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August 21, 2014

MEMORANDUM

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FFS M14-12
BEN-1401
BENX-1401

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

FROM: Kenneth S. Fink, MD, MGA, MPH
Med-QUEST Division Administrator

SUBJECT: HAWAII MEDICAID (QUEST AND QEXA PROGRAMS) GUIDELINE FOR PROPHYLAXIS OF RESPIRATORY SYNCYTIAL VIRUS (RSV) INFECTIONS IN HIGH RISK INFANTS

This memorandum serves as an annual update to the Med-QUEST Division (MQD) guideline for the coverage of RSV prophylaxis with palivizumab (Synagis®). The guideline for RSV prophylaxis has been developed by the MQD in partnership with the Hawaii RSV Consensus Committee which is comprised of a broad representation of physicians with expertise in RSV infections in Hawaii. This RSV prophylaxis guideline allows for standardization across QUEST and QExA health plans, which include AlohaCare QUEST, HMSA QUEST, Kaiser QUEST, Ohana QUEST/QExA, and UnitedHealthcare QUEST/QExA. This guideline will also be applicable effective January 1, 2015 to the QUEST Integration health plans.

Recommendations are based on the American Academy of Pediatrics (AAP) national guideline adjusted for local RSV epidemiology. There have been several significant changes to the MQD guideline this year based on updates to the AAP national guideline "Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection," recently published online July 28, 2014 and published in the August 2014 issue of *Pediatrics*. A copy of the 2014 AAP guideline on RSV prophylaxis can be found on the AAP web site and will replace the Respiratory Syncytial Virus chapter in the current 2012 edition of *Red Book* (p 609-618).

Recommended Immunoprophylaxis

RSV immunoprophylaxis with palivizumab (Synagis®) administered intramuscularly at a dosage of 15 mg/kg is approved by the Food and Drug Administration (FDA) for RSV prophylaxis in high risk infants and children. RSV prophylaxis is covered in Hawaii from September 15, 2014 through March 31, 2015. The first dose can be administered on or after September 15, 2014 and subsequent treatments may continue through March 31, 2015.

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. Patients should receive a maximum of five doses.

RSV prophylaxis with palivizumab (Synagis®) may be covered (subject to exclusions) for patients who meet one of the following:

1. Infants and children younger than two years of age at the start of the RSV season (Born on or after September 15, 2012) with chronic lung disease who required supplemental oxygen for at least 28 days after birth and who continue to require medical intervention such as supplemental oxygen, chronic corticosteroid use, or diuretic therapy.
2. Infants younger than twelve months chronologic age at the start of the RSV season (Born on or after September 15, 2013) with any one of the following:
    a. Hemodynamically significant congenital heart disease and/or persistent pulmonary hypertension requiring medical management.
    b. Infants born prematurely under 29 weeks (28 + 6 or less) gestation.
    c. Infants born prematurely between 29 and 31 weeks (29 + 0 to 31 + 6) gestation who required supplemental oxygen for at least 28 days after birth.
    d. Infants with pulmonary abnormalities or neuromuscular diseases that impair the ability to clear secretions from the upper airways.

RSV prophylaxis with palivizumab (Synagis®) is <u>not</u> covered for the following:

1. Infants and children with hemodynamically insignificant heart disease including but not limited to ostium secundum ASD, small VSD, mild coartation and PDA.
2. Infants and children with cardiac lesions adequately corrected by cardiac surgery unless patient continues to require medication or oxygen management for heart disease.
3. Infants and children with mild cardiomyopathy not requiring medical therapy.
4. Patients with active RSV infection or documented history of RSV infection during the current RSV season. (Palivizumab is indicated for the prevention of RSV infection, not treatment. If the patient had been receiving prophylaxis with palivizumab, it should not be continued once infected.)

Other clinical considerations:

1. RSV prophylaxis for indicated patients should, ideally, be started between September 15, 2014 and September 30, 2014. However, a later start date is also acceptable.

2. RSV prophylaxis should be continued to provide immunity until the end of March 2015 or until a total of five doses have been administered (whichever is earlier).
3. Every effort should be made to provide the doses every 30 days to maintain effective immunity (range 28 – 35 days).
4. Children who undergo cardiopulmonary bypass with indication for RSV prophylaxis should receive an additional dose of palivizumab after discharge and continue to receive subsequent prophylaxis as recommended until the end of the season. Children who undergo cardiopulmonary bypass may receive an additional dose of palivizumab due to a significant drop in protective antibody levels following cardiopulmonary bypass.
5. Infants and children meeting criteria for RSV prophylaxis should also be considered for influenza vaccine if they are over the age of six (6) months.
6. Families of patients at risk should receive education regarding:
   a. Use of good hand washing and cough hygiene;
   b. Breastfeeding;
   c. Avoiding exposure of the infant to smoke and dust especially passive smoke inhalation in the presence of smokers in the family;
   d. Avoiding exposure of infant to ill contacts, especially those with respiratory symptoms;
   e. Avoiding unnecessary exposure to crowds.
7. Profoundly immunocompromised patients may include, but are not limited to, patients who undergo stem cell transplantation, chemotherapy, or have a severe immunocompromised condition who may also be considered for RSV prophylaxis by prior authorization.
8. As palivizumab is given intramuscularly, it must be used with caution in patients with thrombocytopenia and coagulation disorders.

Prior Authorization

1. The MQD requires authorization for palivizumab.
2. For QUEST or QExA providers, authorizations for palivizumab must be obtained from the child's QUEST or QExA (or QUEST Integration after January 1, 2015) health plan.
3. For FFS providers (e.g., Cyrca SHOTT transplant program), authorization must be obtained from Xerox, the MQD's pharmacy fiscal agent. Requests for prior authorization should be faxed on the Standardized Prior Authorization (PA) Form to 1-888-335-8474.
4. Prior authorization will cover palivizumab doses in intervals of 28-35 days during the RSV season administered between September 15, 2014 and March 31, 2015.