Comprehensive Medical and Dental Program
Authorization Guideline

Subject: Palivizumab (Synagis) Administration

Unit: Health Services

Purpose

This guideline is used in the prior authorization and decision-making process regarding requests for palivizumab (Synagis) administration.

This guideline does not represent a standard of care, nor is it intended to dictate an exclusive course of management. Since medical research, physician practice patterns, and health care technology are continuously evolving, please note that the information contained in this guideline may be updated.

Background

Respiratory Syncytial Virus (RSV) is one of the leading causes of upper respiratory illness in children during the winter months. RSV infection is characterized by copious muco-purulent discharge and upper airway congestion. In some cases, RSV infection can progress to pneumonia and cause significant hypoxia. Children with chronic medical condition, such as chronic lung disease, cardiac disease, and reactive airway disease, can become severely ill from RSV infection.

Aside from typical preventative measures (hand washing, hygiene, fomite control), an important aspect of RSV infection prevention has been prophylactic vaccination with RSV immunoglobulin. The currently formulated version of RSV immunoglobulin, Palivizumab, is marketed as Palivizumab (Synagis). Palivizumab is a immunoglobulin, providing passive immunity, meaning it does not induce a immune response in the recipient, and must be given on a regular basis (monthly injections) to continue providing protective immunotherapy.

All prescriptions for Palivizumab must have prior authorization.

Criteria to Substantiate Medical Necessity for Palivizumab (Synagis) Administration

In evaluating a request for prior authorization of a prescription for Palivizumab, the determination of whether the requested prescription is medically necessary will take into account all of the following:

- Prophylaxis is being prescribed for use during Respiratory Syncytial Virus (RSV) season.
- A maximum of 5 monthly doses of palivizumab may be administered during the RSV season to infants who qualify for prophylaxis in the first year of life. Qualifying infants born during the RSV season will require fewer doses. For example, infants born in January would receive their last dose in March, as protection lasts for a full month.

- The infant or child is at risk of developing severe RSV infection as defined by the 2014 American Academy of Pediatrics (AAP) Guidelines on Prevention of RSV Infection.

American Academy of Pediatrics Guidelines for Palivizumab Administration (2014)
Future revisions to the AAP Guidelines on Prevention of RSV Infection will apply when determining medical necessity.

Infants/Children meeting criteria for administration of a **maximum of 5 doses:**

- In the first year of life, palivizumab prophylaxis is recommended for infants born before 29 weeks, 0 days gestation. Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days gestation.

- In the first year of life, palivizumab prophylaxis is recommended for preterm infants with chronic lung disease of prematurity defined as <32 weeks, 0 days gestation **and** a requirement for >21% oxygen for at least 28 days after birth.

- Clinicians may administer palivizumab prophylaxis in the first year of life to certain infants with **hemodynamically** significant heart disease.

- Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways **may be considered** for prophylaxis in the first year of life.

- Palivizumab prophylaxis is not recommended in the second year of life **except** for children who require at least 28 days of supplemental oxygen after birth and **who continue to require medical intervention for chronic lung disease of prematurity** (e.g., supplemental oxygen, chronic corticosteroid or diuretic therapy).

- Children less than 24 months of age who will be profoundly immunocompromised during the RSV season **may be considered** for prophylaxis.

- Insufficient data are available to routinely recommend palivizumab prophylaxis for children with cystic fibrosis or Down syndrome.

Please note: Monthly prophylaxis should be discontinued in any child who experiences a break through RSV hospitalization.

References

1. American Academy of Pediatrics: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. (2014). *PEDIATRICs: Official Journal of the American Academy of Pediatrics, 134*(2), 415-420. Retrieved from http://pediatrics.aappublications.org/content/early/2014/07/23/peds.2014-1665
2. AAP Policy Statement Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections. *Pediatrics;* Vol 124(6) December 2009
3. Principles and Practices of Pediatric Infectious Diseases, 3rd ed. pp. 1112 – 1117.
4. NICU Nursing Education Department, Maricopa Medical Center

____Signature on file_____ _____*4/7/17*_____
Medical Director Date