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August 31, 2018

MEMORANDUM:

MEMO NOS.
FFS 18-05
QI-1813
[Replaces FFS 17-07 and QI-1717]

TO: Medicaid Fee-For-Service (FFS), QUEST Integration Health Plans, Physicians and Pharmacies

FROM: Judy Mohr Peterson, PhD
Med-QUEST Division Administrator

Curtis Toma, MD
Med-QUEST Division Medical Director

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

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 Integration (QI) health plans which include AlohaCare, HMSA, Kaiser Permanente, 'Ohana Health Plan, and UnitedHealthcare. Recommendations are based on the American Academy of Pediatrics (AAP) national guidelines adjusted for local RSV epidemiology. Both the clinical criteria for coverage and the dates of coverage are unchanged. However, Pharmacare will no longer be administering Synagis®. Fortunately, the neonatalology department at Kapiolani Medical

Center for Women and Children will be offering to administer Synagis® and assist with the prior authorization process (See Attachment A).

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 1, 2018 through March 31, 2019. The first dose can be administered on or after September 1, 2018 and subsequent treatments may continue thru March 31, 2019.

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

1. Infants less than 12 months chronologic age at the start of the RSV season (Born on or after September 1, 2017) 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 with pulmonary abnormalities or neuromuscular diseases that impair the ability to clear secretions from the upper or lower airways.

    d. Infants born prematurely under 32 weeks (31 + 6 or less) gestation with history of requiring supplemental oxygen or positive pressure ventilation for at least the first 28 days after birth.

2. Children less than 24 months of chronologic age at the start of RSV season (born on or after September 1, 2016) who meet either criteria below:

    a. Chronic Lung Disease (CLD) requiring medical management, defined as supplemental oxygen, chronic corticosteroid use, or diuretic therapy during the 6-month period prior to the current RSV season.

    b. Severely immunocompromised patients who undergo solid organ or hematopoietic stem cell transplantation, chemotherapy, or have a severe immunocompromised condition may also be considered for RSV prophylaxis.

RSV prophylaxis with palivizumab (Synagis®) is not covered for the following:

1. Infants and children with hemodynamically insignificant heart disease including but not limited to as 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. Palivizumab should be discontinued in patients with RSV infection.

Clinical Considerations

1. RSV prophylaxis for indicated patients should, ideally, be started between September 1, 2018 and September 30, 2018. However, later start date is acceptable.

2. 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.

3. RSV prophylaxis should be continued to provide immunity until the end of March 2019 or until a total of five doses have been administered, whichever is earlier.

4. Children who undergo cardiopulmonary bypass, including extracorporeal membrane oxygenation, with indication for RSV prophylaxis should receive an additional dose of palivizumab after surgery due to a significant drop in protective antibody levels following cardiopulmonary bypass. Children who undergo cardiopulmonary bypass may exceed the usual limit of five (5) RSV prophylaxis doses per season.

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 handwashing and cough hygiene;

   b. Breastfeeding;

   c. Avoiding exposure of the infant to smoke and dust especially passive smoke inhalation; and

   d. Avoiding unnecessary exposure to crowds and avoiding ill contacts.

7. 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. Prior authorizations for palivizumab may be obtained from the Medicaid QI health plan (AlohaCare, HMSA, Kaiser Permanente, 'Ohana Health Plan, and UnitedHealthcare Community Plan).

3. Prior authorizations for patients on the Koan SHOTT transplant program may 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 1, 2018 and March 31, 2019.

Please contact Dr. Curtis Toma, Med-QUEST Division Medical Director, at (808) 692-8106 or via e-mail at ctoma@dhs.hawaii.gov should you have any questions.

Attachment

Attachment A

HAWAI'I PACIFIC HEALTH | KAPI'OLANI MEDICAL SPECIALISTS

Kapiolani.org

September 1, 2018

(Physician's Full Name)
(Physician's Fax Number)

RE: **(Patient Name), (Date of Birth)**

Dear Dr. (Physician's Last Name):

Information extracted from Kapi'olani Medical Center for Women & Children's Health Information System shows that the above-referenced patient meets the criteria for Synagis prophylaxis during this RSV season. As defined by the Hawai'i RSV Consensus Committee, identified infants also fall into the high-risk category.

Synagis (Palivizumab) is a humanized monoclonal antibody that provides passive immunity against RSV infection. Prophylaxis should begin between September 1 and 30, corresponding with the peak incidence of RSV infections in Hawaii. ***It is also recommended that you review the records of other patients in your practice who may qualify for RSV prophylaxis, especially patients with congenital heart disease.***

Starting this 2018 season, unfortunately, Pharmacare will no longer be administering Synagis, as had been done in previous years. In order to continue caring for our high risk patients, Kapi'olani Medical Center for Women and Children will be offering to administer Synagis at our multidisciplinary outpatient clinic on the 3rd floor of our new Diamond Head Tower. We will help with obtaining authorization for outpatient medication. To avoid any delays in the approval process, be sure to include the required information - Date of birth, gestational age at birth, current diagnosis and a current progress note. The patient's discharge summary may be used as the referral document.

If you have never seen this patient or are no longer following (him/her), please let us know by calling the Neonatology Office at 808-983-8670, so that we can try to identify the correct Primary Care Provider.

Thank you for your attention to this very important matter. Please let us know if you have any questions.

Sincerely,

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Kapi'olani Medical Center for Women & Children
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