Emerging Drug List

PALIVIZUMAB (SYNAGIS®)

Generic (Trade Name): Palivizumab (Synagis®)
Manufacturer: Abbott Laboratories Ltd.
Indication: For the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients who are at high risk of RSV.¹

Current Regulatory Status: Palivizumab is currently marketed in both Canada and the United States. A Notice of Compliance was granted by Health Canada on May 15, 2002.² Palivizumab has been marketed in the United States since 1999.¹

Description: Palivizumab is a humanized monoclonal antibody produced by recombinant DNA technology.¹ It acts by binding to the F protein of the RSV. Palivizumab is given as an intramuscular injection on a monthly basis for five months during the period where RSV is more common (i.e. November to April). The approved dose of palivizumab is 15 mg/kg.

Current Treatment: The only available treatment for RSV infection is ribavirin via nebulization (by spray) accompanied by standard supportive respiratory and fluid management.³ Prophylaxis against RSV can be accomplished with respiratory syncytial virus immune globulin intravenous (RespiGam, RSV-IGIV).

Cost: The cost of a single 100 mg vial is $1467.81.² RespiGam is available via the Special Access Program of Health Canada and it is funded by the Canadian Blood Services. Funding criteria include children two years of age or less with bronchopulmonary dysplasia and who have required oxygen within six months preceding the RSV season, or infants born at 32 weeks or less gestation and aged six months or less (with or without bronchopulmonary dysplasia) at the start of the RSV season.⁴

Evidence: The prophylactic efficacy of palivizumab was demonstrated in a single, large, randomized, placebo controlled, multicentre, double-blind trial.³ A total of 1502 children were randomized to palivizumab 15 mg/kg (n=1002) or placebo (n=500) monthly for five months (during the winter and spring). Palivizumab significantly reduced the incidence of hospitalization due to RSV by 5.8% (i.e. 4.8% for the palivizumab group vs 10.6% for the placebo group).

Secondary endpoints were also improved in the palivizumab group. These included fewer days of hospitalization with confirmed RSV (i.e. 36.4 vs 62.6 per 100 infants, p<0.001), fewer days with increased supplemental oxygen (i.e. 30.3 vs 50.6 days per 100 infants, p<0.001), and fewer days with moderate to severe lower respiratory tract illness (i.e. 29.6 vs 47.4 days per 100 infants, p<0.001).
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Adverse Effects: Adverse effects reported to occur more commonly with palivizumab than placebo include injection site reaction, diarrhea and rash.1 Palivizumab was generally very well tolerated with a very low incidence of patient discontinuation due to adverse effects (i.e. 0.3%). Injection site reactions included erythema, pain, hardening or swelling and bruising.

Commentary: RSV is the most common cause of bronchiolitis and pneumonia in young children.6 No data on the incidence of RSV are currently available in Canada. Data from the 1997-1998 RSV season indicated positive isolates in the range of 1078 to 1134 per 100,000 children.7 The rates of acute bronchiolitis for 1998 in children under one year of age were 4606 per 100,000 for boys and 3181 per 100,000 for girls. The average incidence (1996-1998) of hospitalization for acute bronchiolitis among children under one year of age was 3505 per 100,000.7

Palivizumab may be preferred to RSV-IGIV because of its route of administration (intramuscularly versus intravenously), similar efficacy and it does not delay regular childhood immunization schedules. The Canadian Pediatric Society has published a position statement and recommendations regarding the use of both of these agents.4

Several pharmacoeconomic analyses in a US setting have been performed.8-11 Since infection rates and US population characteristics used in these analyses differ historically, the generalizability of results to a Canadian model remains to be proven.

References:


This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada. These summaries have not been externally peer reviewed.

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