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530 West 16th Street, Suite B • Merced, CA 95340-4710 • (209) 381-5300

DATE: October 1, 2013
FROM: Provider Services Department
RE: Recommendation for Synagis 2013-2014

Please find enclosed the following important information:

- **Recommendations for Synagis 2013 – 2014 Season**
- **Statement of Medical Necessity Form**

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



Recommendations for Synagis 2013-2014 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 11/1/13
2. Infants 29 weeks, 0 days through 31 weeks, 6 days gestation at birth, and chronological age < 6 months on 11/1/13
3. Infants 32 weeks, 0 days through 34 weeks, 6 days gestation at birth, and < 3 months on 11/1/13 (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.

CCS Authorization:

CCS, not Alliance, authorizes Synagis for children who meet CCS Synagis criteria. The process for CCS has not changed from previous years. Please complete a CCS Synagis Request Form and a SAR Request Form. FAX your request, with medical documentation, to (209) 381-1102. For more information, please contact Leo Martinez, P.H.N. Supervisor, at (209) 381-1138. For billing information, please contact June Contreras at (209) 381-1109.

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.

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.

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 chart).

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 ^b
November 1– March 31 of previous RSV season	5 ^c	0 ^d	0 ^e
April	5	0 ^d	0 ^e
May	5	5	0 ^e
June	5	5	0 ^e
July	5	5	0 ^e
August	5	5	1 ^f
September	5	5	2 ^f
October	5	5	3 ^f
November	5	5	3 ^f
December	4	4	3 ^f
January	3	3	3 ^f
February	2	2	2 ^f
March	1	1	1 ^f

^aIf infant is discharged from the hospital during RSV season, fewer doses may be required.

^bFor risk factors, see p 565–566.

^cSome of these infants may have received 1 or more doses of palivizumab 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.

^dZero doses because infant will be older than 6 months of age at start of RSV season.

^eZero doses because infant will be older than 90 days of age at start of RSV season.

^fOn 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. at (831) 430-5553.

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) _____

2

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)

3

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

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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 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: _____