

February 11, 2003

N.L.: 01-0203  
(Supercedes N.L.: 13-0999)

TO: ALL COUNTY CALIFORNIA CHILDREN'S SERVICES (CCS)  
PROGRAM ADMINISTRATORS, MEDICAL CONSULTANTS, AND  
STATE CHILDREN'S MEDICAL SERVICES (CMS) STAFF

SUBJECT: PALIVIZUMAB (SYNAGIS™)

## I. PURPOSE

NL 13-0999 has been revised and is superceded by this letter in order to add specified types of congenital heart disease to the list of conditions that qualify for CCS palivizumab authorization for the prevention of respiratory syncytial virus (RSV) in at risk children.

## II. BACKGROUND

Palivizumab (trade name Synagis) is a humanized monoclonal antibody produced by recombinant DNA technology used for the prevention of serious lower respiratory tract infection due to RSV infections in pediatric patients at high risk for RSV disease. Patients with congenital heart disease (CHD) were excluded from the original studies and therefore palivizumab is not currently federal Food and Drug Administration licensed for use in children with CHD. However, new data from a randomized, Double blind, placebo-controlled trial conducted in 76 centers, presented at the Cardiology Section of the American Academy of Pediatrics (AAP) meeting of October 18, 2002, demonstrated that palivizumab was safe and effective when used in children with both cyanotic and acyanotic congenital heart disease. A total of 1287 children were enrolled in this four-year worldwide study. The treatment group had 45 percent fewer hospitalizations because of RSV than the control group. The frequency and types of adverse events were similar in both the control and treatment groups.



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In light of this new information, the manufacturer will be seeking an expansion of the product label to add congenital heart disease to the indications. The AAP is also changing its recommendations regarding the use to palivizumab to include young children with certain types of congenital heart disease. In addition, Medi-Cal has issued a policy statement, 2002-12, that makes Synagis a covered benefit as "prophylactic treatment against RSV for infants and children with cyanotic or acyanotic congenital heart disease who are less than 24 months of age at the time that therapy is begun." As before, RSV intravenous immune globulin remains contraindicated in children with cyanotic congenital heart disease.

### III. POLICY GUIDELINES

Effective the date of this letter:

A. Palivizumab is a benefit of the CCS Program to treat those CCS-eligible infants and children\* who are receiving care from a CCS-paneled pediatric pulmonologist, neonatologist, or pediatric intensivist associated with a CCS-approved Pulmonary SCC, Neonatal Intensive Care Unit (NICU), or Pediatric Intensive Care Unit (PICU) and who are:

1. infants with significant CLD, requiring medical therapy (such as oxygen and/or medications for their CLD) in the past six months and who are 24 months of age at the time of initial administration of palivizumab, or,
2. premature infants, in which RSV infection would complicate or adversely affect the CCS-eligible condition, including:
  - a. infants born at 28 weeks of gestation, or earlier, who are under 12 months of age at the time of initial administration of age at the time of initial administration of palivizumab, or,
  - b. infants born at 29 to 32 weeks gestation, who are under six months of age at the time of the initial administration of palivizumab, or,
  - c. infants born at 32 to 35 weeks' gestation, in which careful consideration is given regarding RSV risk factors, who are under six months of age at the time of the initial administration of palivizumab.

\*NOTE: Prematurity, in and of itself, is not a CCS-eligible condition.

B. Premature infants who are currently only eligible for high-risk infant follow-up services are not eligible for CCS reimbursement of palivizumab.

- C. Palivizumab is a benefit of the CCS Program to treat selected CCS-eligible infants and children with severe immunodeficiency diseases who are receiving care from and when ordered by a CCS approved Infectious Disease /Immunology Disorders SCC or a CCS approved Hematology/Oncology SCC medical director.
- D. Palivizumab is a benefit of the CCS Program to treat CCS-eligible children with CHD when:
  - 1. The child is receiving care from a CCS approved Cardiac SCC
  - 2. The palivizumab authorization request is from the SCC pediatric cardiologist
  - 3. The child is less than 12 months of age and
  - 4. The child is receiving medication for congestive heart failure, or has as moderate to severe pulmonary artery hypertension, or has cyanotic heart disease.

NOTE: Children with mild cardiomyopathy who are not receiving medical therapy or who have hemodynamically insignificant heart disease, such as secundum atrial septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta or patent ductus arteriosus who are not at increased risk for RSV generally should not receive immunoprophylaxis. Children with lesions adequately corrected by surgery do not need continuing immunoprophylaxis following recovery from corrective surgery unless they continue to require medication for congestive heart failure.

#### IV. IMPLEMENTATION GUIDELINES

- A. The CCS Program medical director or designee shall:
  - 1. review the request for palivizumab to ensure that the initial request, whether as an inpatient or outpatient, is:
    - a. from a CCS-paneled pulmonologist, neonatologist, or pediatric intensivist associated with a CCS-approved, Pulmonary SCC, NICU, or PICU, or,
    - b. from a CCS-paneled community-based pediatrician who, because of constraints of distance and access, is caring for the patient in consultation with specialists mentioned above in Implementation Guidelines A., 1., a., and
  - 2. ensure that the request is accompanied with the necessary documentation to determine medical necessity, and

3. consider palivizumab as a CCS benefit for a very select group of immunocompromised children with severe immunodeficiencies only if ordered by the CCS-approved Infectious Disease/Immunology SCC medical director or by the CCS-approved Hematology/Oncology SCC medical director, and
4. authorize palivizumab as a CCS benefit for infants with CHD as outlined in Policy Guidelines, III, D., if ordered by the CCS-approved Cardiac SCC medical director, or cardiac team physician.

B. Authorizations

1. Palivizumab will be authorized for up to six total injections over a six-month period of time if ordered by the CCS paneled cardiologist, pulmonologist, neonatologist, immunologist or intensivist associated with a CCS-approved Cardiac SCC, Infectious Disease/Immunology Disorders SCC, Hematology/Oncology SCC, Pulmonology SCC, NICU, or PICU.
2. Community based pediatricians may request authorization for children whose care is directed by a CCS-approved Pulmonary SCC, NICU, or PICU and collaboration between the SCC physician and the community-based pediatrician is documented.
3. Community based pediatricians may not request palivizumab authorization for children with either cardiac or immune disorders. These requests shall originate from the child's Cardiac, Infectious Disease and Immune Disorders, or Hematology-Oncology SCC physician.
4. Palivizumab does not need a separate authorization for inpatient administration.
5. Synagis (palivizumab) is a Medi-Cal benefit and must be billed using HCPCS code X7439. Pharmacies cannot be authorized to dispense this drug using an NDC number.
6. Each injection will be reimbursed once in a 25-day period.
7. Authorization for palivizumab for CCS-eligible children with CLD under 2 years of age or with gestational age at birth less than 32 weeks (with the post-natal age qualifiers discussed in Policy Guidelines A.,2.), shall be made by the CCS Program medical director or designee.

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8. Any denial of palivizumab shall be made by the CCS Program medical /consultant director.

Note: Authorization for palivizumab in 32 to 35 week gestation premature infants or in children with CHD must be made by the CCS Program medical director.

**Original Signed by Maridee Gregory, M.D.**

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Children's Medical Services Branch