
September	5	5	2 <sup>f</sup>
October	5	5	3 <sup>f</sup>
November	5	5	3 <sup>f</sup>
December	4	4	3 <sup>f</sup>
January	3	3	3 <sup>f</sup>
February	2	2	2 <sup>f</sup>
March	1	1	1 <sup>f</sup>

<sup>a</sup>If infant is discharged from the hospital during RSV season, fewer doses may be required.  
<sup>b</sup>For risk factors, see p 565–566.  
<sup>c</sup>Some of these infants may have received 1 or more doses of palivizimab in the previous RSV season if discharged from the hospital during that season; if so, they still qualify for up to 5 doses during their second RSV season.  
<sup>d</sup>Zero doses because infant will be older than 6 months of age at start of RSV season.  
<sup>e</sup>Zero doses because infant will be older than 90 days of age at start of RSV season.  
<sup>f</sup>On the basis of the age of patients at the time of discharge from the hospital, fewer doses may be required, because these infants will receive 1 dose every 30 days until the infant is 90 days of age.

Thank you for caring for young, at risk infants. If you have any questions about the Synagis recommendations, please feel free to call Richard Johnson, Pharm. D. (831) 430-5553.

Sincerely,

Richard Helmer, 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

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### 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 \_\_\_\_\_ Independent Health Provider # \_\_\_\_\_  
(If Required for Mid-Level Practitioner)

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**Fax Completed Form With TAR Form To (831) 430-5851**  
**OR CALL (831) 430-5553**

### 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 FOR PREMATURITY

##### Prematurity:

- Gestational age of < 28 weeks, 6 days and <12 months of age at the start of RSV season
- Gestational age of 29 weeks, 0 days through 31 weeks, 6 days and <6 months of age at the start of RSV season
- Gestational age of 32 weeks, 0 days through 34 weeks, 6 days and <3 months at the start of RSV season **AND:**

If the gestational age at birth was between 32 weeks, 0 days and 34 weeks, 6 days, and the infant is less than 3 months at the start of RSV season or born during RSV season, check all the following risk factors that apply:

##### Clinically has the following risk factor (check all that apply):

- Sibling younger than 5 years of age
- Child care attendance
- Other medical history/medications: \_\_\_\_\_

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 Synagis for ex-premature infants open to CCS with ongoing CCS condition: Chronic lung disease; Congenital Heart Disease; Immunodeficiency; or other CCS condition that may be severely complicated by RSV.

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: \_\_\_\_\_



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## SYNAGIS TAR INFORMATION FORM 2012-2013 SEASON

Member Name: \_\_\_\_\_ CIN#: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Physician: \_\_\_\_\_

1. Gestation Age at Birth: weeks \_\_\_\_\_ days \_\_\_\_\_ (specify both weeks and days)  
Age at the start of RSV season (Usually November 1<sup>st</sup>) \_\_\_\_\_
2. If the gestational age at birth was between 32 weeks, 0 days and 34 weeks, 6 days, and the infant is <3 months at the start of RSV season or born during RSV season, does the infant have either of the following risk factors?  
\_\_\_\_\_ Child care attendance  
\_\_\_\_\_ Sibling younger than 5 years of age
3. Infant's current weight: \_\_\_\_\_ as of (date): \_\_\_\_\_
4. Date of most recent Synagis dose if received prior to hospital discharge: \_\_\_\_\_

**Please fax this completed form with TAR to (831)430-5851**

This form, along with a TAR form, both are to be submitted for all providers that are having Synagis administered in a "Synagis Clinic" for a CCAH child. Do not submit this form, but instead submit a "Statement of Medical Necessity Form" if the Synagis dose will be administered in your office.

For questions concerning Synagis, contact Rich Johnson, Pharm. D. at (831) 430-5553

Synagis requests and current medical reports from a CCS-Special Care Center and/or collaborating CCS-panel physician should be submitted directly to CCS on children < 24 mos with the following:

1. Chronic lung disease (document collaboration with Special Care Center)
2. Severe Immunodeficiency (requests accepted from Special Care Centers only)
3. Congenital Heart Disease (requests accepted from Special Care Centers only)
4. Prematurity per AAP guidelines and a CCS eligible condition (documentation of collaboration with Special Care Center required)

For specific billing information, contact Kathy McCoy, P.H.N. in Monterey at (831) 796-1384  
or Santa Cruz at (831) 763-8410