VENTURA COUNTY
HEALTH CARE PLAN

SYNAGIS (palivizumab)

Effective Date: 4/22/14
Date Developed: 4/9/14 by Robert Sterling, MD
Last Approval Date: 1/26/16, 1/24/17, 1/23/18
(Archived 1/22/19)

Palivizumab is a monoclonal antibody produced by recombinant DNA technology directed to a surface protein antigen of Respiratory Syncytial Virus (RSV).

Authorization Criteria: *prevention* of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. (**Note**: The safety and efficacy of Synagis have not been established for *treatment* of RSV disease)

The American Academy of Pediatrics recommends RSV prophylaxis with palivizumab during RSV season for:

- Infants <3 months of age who were born between 32 and 34 6/7 weeks gestational age and have one of the following:
  - Day care attendance
  - One or more siblings <5 years of age living in the same household
- Infants <6 months of age who were born between 29 and 31 6/7 weeks gestational age
- Infants <12 months of age who were born <28 weeks gestational age
- Infants <12 months of age with congenital airway abnormality or neuromuscular disorder that decreases the ability to manage airway secretions
- Infants and children <24 months of age with chronic lung disease (CLD) necessitating medical therapy within 6 months prior to the beginning of RSV season
- Infants and children ≤24 months of age with congenital heart disease and one of the following:
  - Receiving medication to treat congestive heart failure
  - Moderate-to-severe pulmonary hypertension
  - Cyanotic heart disease

Dosing: 15 mg per kg of body weight given monthly by intramuscular injection; first dose prior to RSV season (approximately November) then monthly throughout RSV season (approximately through April); Continue to administer Synagis even if the child develops an RSV infection.

How Supplied: 50 mg and 100 mg single-dose vials

Contraindications/Warnings: contraindicated with documented history of previous hypersensitivity reaction; may induce false negative RSV test results (except PCR-based tests)

Major Adverse Reactions: hypersensitivity (<1%); thrombocytopenia

Major Drug Interactions: none reported

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REFERENCES

American Academy of Pediatrics (AAP) Committee on Infectious Diseases, "Modified Recommendations for the Use of Palivizumab for the Prevention of Respiratory Syncytial Virus Infections," *Pediatrics*, 2009, 124:1-8.

Johnson S, Oliver C, Prince GA, et al, "Development of a Humanized Monoclonal Antibody (MEDI-493) With Potent *In Vitro* and *In Vivo* Activity Against Respiratory Syncytial Virus," *J Infect Dis*, 1997, 176(5):1215-24.

"Palivizumab, a Humanized Respiratory Syncytial Virus Monoclonal Antibody, Reduces Hospitalization From Respiratory Syncytial Virus Infection in High-Risk Infants. The IMpact-RSV Study Group," *Pediatrics*, 1998, 102(3 Pt 1):531-7.

Subramanian KN, Weisman, LE, Rhodes T, et al, "Safety, Tolerance and Pharmacokinetics of a Humanized Monoclonal Antibody to Respiratory Syncytial Virus in Premature Infants With Bronchopulmonary Dysplasia. MEDI-493 Study Group," *Pediatr Infect Dis J*, 1998, 17(2):110-5.

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