



Comprehensive Medical and Dental Program Authorization Guideline

TITLE Synagis (Palivizumab) Prior Authorization Guideline
RESPONSIBLE AREA Health Services
History of Review: 11/2008, 12/2009, 2/22/2011, 9/4/2013, 8/19/2014, 1/23/15, 7/11/16, 4/7/17, 12/9/18; 06/03/19 Approval Date: 06/03/19

DESCRIPTION

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

DEFINITIONS

RSV Respiratory Syncytial Virus

CLINICAL GUIDELINE

Indications for Palivizumab (Synagis) Administration

Prophylaxis of respiratory syncytial virus (RSV) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients

Prophylaxis is covered for use during 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.

CMDP follows the 2014 American Academy of Pediatrics (AAP) Guidelines on Prevention of RSV Infection, to determine which children qualify for RSV prophylaxis. Future revisions to the AAP Guidelines on Prevention of RSV Infection will apply when determining medical necessity.

CMDP considers Palivizumab (Synagis) medically necessary in the following circumstances:

1. The infants born before 29 weeks, 0 days gestation and less than 12 months old at the start of RSV season.
 - Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days gestation.
2. Preterm infants defined as <32 weeks, 0 days gestation with chronic lung disease of



prematurity **and** a requirement for >21% oxygen for at least 28 days after birth, who are under 12 months of age at the beginning of RSV season.

3. In the second year of life, children with chronic lung disease who required 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) during the 6 month period before the start of the current RSV season.
 - For children with chronic lung disease who do not continue to require medical support in the 2nd year of life, prophylaxis is not recommended.
4. Infants with **hemodynamically** significant heart disease who are 12 months or younger at the start of RSV season. This includes infants with:
 - acyanotic heart disease who are receiving medication to control congestive heart failure
 - will require cardiac surgical procedures and
 - infants with moderate to severe pulmonary hypertension
5. 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.
6. Children less than 24 months of age who will be profoundly immunocompromised during the RSV season **may be considered** for prophylaxis.
7. Routine prophylaxis of Palivizumab prophylaxis for children with Down syndrome is not covered unless the infant has a qualifying illness, such as Chronic lung disease , qualifying heart disease, airway clearance issues or prematurity (<29 weeks, 0 days gestation)
8. Routine prophylaxis of infants Diagnosed with Cystic fibrosis by newborn screen is not covered unless other indications are present. Other issues that may qualify the infant for prophylaxis include:
 - Clinical evidence of chronic lung disease and or nutritional compromise in the first year of life
 - In the second year of life, manifestation of severe lung disease (abnormal chest x-ray or CT, previous hospitalization for pulmonary exacerbation) or weight less than the 10th percentile.
9. **Please note:** Monthly prophylaxis should be discontinued in any child who experiences a breakthrough 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. CDC: <https://www.cdc.gov/rsv/clinical/index.html>

PLEASE NOTE: State and Federal law take precedence over prior authorization guidelines. CMDP reserves the right to review and update guidelines periodically.