



**STATE OF HAWAII**  
**DEPARTMENT OF HUMAN SERVICES**  
Med-QUEST Division  
Medical Standards Branch  
P. O. Box 700190  
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September 28, 2007

MEMORANDUM

ACS M07-18  
Replaces ACS M06-14

TO: Medicaid Physicians and Pharmacies

FROM: Lois Lee, Acting Med-QUEST Division Administrator

SUBJECT: PREVENTION OF SERIOUS LOWER RESPIRATORY TRACT INFECTIONS  
CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV)

This memorandum updates and supersedes previous guidelines for the coverage of RespiGam<sup>®</sup> and Synagis<sup>®</sup>. Changes to the previous memorandum are underlined.

RespiGam<sup>®</sup> (human RSV immune globulin), administered intravenously, and Synagis<sup>®</sup> (Palvizumab), administered intramuscularly, are agents approved by the Federal Drug Administration (FDA) for the prevention of serious lower respiratory tract infections in infants with RSV. As RespiGam<sup>®</sup> is infrequently used, most of the guidelines that follow were developed based on Hawaii's experience with Synagis<sup>®</sup>.

The following guidelines for the prevention of RSV and coverage of these agents by Hawaii QUEST medical plans and the fee-for-service Medicaid Program have been developed by the medical directors of the QUEST plans and the Med-QUEST Division (MQD) and are based on guidelines for prophylaxis for RSV infections in high risk infants in Hawaii developed by the Consensus Committee during its meeting of August 31, 2007. The Consensus Committee is comprised of physicians associated with the Department of Pediatrics of the University of Hawaii School of Medicine with expertise in RSV infection in Hawaii.

**General Prevention**

Parents and caregivers of former premature infants, infants with bronchopulmonary dysplasia (BPD), and infants with congenital heart disease should receive education in the following:

- Strict hand washing techniques;
- Avoidance of exposure of their infants to crowds;

- Avoidance of exposure of their infants to smoke and dust especially passive smoke exposure in presence of smokers in the family; and
- Avoidance of exposure of their infants to all sick persons especially those with respiratory symptoms.

### **Recommended Guidelines for Use of RespiGam<sup>®</sup> and Synagis<sup>®</sup>**

Patients who should be considered for RSV prophylaxis should be in one or more of the following groups:

- Infants and children less than two (2) years of age at the start of the RSV season with chronic lung disease (CLD) who require significant medical therapy such as oxygen for treatment of their CLD within six (6) months before the anticipated RSV season. (Born on or after September 15, 2005; continuing medical treatment after March 15, 2007).
- All children two (2) years or younger at the beginning of the season with hemodynamically significant Congenital Heart Disease (CHD) requiring medical management within six (6) months before the anticipated RSV season. (Born on or after September 15, 2005; continuing medical treatment after March 15, 2007). Infants younger than 12 months with CHD who are most likely to benefit from immunoprophylaxis include:
  1. Infants who are receiving medication to control congestive heart failure;
  2. Infants with moderate to severe pulmonary hypertension; and
  3. Infants with cyanotic heart disease.
- Infants born prematurely at 28 weeks gestation or earlier and who are less than 12 months chronological age at the start of the RSV season. (Born on or after September 15, 2006).
- Infants born prematurely between 29 and 32 weeks gestation who are less than six (6) months chronological age at the beginning of the RSV season. The definition of 32 weeks is 32 + 0 weeks. (Born on or after March 15, 2007).
- Infants born prematurely between 33 and 35 weeks gestation requiring significant respiratory support in the neonatal period (positive pressure support) and having at least one (1) of the following risk factors--day care attendance, school-aged siblings, congenital abnormalities of the airways or severe neuromuscular disease--and who are less than six (6) months chronological age at the beginning of the RSV season. (Born on or after March 15, 2007).
- Children two (2) years and younger with chronic illnesses other than those listed above should be evaluated on a case-by-case basis.

***For children who have undergone cardiopulmonary bypass who still require prophylaxis, a post-operative dose of Synagis<sup>®</sup> should be considered as soon as the patient is medically stable.***

***Children meeting the criteria for Synagis<sup>®</sup>/RespiGam<sup>®</sup> should also be considered for influenza immunization if they are over the age of six (6) months.***

### **Recommended Treatment**

RSV infections occur in the community all year round. Based on available epidemiological data, the incidence is significantly higher from September through February. Therefore, the season for late 2007 to early 2008 this year for Hawaii will be from September 15, 2007 to February 29, 2008.

When children meet criteria for prophylaxis based on their age, treatment should be continued for the duration of the RSV season.

- Maximum of five (5) doses to start no earlier than September 15, 2007 and to end no later than February 29, 2008. No coverage for Synagis<sup>®</sup> will be allowed in March 2008.
- The interval between the first and second dose should be no less than 28 days. All subsequent doses should be given at intervals of 30 days with the range being 28-35 days.
- RespiGam<sup>®</sup> and Synagis<sup>®</sup> are indicated for the PREVENTION of RSV and should NOT be used in patients who have RSV infections. However, if a child who meets the criteria for coverage develop RSV during the season, prophylaxis should be resumed after recovery and until the end of February 2008.

### **Additional Considerations**

- The MQD requires authorization for Synagis<sup>®</sup> and RespiGam<sup>®</sup>. Authorization must be obtained from Affiliated Computer Services (ACS), the MQD's pharmacy fiscal agent in Atlanta, Georgia. Requests for prior authorization should be faxed on the 1144B (Attachment 1) to 1-888-335-8474. (For QUEST memo: Authorization for Synagis<sup>®</sup> and RespiGam<sup>®</sup> must be obtained from the child's QUEST medical plan).
- The physician must weigh the side effects of these agents against the benefit gained from preventing RSV infections.
- RespiGam<sup>®</sup> should not be administered at the same time as routine childhood immunizations and may interfere with response to immunizations. RespiGam<sup>®</sup> is contraindicated in cyanotic CHD.
- As Synagis<sup>®</sup> is given intramuscularly, it must be used with caution in patients with thrombocytopenia and coagulation disorders.
- A second (2<sup>nd</sup>) course of Synagis<sup>®</sup> therapy in the following season is rarely indicated.

### Attachment

MQD/MSB:jj  
LDonovan/28116  
(ACS M07-18 – Prevention of Serious Lower Respiratory Tract Infections)