



California
Department of
Health Services

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Date: October 5, 2005

N.L.: 27-1005

Index: Benefits

(Supercedes N.L. No.: 05-0904)

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

SUBJECT: PALIVIZUMAB (SYNAGIS™)

I. PURPOSE

The purpose of this numbered letter, which supercedes N.L.: 05-0904, is to update current CCS policy regarding the authorization of Palivizumab.

II. BACKGROUND

Palivizumab (trade name Synagis®) is a humanized monoclonal antibody produced by recombinant DNA technology licensed by the FDA and indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

Palivizumab is the agent of choice for monthly prophylaxis in most high-risk infants and children because of ease of intramuscular administration, safety, efficacy, and non-interference with the immune response to measles-mumps-rubella and varicella vaccines. Typically November through April is considered RSV season, but it may occur earlier or persist later, depending on the community. Immunoprophylaxis against RSV is usually initiated at the beginning of November, and the last dose is usually administered at the beginning of March providing protection into April. However, it is dependent upon the physician requesting Palivizumab to determine when immunoprophylaxis begins and ends. In some instances, this may be as early as September.

A brief review of recent history of Palivizumab indicates that in December 2002, Medi-Cal expanded the Palivizumab policy of 1998 and issued Policy Statement 2002-12: Addendum to Policy Statement 98-9: Palivizumab (Synagis™) making Palivizumab 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.” The addendum was issued based on results of a four-year clinical trial that demonstrated Palivizumab was safe and effective when used in infants and young children with both cyanotic and acyanotic congenital heart disease (CHD). The study was presented at the Cardiology Section of the AAP Conference, October 18, 2002.

In September 2003, the FDA granted approval to expand the product label for the use of Palivizumab to young children with hemodynamically significant CHD. RSV immune globulin intravenous (RSV-IGIV), the other current option for immunoprophylaxis for preventing RSV infection, remains contraindicated in children with hemodynamically significant CHD.

In October 2003, the AAP issued a Policy Statement (www.aap.org/policy/rsvpolicy.pdf) regarding usage of Palivizumab and RSV-IGIV for the prevention of RSV infection and provided revised recommendations for:

- Administering RSV prophylaxis to infants and children with CHD;
- Identifying infants with a history of preterm birth and chronic lung disease (CLD) who are most likely to benefit from immunoprophylaxis; and
- Reducing the risk of RSV exposure and infection in high-risk children.

III. POLICY

Effective the date of this letter, the following policy supercedes the policy promulgated in N.L.: 05-0904:

- A. Palivizumab requires separate authorization for outpatient administration for RSV prophylaxis. It is a benefit for CCS clients, regardless of the eligible medical condition, who also meet one of the following criteria:

1. Children 24 months of age or younger at the start of RSV season with CLD requiring medical treatment (supplemental oxygen, bronchodilator, diuretic, corticosteroid, or other treatment) within six months before the anticipated start of the RSV season.
2. Infants born at 28 weeks of gestation or earlier and who are less than 12 months of age at the start of RSV season.
3. Infants born at 29 to 32 weeks of gestation who are less than six months of age at the start of RSV season.
4. Infants born between 32 weeks and 35 weeks of gestation who are less than six months of age at the start of RSV season and who have two or more of the following risk factors:
 - Child care attendance
 - School-aged siblings
 - Exposure to environmental air pollutants (tobacco smoke, wood-burning stove, etc.)
 - Congenital abnormalities of the airways
 - Severe neuromuscular disease
5. Children who are 24 months of age or younger at the start of RSV season with cyanotic or acyanotic CHD and the request for service is from the CCS approved Cardiac Special Care Center (SCC) or a cardiologist from a CCS approved Cardiac SCC, or the request is from a CCS paneled pediatrician authorized in conjunction with a CCS approved Cardiac SCC or a CCS paneled cardiologist from the Cardiac SCC.
6. Children with severe immunodeficiencies (e.g., severe combined immunodeficiency or severe acquired immunodeficiency syndrome) and the request for service is from a CCS approved Infectious Disease and Immunologic Disorder SCC or a CCS approved Hematology/Oncology SCC, or the request is from a CCS paneled pediatrician authorized in conjunction with one of these SCCs.
7. Children who are 24 months of age or younger at the start of RSV season with a CCS eligible condition that may worsen with RSV infection.

- B. Authorization of Palivizumab for children over 24 months of age, who meet criteria in III.A.1, 5, or 7, may be granted upon review of the individual's medical condition and history.
- C. For children who meet criteria III.A.1, 2, 3, 4 and 7, the request for service shall be from the CCS authorized pediatric subspecialist or CCS approved SCC; or the request shall be from a CCS paneled pediatrician authorized in conjunction with a CCS paneled pediatric subspecialist or CCS approved SCC.
- D. Premature infants who are currently only eligible for high-risk infant follow-up services are not eligible for authorization of palivizumab.
- E. When palivizumab is authorized as a benefit, it must be authorized as requested through the end of RSV season. For example, a CCS client who was born at 31 weeks and is five months old at the initial injection in November shall be authorized for injections for the entire RSV season.
- F. Though it is preferred that the care of a CCS eligible infant/child be authorized to a CCS paneled pediatrician in conjunction with a CCS paneled pediatric subspecialist or CCS approved SCC, there are circumstances when there is no CCS paneled pediatrician in an infant's/child's area of residence. In these circumstances references to "CCS paneled pediatricians" in III.A.5 and 6, and in III.C, can be substituted with "CCS paneled family practitioners". These family practitioners also need to be authorized in conjunction with a CCS paneled pediatric subspecialist or CCS approved SCC.

IV. POLICY IMPLEMENTATION

Authorizations:

- A. Palivizumab injections are administered monthly and may be authorized for up to a total of six injections over a six-month period of time (unless there is documentation by the requesting physician of longer need due to a lengthier RSV season). The drug requires separate authorization for outpatient administration.
- B. Palivizumab does not need a separate authorization for inpatient administration.

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- C. If an infant or child experiences a breakthrough RSV infection, prophylaxis should continue through the RSV season.
- D. Palivizumab is a Medi-Cal benefit. Due to annually changing Medi-Cal policy, please refer to "This Computes!" for the current method of authorizing Palivizumab.
- E. Palivizumab authorizations need to be expedited to help ensure prompt initiation of protection from RSV for the infant/child and to prevent a lapse in protection especially for the infant who will frequently receive the first injection in the hospital prior to discharge.

If you have any questions regarding this numbered letter, please contact your state regional office medical consultant.

Original signed by Marian Dalsey, M.D., M.P.H.

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