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DEPARTMENT OF HUMAN SERVICES
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Kapolei, Hawaii 96709-0190

August 14, 2006

MEMORANDUM ACS M06-14

TO: Medicaid Physicians and Pharmacies

FROM: Wesley Mun, Acting Med-QUEST Division Administrator

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

This memorandum updates and supercedes previous guidelines for the coverage of RespiGam and Synagis. Changes to the previous memorandum are underlined.

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

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 July 17, 2006. 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; and
- Avoidance of exposure of their infants to all sick persons.

Recommended Guidelines for Use of RespiGam and Synagis

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

- 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, 2006).
- Infants born prematurely at 28 weeks gestation or earlier and who are less than twelve (12) months chronological age at the start of the RSV season. (Born on or after September 15, 2005).
- 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 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 6 months of age at the beginning of the RSV season. (Born on or after March 15, 2006).
- 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 6 months before the anticipated RSV season.
- All children 2 years or younger at the beginning of the season with hemodynamically significant Congenital Heart Disease (CHD) requiring medical management. (Born on or after September 15, 2004). 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.

- Children 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 (15 mg/kg) should be considered as soon as the patient is medically stable.

Children meeting the criteria for Synagis/Respigam should also be considered for influenza immunization if they are over the age of 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 2006 to early 2007 this year for Hawaii will be from September 15, 2006 to February 28, 2007.

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, 2006, and to end no later than February 28, 2007. No coverage for Synagis will be allowed in March 2007.

- 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 and Synagis 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, 2007.

Additional Considerations

- The MQD requires authorization for Synagis and RespiGam. 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 1144 b (attachment 1) to 1-888-335-8474.

- The physician must weigh the side effects of these agents against the benefit gained from preventing RSV infections.

- RespiGam should not be administered at the same time as routine childhood immunizations and may interfere with response to immunizations. RespiGam is contraindicated in cyanotic CHD.

- As Synagis is given intramuscularly, it must be used with caution in patients with thrombocytopenia and coagulation disorders.

- A second (2^{nd}) course of Synagis therapy in the following season is rarely indicated.

Attachment

STATE OF HAWAII
Department of Human Services
Med-QUEST Division

ACS – Hawaii Sate Medicaid Fee for Service Program
Attention: DUR, P.O. Box 967
Henderson, NC 27536-0967

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] Patient's Name (Last, First, M.I.)	[3] Gender [ ]M [ ]F	[4] Date of Birth / /
[5] Medicare Coverage? [ ] Yes [ ] No Is Patient receiving Medicare Home Health Benefits? [ ] Yes [ ] No	[6] Currently at: [ ] Home [ ] Hospital [ ] SNF/ICF/ICF-MR Facility Patient's Mailing Address (St., City, Zip Code)	[7] Expanded Early & Periodic Screening Diagnosis & Treatment (EPSDT): [ ] Yes [ ] 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 From:	To:
1						
2						
3						
4						
5						

Physician Section

[13] Diagnosis or ICD-9 code [14] BMI (for anorexiants):

[15] Period Requested [16] Prognosis

[17] Justification (include history of previous treatment) ([ ] Attachment)

[18] Print Physician's Name/Mailing Address	[19] Physician's Signature	
	[20] DEA or Medicaid Provider #	[21] Date
	[22] Telephone #	
	[23] Fax #	[24] Contact Name

Supplier Section

[25] Print Supplier's Name/Mailing Address			[26] Comments
[27] Contact Name	[28] Telephone #	[29] Fax #	
[30] Supplier's Signature	[31] NABP #	[32] Date	

INSTRUCTIONS

DHS 1144B

HAWAII STATE MEDICAID FEE FOR SERVICE PROGRAM

REQUEST FOR MEDICAL AUTHORIZATION

1. **Medicaid ID Number :** Enter the Medicaid ID.
2. **Patient's Name:** Enter the patient's name (last, first, MI).
3. **Gender:** Check the patient's gender.
4. **Date of Birth:** Enter the member's date of birth: mm/dd/yyyy.
5. **Medicare Coverage:** Check whether the patient has Medicare coverage and is receiving Medicare Home Health Benefits.
6. **Currently At:** Check where the patient is currently located and enter the mailing address.
7. **Expanded Early & Periodic Screening Diagnosis & Treatment (EPSDT):** Check whether the patient has received expanded early and periodic screening diagnosis & treatment.
8. **NDC Number or Drug Name, Strength, Units, or Global Code, or HCPCS:** Enter the NDC Number, Drug Code, or HCPCS code.
9. **QTY:** Enter the quantity.
10. **Purchase Price:** Enter the purchase price.
11. **Rent/Repair:** Circle whether this request is for rent or repair and enter the amount.
12. **Period Requested:** Enter the Period Requested From: and To:.
13. **Diagnosis or ICD-9 code:** Enter the diagnosis code or the ICD-9 code.
14. **BMI (for anorexiants):** Enter the BMI.
15. **Period Requested:** Enter the period requested.
16. **Prognosis:** Enter the prognosis.
17. **Justification:** Enter the justification and include any history of previous treatment. Check if any attachments are included.
18. **Print Physician's Name / Mailing Address:** Print the physicians name and mailing address.
19. **Physician's Signature:** Physicians: Sign the form.
20. **DEA# or Medicaid Provider #:** Enter the physician DEA number or the Medicaid Provider number.
21. **Date:** Enter the date of signature.
22. **Telephone #:** Enter the physician's telephone number.
23. **Fax #:** Enter the physician's fax number.
24. **Contact Name:** Enter the name of the person to contact.
25. **Print Supplier's Name / Mailing Address:** Print the supplier's name and mailing address.
    Suppliers
26. **Comments:** Enter any comments.
27. **Contact Name:** Enter the name of the person to contact.
28. **Telephone #:** Enter the supplier's telephone number.
29. **Fax#:** Enter the supplier's fax number.
30. **Supplier's Signature:** Sign the request.
31. **NABP#:** Enter the NSBP number.
32. **Date:** Enter the date of signature.