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MEMORANDUM

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TO: Medicaid Fee-For-Service (FFS), QUEST, QUEST Expanded Access (QExA),
Physicians and Pharmacies

FROM: Kenneth S. Fink, MD, MGA, MPH ↙
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SUBJECT: FEE-FOR-SERVICE, QUEST, AND QEXA PROGRAMS
PREVENTION OF SERIOUS LOWER RESPIRATORY TRACT INFECTIONS
CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV)

This memorandum updates and supersedes previous guidelines for the coverage of RSV prophylaxis.

Palvizumab (Synagis®) administered intramuscularly, is approved by the Federal Drug Administration (FDA) for the prevention of serious lower respiratory tract infections in infants. The guidelines that follow are developed based on Hawaii's experience with RSV and Palvizumab.

The following guidelines for the prevention of RSV and coverage of Palvizumab by the Hawaii QUEST and QUEST Expanded Access (QExA) medical plans and the Fee-For-Service (FFS) Medicaid Program have been developed by the medical directors of the QUEST and QExA medical plans and the Med-QUEST Division (MQD). They are based on the "Guidelines for Prophylaxis for RSV Infections in High Risk Infants in Hawaii" developed by the Consensus Committee during its meeting of August 27, 2010. The Consensus Committee is comprised of a broad representation of physicians with expertise in RSV infections in Hawaii and bases the Consensus Guidelines on the national recommendations as well as local RSV epidemiology.

General Prevention

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

- Strict hand washing techniques;
- Avoidance of unnecessary 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.

Patient Population

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

- Infants and children younger than two (2) years of age at the start of the RSV season with Chronic Lung Disease (CLD) requiring 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, 2008; continuing medical treatment after March 15, 2010).
- Infants and children younger than two (2) years of age at the start of the RSV 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, 2008; continuing medical treatment after March 15, 2010). Infants younger than 24 months with CHD who are most likely to benefit from immunoprophylaxis include:
 - Infants who are receiving medication to control congestive heart failure;
 - Infants with moderate to severe pulmonary hypertension; and
 - 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, 2009).
- Infants born prematurely between 29 and 32 weeks gestation and who are less than six (6) months chronologic age at the start of the RSV season (born on or after March 15, 2010).
- Infants born prematurely between 32 and 35 weeks gestation requiring significant respiratory support in the neonatal period (significant positive pressure support with oxygen requirement) and having at least one (1) of the following additional risk factors – day care attendance, school-aged siblings, congenital abnormalities of the airways, or severe neuromuscular disease – and who are less than three (3) months chronological age at the start of the RSV season (born on or after June 15, 2010).
- There are several children with other illnesses in the pediatric age group who may be considered for prophylaxis. Pediatricians should evaluate these children on a case-by-case basis and, if necessary, in consultation with an appropriate sub-specialist.

- Because a mean decrease in Palvizumab serum concentration of 58% was observed after surgical procedures that use bypass, all children after cardiopulmonary bypass and with indication for use of Palvizumab should be considered for additional prophylaxis after discharge. Children with cardiac disease undergoing cardiopulmonary bypass during the season and currently receiving prophylaxis should receive an additional dose of prophylaxis within a few days after bypass and should continue to receive subsequent prophylaxis until the end of the season.

RSV Season

RSV infections occur in our community all year round. Based on available epidemiological data, the incidence is significantly higher from September to February. Therefore, the season for late 2010 to early 2011 this year for Hawaii will be from **September 15, 2010 to February 28, 2011**.

Recommended prophylaxis

- Prophylaxis should start no earlier than September 15, 2010 and end no later than February 28, 2011. A maximum number of five (5) doses will be covered for the identified regular season.
- The interval between the first and second dose should be no less than and as close as possible to 28 days. All subsequent dose intervals should be as close as possible to 30 days with the range being 28-35 days.
- When children meet criteria for prophylaxis based on their age, prophylaxis should be continued for the duration of the RSV season.
- Should a child develop RSV during the course of the season, prophylaxis should resume after recovery until the end of the season.

Additional Considerations

- The MQD requires authorization for Palvizumab. For FFS providers, authorization must be obtained from Affiliated Computer Services (ACS); the MQD's pharmacy fiscal agent. Requests for prior authorization should be faxed on the 1144B (Attachment) to 1-888-335-8474. For QUEST or QExA providers, authorizations for Palvizumab must be obtained from the child's QUEST or QExA medical plan.
- Prior authorization will cover Palvizumab doses in intervals of 28-35 days during the RSV season from September 15, 2010 to February 28, 2011.
- Families should be educated that although prophylaxis is not 100% effective, it may lead to a decrease in severity of subsequent illness. Consideration should be given to obtaining an informed consent prior to drug administration.
- Vulnerable children meeting criteria for RSV prophylaxis should also be considered for influenza vaccine in addition to RSV prophylaxis if they are over the age of six (6) months.
- As Palvizumab is given intramuscularly, it must be used with caution in patients with thrombocytopenia and coagulation disorders.

Attachment

REQUEST FOR MEDICAL AUTHORIZATION

Check only One - Different Types of Services Must Be Requested on Separate 1144B Forms. Home Infusion PA Non-home infusion (Medication only) PA

NOTE: INCOMPLETE FORM WILL DELAY THE AUTHORIZATION PROCESS. Approval of this request is not an authorization for payment or an approval of charges. Payment by the Medicaid Program is contingent on the patient being eligible and the provider of service being certified by Medicaid. The provider of service must verify patient eligibility at the time the service is rendered. Authorization expires 60 days from date of approval unless otherwise noted by the consultant.

1 Medicaid ID Number		2 Recipient's Name (Last, First, M.I.)		3 Gender <input type="checkbox"/> M <input type="checkbox"/> F		4 Date of Birth / /	
5 Medicare Coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No Is Patient receiving Medicare Home Health Benefits? <input type="checkbox"/> Yes <input type="checkbox"/> No		6 Currently at: <input type="checkbox"/> Home <input type="checkbox"/> Hospital <input type="checkbox"/> SNF/ICF/CF-MR Facility Recipient's Mailing Address (St., City, Zip Code)		7 Expanded Early & Periodic Screening Diagnosis & Treatment (EPSDT): <input type="checkbox"/> Yes <input type="checkbox"/> No			
Physician Section				Supplier Section (Circle Rent or Repair)			
8 NDC Number or Drug Name, Strength, Units, Global Code, or HCPCS code		9 QTY		10 Purchase Price		11 Rent/Repair	
12 Period Requested		13 BMI (for anorexiant):		14 From		15 Period Requested To	
Physician Section							
16 Diagnosis or ICD-9 code							
17 Justification (include history of previous treatment) (<input type="checkbox"/> Attachment)							
18 Print Prescriber's Name/Mailing Address							
19 Prescriber's Signature				20 Prescriber's NPI			
21 Telephone #				22 Date			
23 Fax #				24 Contact Name			
Supplier Section							
25 Print Supplier's Name/Mailing Address							
26 Comments							
27 Contact Name				28 Telephone #			
29 Supplier's Signature				30 Supplier's NPI			
				31 Date			