Palivizumab (Synagis)

Policy Number: MM.04.025
Original Effective Date: 11/13/2001
Line(s) of Business: HMO; PPO; QUEST
Current Effective Date: 08/15/2012
Section: Prescription Drugs
Place(s) of Service: Outpatient

I. Description

Palivizumab (Synagis) is a monoclonal antibody produced by recombinant DNA technology. It is an intramuscular injection used as a prophylaxis against respiratory syncytial virus (RSV).

RSV is found worldwide and occurs throughout the year. It is the leading cause of lower respiratory tract disease in infants and young children. Each year in the United States, nearly 90,000 children are hospitalized due to infection with RSV. In the continental U.S., the season generally begins in early November and continues through April. In Hawaii, RSV infections generally peak from September through February.

II. Criteria/Guidelines

A. For infants eligible for immunoprophylaxis, the beginning of the season will be considered September 15, 2012 continuing through the month of March 2013.
B. Palivizumab (Synagis) will be covered (subject to Limitations/Exclusions and Administrative Guidelines) for the following patients:
   1. Children younger than two years old at the beginning of the RSV season with chronic lung disease requiring ongoing, significant treatment, such as oxygen, within six months of the anticipated season. (Born on or after September 15, 2010; continuing medical treatment after March 15, 2012).
   2. All children younger than 2 years at the beginning of the season with hemodynamically significant congenital heart disease requiring medical management to control congestive heart failure, infants with cyanotic heart disease, or infants with moderate to severe pulmonary hypertension.
   3. For children who have undergone cardiopulmonary bypass who still require prophylaxis, a post-operative dose of palivizumab (15 mg/kg) should be considered as soon as the patient is medically stable.
4. Children born prematurely under 29 weeks (28 + 6 or less) gestation who are less than one year chronological age at the beginning of the season (Born on or after September 15, 2011).

5. Children born prematurely between 29 + 0 and 31 + 6 weeks gestation who are less than six months chronological age at the beginning of the season (Born on or after March 15, 2012).

For children meeting the criteria above, a maximum of five doses can be given from September 15, 2012 through the month of February 2013 as outlined in the following table. The interval between the first and second dose should be as close as possible to 28 days. All subsequent dose intervals should be as close to 30 days as possible (range 28-35 days).

<table>
<thead>
<tr>
<th>First Dose Administered</th>
<th>Maximum Number of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 15, 2012 to October 31, 2012</td>
<td>5</td>
</tr>
<tr>
<td>November 1, 2012 to November 30, 2012</td>
<td>4</td>
</tr>
<tr>
<td>December 1, 2012 to December 31, 2012</td>
<td>3</td>
</tr>
<tr>
<td>January 1, 2013 to January 31, 2013</td>
<td>2</td>
</tr>
<tr>
<td>February 1, 2013 to February 28, 2013</td>
<td>1</td>
</tr>
</tbody>
</table>

6. Children born prematurely between 32 + 0 and 34 + 6 weeks gestation requiring significant respiratory support in the neonatal period (significant positive pressure support, i.e. ventilator, CPAP or high flow nasal cannula, and with oxygen requirements above 30 percent in the first 72 hours of life) and having an additional risk factor (attend child care or have a sibling less than 5 years of age) born on or after June 15, 2012.

A maximum of three doses can be administered as outlined in the following table. Doses should be administered between 28 and 35 days apart.

<table>
<thead>
<tr>
<th>Birth Date</th>
<th>Maximum Number of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 15, 2012 to July 14, 2012</td>
<td>1 dose, before 90 days of age</td>
</tr>
<tr>
<td>July 15, 2012 to August 14, 2012</td>
<td>2 doses, before 90 days of age</td>
</tr>
<tr>
<td>August 15, 2012 to December 31, 2012</td>
<td>3 doses, before 90 days of age</td>
</tr>
<tr>
<td>January 1, 2013 to January 31, 2013</td>
<td>2 doses</td>
</tr>
<tr>
<td>February 1, 2013 to February 28, 2013</td>
<td>1 dose</td>
</tr>
</tbody>
</table>

C. Should a child who meets the requirements for coverage develop RSV during the season, prophylaxis should be resumed after recovery and until the end of the season.
III. Limitations/Exclusions

A. Palivizumab prophylaxis is provided only during the peak months of RSV infections (September through March, with a five-dose schedule below that ends in February in order to cover a patient therapeutically into the month of March).

B. Palivizumab is indicated for the prevention of RSV and should not be used in patients who have an active RSV infection.

C. The following groups of infants are not at increased risk from RSV and generally should not receive immunoprophylaxis:
   1. Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta and patent ductus arteriosus).
   2. Infants with lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure.
   3. Infants with mild cardiomyopathy who are not receiving medical therapy.

IV. Administrative Guidelines

A. Precertification is required. To precertify, please complete HMSA’s Drug Review Request and mail or fax the form as indicated.

B. The dosing for palivizumab (15 mg/kg) is determined by the patient’s weight; therefore, this information must be included on every claim submitted. The weight in kilograms (kg) should be documented in the comments field (block 19) on the CMS 1500 claim form or in the comments field in EMC.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>90378</td>
<td>Respiratory Syncytial Virus Immune Globulin (RSV-IGIM), for intramuscular use per 50mg</td>
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</tbody>
</table>

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.
This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References

7. QUEST Memo, BEN-9804.
8. QUEST Memo, BEN-0006.
9. QUEST Memo, BEN-0103.