

Pharmacy Benefit Determination Policy

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| Policy Subject: Synagis | Dates: |
| Policy Number: SHS PBD04 | Effective Date: October 1999 |
| Category: Child & maternal Medicine | Revision Date: December 6, 2017 |
| Policy Type: <input checked="" type="checkbox"/> Medical <input type="checkbox"/> Pharmacy | Approval Date: December 5, 2018 |
| Department: Pharmacy | Next Review Date: December 2019 |

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| Product (check all that apply): | Clinical Approval By: |
| <input checked="" type="checkbox"/> Group HMO/POS | Medical Directors |
| <input checked="" type="checkbox"/> Individual HMO/POS | PHP: Peter Graham, MD |
| <input checked="" type="checkbox"/> PPO | Pharmacy and Therapeutics Committee |
| <input checked="" type="checkbox"/> ASO | PHP: Peter Graham, MD |

Policy Statement:

Physicians Health Plan and PHP Insurance & Service Company and Sparrow PHP, will cover Synagis through the Medical Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines:

Drugs and Applicable Coding:

HCPCS Code: Synagis - 90378

Clinical Determination Guidelines:

Document the following with chart notes

- A. Chronic Lung Disease (all below):
 - 1. Age (both below)
 - a. Gestational: <32 weeks.
 - b. Chronological: ≤ 24 months of age
 - 2. Diagnosis and severity: Chronic Lung Disease (required ≥ 28 days of > 21% oxygen).
 - 3. Other therapies (>12 months of age):
 - a. Chronic corticosteroid therapy, diuretic therapy or supplemental oxygen meet all criteria as listed
 - b. Received within 6 months (June - October) of the onset of RSV season (mid-November)
- B. Prematurity (all below)
 - 1. Age:
 - a. Gestational: <29 weeks gestational age
 - b. Chronological: ≤12 months at the beginning of the RSV season
 - 2. Diagnosis: Prematurity

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C. Heart Disease (must meet 1 and 2)

1. Age: \leq 12 months
2. Diagnosis and severity: Hemodynamically significant acyanotic heart disease
 - a. Receiving medication to control congestive heart failure and will require future cardiac surgical procedures or
 - b. Moderate to severe pulmonary hypertension:

B. May consider RSV Prophylaxis (no population-based data and/or prospective studies available)

1. Anatomical Pulmonary Abnormalities or Neuromuscular Disorder
 - a. Age: < 24 months
 - b. Diagnosis and severity
 - Neuromuscular disease or congenital anomaly
 - Impaired clearance of secretions from upper airways because of ineffective cough
2. Immunocompromised Children (solid organ/stem cell transplant or receiving chemotherapy)
 - a. Diagnosis: Profoundly immunocompromised during RSV season
 - b. Age: < 24 months.

D. Dosage and Administration

1. Dosage Frequency: Administer 5 monthly doses from November to March
 - a. Administration of >5 doses not recommended in the Continental United States
 - b. Five doses provides 6 months of coverage
2. Dosage Range: Allow for 50mg dosage range from beginning to end of season to accommodate weight change (< ½ vial - round ↓, > ½ vial - round ↑)
3. Breakthrough RSV hospitalization during treatment: Discontinue Synagis
4. Influenza vaccine: Administer to patients > 6 months of age

E. Exclusions

1. \geq 29 weeks gestational age
2. Heart Disease:
 - a. Age: >12 months
 - b. Hemodynamically insignificant heart disease: Secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis and mild coarctation of the aorta and patent ductus arteriosus
 - c. Cardiac lesions: Adequately corrected by surgery unless requires medication(s) for CHF
 - d. Mild cardiomyopathy without medical therapies
2. Downs Syndrome: Insufficient data
3. Cystic Fibrosis: Not recommended
4. Primary asthma prevention or to decrease subsequent episodes of wheezing

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Appendix: I Monitoring and Patient Safety

| Drug | Adverse Reactions | Monitoring | REMS |
|-----------------------|---|--|------------|
| Synagis (palivizumab) | <ul style="list-style-type: none"> • Derm: Skin rash (12%) • Misc.: Fever (27%) | Anaphylaxis: monitor for an appropriate time post infusion | Not needed |

References and Resources:

1. Pediatric Infectious Disease Journal. 2012;18(3):223-231.
2. Pediatrics 1999;104(3):419-427.
3. Update Guidance for Palivizumab Prophylaxis Among Infants and Young children at Increased Risk of Hospitalization for RSV Infections. Pediatrics 2014;134:415
4. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Synagis, accessed Nov. 2018

Approved By:



12/5/18

Peter Graham, MD – PHP Executive Medical Director

Date

12/5/18

Human Resources – Kurt Batteen

Date