



State of California—Health and Human Services Agency
Department of Health Care Services



EDMUND G. BROWN JR.
GOVERNOR

DATE: September 19, 2014

N.L.: 13-0914
Index: Benefits

TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM ADMINISTRATORS, MEDICAL CONSULTANTS, AND STATE SYSTEMS OF CARE DIVISION (SCD) STAFF

SUBJECT: PALIVIZUMAB (SYNAGIS™)

I. PURPOSE

The purpose of this numbered letter, which supersedes N.L.: 01-0113, is to update the CCS Program policy regarding the authorization of Palivizumab.

II. BACKGROUND

This update reflects consideration of recent guidance for immunoprophylaxis of Respiratory Syncytial Virus (RSV) published by the Committee on Infectious Diseases and Bronchiolitis Guidelines Committee of the American Academy of Pediatrics (Pediatrics, Volume 134, Number 2,415-20, 2014), and opinions and medical literature offered by stakeholders. Palivizumab (trade name Synagis) is an approved agent for immunoprophylaxis of RSV in particular circumstances.

III. POLICY

- A. Palivizumab is a benefit for the CCS Program clients, regardless of the eligible medical condition, who meet at least one of the following criteria. Five monthly doses of palivizumab will provide more than 6 months (24 weeks) of protective serum antibody concentration. Therefore, up to five doses may be authorized for use between November and the following March. If prophylaxis is initiated in December, the fifth and final dose should be administered in April. Note that qualifying infants **born during** the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March.

1. **Preterm infants without Chronic Lung Disease of Prematurity or Congenital Heart Disease.** The RSV prophylaxis may be administered to infants born at 29 0/7 weeks' gestation or less, who are less than 12 months

- of age at the start of RSV season. Infants **born during** the RSV season do not require five monthly doses. For example, infants born in January would receive their last dose in March.
2. **Preterm infants with Chronic Lung Disease (CLD).** CLD of prematurity is defined as gestational age <32 0/7 weeks and FIO₂ > 0.21 for at least the first 28 days after birth. The RSV prophylaxis may be administered to infants with CLD during the first year of life. The RSV prophylaxis may be administered to infants with CLD during the second year of life only for such infants who continue to require corticosteroids, diuretics, bronchodilators, or supplemental O₂ during the 6-month period before the start of the second RSV season.
 3. **Infants with hemodynamically significant Congenital Heart Disease (CHD).** For infants in the first year of life who are born within 12 months of the beginning of RSV season, Palivizumab prophylaxis is authorized for infants with acyanotic heart disease who receives medication to manage congestive heart failure and will require cardiac surgery, and for 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.
 - a. 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).
 - b. Children younger than 24 months who receive a cardiac transplant during RSV season may qualify for palivizumab prophylaxis.
 4. **Anatomic pulmonary abnormalities or neuromuscular disorder.** Immunoprophylaxis may be considered **during the first year of life** for infants who have impaired ability to clear respiratory secretions from the upper airway because of ineffective cough. Infants and young children in this category should receive a maximum of five doses of palivizumab.
 5. **Immunocompromise.** Prophylaxis may be considered for children younger than 24 months of age who are profoundly immunocompromised during RSV season. See section IV.A. for details.
 6. **Down syndrome.** Prophylaxis is authorized only if qualifying heart disease, CLD, airway clearance issues, or qualifying prematurity are present.

7. Cystic Fibrosis. Prophylaxis may be considered only if clinical heart disease and/or nutritional compromise are present in the first year of life. Prophylaxis in the second year of life may be considered for infants with severe lung disease evidenced by previous hospitalization for pulmonary exacerbation in the first year of life, persistent abnormalities on chest imaging when clinically stable, or weight for length < 10 percentile.

- B. Among children who experience breakthrough RSV hospitalization, discontinuation of Palivizumab prophylaxis is indicated because a second RSV hospitalization in the same season is extremely unlikely.
- C. Palivizumab is not effective in treatment of RSV disease and therefore is not authorized for such use.

IV. POLICY IMPLEMENTATION

Authorizations:

- A. Palivizumab requires separate authorization for outpatient administration. Palivizumab injections are administered monthly.
 - 1. Except as noted immediately below, the request for service shall be from the CCS Program authorized pediatric subspecialist or the CCS-approved Special Care Center (SCC); or the request shall be from a CCS-approved pediatrician authorized in conjunction with a CCS-approved pediatric subspecialist or CCS-approved SCC.
 - 2. For qualifying patients with CHD, the request for service should come from a CCS- approved: Cardiac Special Care Center (SCC); cardiologist from a CCS-approved Cardiac SCC; or a CCS-approved pediatrician authorized in conjunction with such a Cardiac SCC or cardiologist, in which case the cardiologist must explicitly indicate medical necessity.
 - 3. For qualifying patients with severe immunodeficiencies, the request for service should come from a CCS-approved : Infectious Disease and Immunologic Disorder SCC; Transplant SCC; Hematology/Oncology SCC; or CCS-approved pediatrician authorized in conjunction with one of these SCCs, in which case the approved SCC must explicitly indicate medical necessity.
- B. Palivizumab does not need a separate authorization for inpatient administration.

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- C. Palivizumab is a Medi-Cal benefit. Please refer to “This Computes!” for the current method of authorizing Palivizumab.
- D. Expedite Palivizumab authorizations 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.

Sincerely,

SIGNED BY ROBERT J. DIMAND

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Chief Medical Officer
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