Technology Guidance

Palivizumab

for preventing serious lower respiratory tract disease caused by respiratory syncytial virus

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendations

The Ministry of Health's Drug Advisory Committee has not recommended palivizumab for inclusion on the MOH List of Subsidised Drugs for prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease, because it does not represent a cost-effective use of healthcare resources at the price proposed by the company.

Published: 8 February 2023

Factors considered to inform the recommendations for funding

Technology evaluation

1.1. The MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of palivizumab for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from the public healthcare institutions. Published clinical and economic evidence for palivizumab was considered in line with its registered indication.

1.2. The evidence was used to inform the Committee's deliberations around four core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost-effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives; and
- Estimated annual technology cost and the number of patients likely to benefit from the technology.

1.3. Additional factors, including social and value judgments, may also inform the Committee's funding considerations.

Clinical need

2.1 The Committee noted that RSV is a common respiratory pathogen that infects over 80% of children by the age of 2 years. While the infection usually causes mild cold-like symptoms in most children, it can cause serious lower respiratory tract infections such as bronchiolitis and pneumonia in children who are at high risk of developing RSV disease. These include preterm infants, and children with bronchopulmonary dysplasia or haemodynamically significant congenital heart disease.

2.2 The Committee noted that there is currently no RSV vaccine available, hence palivizumab is used to provide short-term passive immunity against RSV infection in children who are at high risk of RSV disease in local practice. The Committee acknowledged the clinical need to consider palivizumab for subsidy to improve affordability for patients.

Clinical effectiveness and safety

3.1. The Committee reviewed the clinical evidence from a Cochrane systematic review (Garegnani et al. 2021) which included five randomised controlled trials (RCTs) that compared palivizumab with placebo or no intervention in children at high risk of RSV disease.

3.2. Results of the Cochrane review indicated that palivizumab reduced the incidence of hospitalisation due to RSV infection compared with placebo or no intervention. However, palivizumab probably resulted in little to no difference in mortality, length of stay in the hospital or intensive care unit, or days on mechanical ventilation or supplemental oxygen.

3.3. The Committee also reviewed the individual RCT results which showed that palivizumab was associated with small reductions (4.4 - 5.8%) in absolute risk of RSV hospitalisation compared with placebo. The corresponding number needed to treat (NNT) was 17 - 23 to prevent one hospitalisation. The Committee also noted that there was no evidence to show significant long-term benefit with palivizumab prophylaxis.

3.4. In terms of safety, adverse drug reactions (ADRs) occurred at similar frequencies in the palivizumab and placebo groups, and most were mild to moderate in severity. The common ADRs reported with palivizumab were injection site reactions, fever, diarrhoea and nervousness.

Cost effectiveness

4.1 The company of palivizumab was invited to submit a value-based pricing (VBP) proposal for their product for subsidy consideration. No local cost-effectiveness analysis (CEA) for palivizumab was identified. Hence, the Committee reviewed the evaluations from overseas HTA agencies, which reported that the cost-effectiveness of palivizumab was unfavourable given that the cost of palivizumab was likely to be in excess of any savings achieved by a reduction in hospitalisation rate.

4.2 The Committee acknowledged that the local proposed price of palivizumab was higher than prices in overseas reference jurisdictions. Furthermore, based on NNTs of 17 - 23, palivizumab prophylaxis did not represent good value for money in view of the high cost of palivizumab needed to prevent one RSV hospitalisation.

Estimated annual technology cost

5.1 The Committee noted that the annual cost impact to the public healthcare system was estimated to be between SG$1 million to less than SG$3 million in the first year of listing palivizumab on the Medication Assistance Fund (MAF) for prevention of serious lower respiratory tract disease caused by RSV.

Recommendations

6.1 Based on available evidence, the Committee recommended not listing palivizumab on the MOH List of Subsidised Drugs for prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease, because it does not represent a cost-effective use of healthcare resources at the price proposed by the company.