Approval Criteria Department of Pharmacy Services

Generic Name: Palivizumab

Brand Name: Synagis®

Medication Class: Monoclonal antibody. Immunoprophylaxis for RSV

FDA Approved Uses
- Respiratory syncytial virus (RSV): For the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease.

Criteria for use
- Children younger than 2 years of age at the start of RSV season with chronic lung disease (CLD) requiring medical therapy for CLD within the past 6 months
- Children 2 years of age and younger at the start of RSV season with hemodynamically significant cyanotic and acyanotic congenital heart disease
- Infants younger than 12 months of age with congenital heart disease who have moderate to severe pulmonary hypertension
- Infants 12 months and younger at the start of RSV season and ≤ 28 weeks, 6 days of gestation
- Infants up to 6 months of age at the start of RSV season and 29 weeks, 0 days and 31 weeks, 6 days of gestation
- Infants younger than 3 months of age at the start of RSV season, and born during RSV season, and 32 weeks, 0 days and 34 weeks, 6 days of gestation with 1 or more risk factors
  - Child care attendance (ie. Day care)
  - Sibling < 5 years of age
- In the Northern Hemisphere, the first dose should be administered at the beginning of November, and the last dose should be administered at the beginning of March.
- Prior authorization requests will not be processed or approved until on or after October 15th.

Required Medical Information
- Appropriate documentation to support above, chart notes, statement of medical necessity

Contraindications
- Patients with a history of a severe reaction to palivizumab or other components of the product (histidine & glycine)

Not Approved if
- Pt does not meet Criteria for Use above
- 6th dose, if requested
Authorization

- Ordered by Pediatrician or Family Practice physician
- Maximum number of doses allowed

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<tr>
<th>Month of Birth</th>
<th>Maximum number of doses for season beginning November 1</th>
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<tbody>
<tr>
<td></td>
<td>≤ 28 wks, 6 d of gestation and &lt; 12 mo of age at start of RSV season</td>
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<td>29 wks, 0 d through 31 wks, 6 d WITH RISK FACTOR and &lt; 6 mo of age at start of RSV</td>
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<td>≥ 32 wks, 0 d through 34 wks, 6 d and &lt; 3 mo of age at start of RSV WITH RISK FACTOR</td>
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Dosing

- 15mg/kg/dose IM once monthly

Criteria for continuation of therapy

- Refer to Criteria for Use above

Approved by P&T: 07/16/2013, 7/15/2014

References

8. Gala CL, Hall CB, Schnabel KC, et al. The use of eye-nose goggles to control nosocomial respiratory syncytial virus