



Indiana Medicaid Therapeutics Committee **Therapeutic Class Review Summary**

Therapeutic Class:

Monoclonal Antibody Agents for Respiratory Syncytial Virus

Overview:

Palivizumab (Synagis®) is a novel agent for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Safety and efficacy were established in infants with bronchopulmonary dysplasia (BPD), a history of premature birth (≤ 35 weeks gestational age), and in children with hemodynamically significant congenital heart disease. Palivizumab exhibits neutralizing and fusion-inhibitory activity against RSV, thereby inhibiting RSV replication.

Palivizumab injection is available in 50mg and 100mg (100mg/ml) single-dose vials. The drug is for intramuscular administration only at 15mg/kg and is given monthly during RSV season. The first dose of palivizumab should be given prior to the start of RSV season, which in the Northern hemisphere is typically November. The season commonly lasts through the end of April, but varies by region. Common adverse effects associated with the use of palivizumab include upper respiratory infection, otitis media, fever, and rhinitis. Black box warnings associated with palivizumab do not exist.

Generic Name	Brand Name	Manufacturer
Palivizumab	Synagis®	MedImmune

Summary:

Palivizumab, the only monoclonal antibody available for the treatment of RSV, has produced significant reductions in RSV hospitalizations in premature infants, those with bronchopulmonary dysplasia, and in those with hemodynamically significant congenital heart disease. It has also shown reduction of recurrent wheezing in premature infants who were followed for two years after administration of the drug. At this time, no research has shown an impact on mortality as a result of administering palivizumab. The most common adverse effects associated with palivizumab are upper respiratory infection, otitis media, fever, and rhinitis.