Drug Therapy Guidelines	Applicable*	Synagis® (palivizumab injection)
Medical Benefit	x	**Effective:** 8/15/18
Pharmacy- Formulary 1		**Next Review:** 6/19
Pharmacy- Formulary 2		**Date of Origin:** 6/05
Pharmacy- Formulary 3/Exclusive		**Review Dates:** 6/15/05, 2/1/06, 10/15/06, 11/5/07, 12/15/08, 12/09, 12/10, 12/11, 12/12, 12/13, 12/14, 6/15, 6/16, 6/17, 6/18
Pharmacy- Formulary 4/AON		

I. Medication Description

Palivizumab is a monoclonal antibody which exhibits neutralizing and fusion inhibitory activity against respiratory syncytial virus (RSV). Palivizumab binds to the highly conservative A antigenic site of the 'F' protein inhibiting RSV from replicating and thus further infecting cells. RSV causes acute upper respiratory tract infection in patients of all ages with virtually all children having been infected at least once by their second birthday. Lower respiratory tract infections occur in the minority of cases and primarily during the first infection.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage for Synagis is provided during the local RSV season for infants and young children who are at high risk of RSV-related hospitalization due to one or more of the following conditions:

- Prematurity**:** Infants with a **gestational age of up to 28 weeks/6 days** who are younger than 12 months of age at the start of RSV season will be covered up to a maximum of 5 monthly doses.
- Premature infants with chronic lung disease (CLD):
  - For infants in their first year of life (age < 12 months at the start of RSV season):
    - Prematurity defined as gestational age up to 31 weeks/6 days **AND**
    - Requirement for >21% oxygen for at least the first 28 days after birth is documented
  - For infants in their second year of life (age < 24 months at the start of RSV season):
    - Prematurity defined as gestational age up to 31 weeks/6 days **AND**
    - Requirement for >21% oxygen for at least the first 28 days after birth is documented **AND**
    - Requirement of ongoing medical support during the 6 month period preceding the second RSV season. Continued medical support is defined as:
      - Chronic corticosteroid therapy **OR**
      - Diuretic therapy **OR**
      - Supplemental oxygen
- Hemodynamically significant congenital heart disease (CHD): for infants in the first year of life (age < 12 months at the start of RSV season) with at least one of the following:
  - Acyanotic heart disease:
    - Member is receiving medication to control congestive heart failure **AND**
    - Member will require cardiac surgical procedures **OR**
  - Moderate to severe pulmonary hypertension **OR**
  - Cyanotic heart disease where RSV prophylaxis was specifically recommended by a pediatric cardiologist.

- Cardiac transplant patients younger than 24 months of age at the start of RSV season who underwent transplantation during the RSV season
- Neuromuscular disease or congenital pulmonary abnormality that impairs the ability to clear secretions from the upper airway because of ineffective cough when member is younger than 12 months of age at the start of RSV season.
- Profound immune compromise (i.e. chemotherapy, solid organ transplant, hematopoietic stem cell transplant, etc) for children younger than 24 months of age at the start of RSV season
- Cardiopulmonary bypass: for children younger than 24 months of age at the start of RSV season who are already receiving RSV prophylaxis and who continue to require RSV prophylaxis after a surgical procedure, a post-operative dose of palivizumab should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation.
- Cystic Fibrosis:
    - Member is younger than 12 months of age at the start of RSV season and has at least one of the following:
        - Clinical evidence of chronic lung disease **OR**
        - Nutritional compromise
    - Member is younger than 24 months of age at the start of RSV season and has at least one of the following:
        - Weight for length less than the 10th percentile **OR**
        - Manifestations of severe lung disease, defined as
            - Previous hospitalization for pulmonary exacerbation in the first year of life **OR**
            - Abnormalities on chest radiography or chest computed tomography that persist when stable
- Discontinuation of prophylaxis**:** If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued.

IV. Quantity Limitations

The following pertain to seasonal limits:

- Prematurity: up to 5 monthly doses through the end of RSV season
- Cystic fibrosis or prematurity with chronic lung disease:
    - In the first year of life: up to five monthly doses through the end of RSV season
    - In the second year of life: up to 5 monthly doses through the end of RSV season
- Congenital heart disease, neuromuscular disease or congenital pulmonary abnormality: up to 5 monthly doses through the end of RSV season
- Cardiopulmonary bypass: one additional dosage can be considered for coverage during RSV season
- Immune compromise or cardiac transplant: up to 5 monthly doses through the end of RSV season

V. Coverage Duration

- The duration of authorization will be dependent on the requirements of the individual case due to age and risk factors.
- Duration of coverage greater than 5 months is not available.

VI. Coverage Renewal Criteria

One season of prophylaxis can be approved at a time. Coverage for a second season of RSV prophylaxis would be dependent upon meeting the criteria outlined in Section III above.

VII. Billing/Coding Information

- Synagis® single dose vials- 50mg/0.5ml, 100mg/1ml
- CPT 90378 – 50mg each unit
- ICD-10: P07.21-P07.26, P07.31, Q20.1, Q20.3, Q20.4, Q20.6, Q20.8, Q21.0-21.4, Q21.8-22.6, Q22.8-23.4, Q24.2-24.6, Q24.8, Q25.0-25.6, Q25.71, Q25.72, Q25.79, Q26.0, Q26.1, Q26.8, Z51.1, Z92.2, Z94.1, Z94.3, Z99.81

VIII. Summary of Policy Changes

- 3/1/11: Format updated, Addition of Warnings/Precautions
- 6/15/12: no policy changes
- 3/15/13: removal of coverage for members with immunodeficiency as this is not a recommended routine use of Synagis per 2009 AAP Guidelines
- 3/15/14: Use in children with neuromuscular disease or airway abnormalities: 35 week prematurity provision removed.
- 8/15/14: Updated policy to comply with new AAP Guidelines published online on 7/28/14.
- 3/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 9/15/15: no policy changes
- 7/19/16: no policy changes
- 6/21/17: no policy changes
- 8/15/18: updated quantity limitations, clarified coverage criteria ages

IX. References

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**These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.*

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.