Technology Guidance

Biologics as add-on therapy

for treating chronic rhinosinusitis with nasal polyps

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendations

The Ministry of Health's Drug Advisory Committee has not recommended dupilumab, mepolizumab or omalizumab reference biologic (Xolair) for inclusion on the MOH List of Subsidised Drugs for treating chronic rhinosinusitis with nasal polyps, as they were unlikely to represent a cost-effective use of healthcare resources.

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Technology evaluation

1.1. At the November 2025 meeting, the MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of dupilumab, mepolizumab and omalizumab reference biologic (Xolair) for treating chronic rhinosinusitis with nasal polyps (CRSwNP). The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for each biologic was considered in line with their registered indications.

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. Chronic rhinosinusitis is a condition in which the lining of the sinuses becomes inflamed. The chronic inflammation may lead to bilateral development of benign tissue growths in the nasal passages and sinuses (nasal polyps). When nasal polyps are present, the condition is referred to as CRSwNP, and characterised by nasal congestion, discharge, decreased or lost sense of smell, and facial pain. These symptoms may persist for years, impairing quality of life, and affecting productivity, sleep and physical activity.

2.2. In local practice, intranasal corticosteroids and nasal saline irrigation are typically used as first-line treatment for CRSwNP. Short courses of oral corticosteroids may be added to shrink the polyps. In patients with inadequate response to optimised first-line treatment, surgical removal of the polyps may be considered. However, surgery does not address the underlying inflammation, and polyps tend to recur.

2.3. For patients with inadequately controlled CRSwNP despite the above treatments, biologic therapy may be considered as an add-on treatment, in line with international guidelines.

Clinical effectiveness and safety

3.1. The Committee reviewed clinical evidence from randomised controlled trials of dupilumab (SINUS-24 and SINUS-52), mepolizumab (SYNAPSE) and omalizumab (POLYP 1 and POLYP 2). The biologics were superior to placebo in improving both nasal polyp score and nasal congestion (measured using either nasal congestion score or nasal obstruction visual analogue scale) in patients with inadequately controlled CRSwNP despite optimised first-line therapy.

3.2. In the absence of head-to-head evidence comparing these biologics for CRSwNP, the Committee acknowledged overseas HTA agencies' conclusions, which were based on the results of indirect treatment comparisons. Despite limitations due to differences in trial design, patient population, treatment duration, and outcome measurement scales, both the CDA (Canada) and PBAC (Australia) concluded that dupilumab and omalizumab, respectively, were non-inferior to mepolizumab.

3.3. A head-to-head trial comparing dupilumab and omalizumab in a subset of patients with CRSwNP and coexisting asthma (EVEREST) reported results in favour of dupilumab. However, not all results were clinically meaningful based on the nominated minimal clinically important differences. Considering the narrow study population, which limits generalisability to the overall CRSwNP population, and uncertainty in the long-term comparative effectiveness, the Committee concluded that the evidence was insufficient to demonstrate the superiority of dupilumab over omalizumab.

3.4. The Committee heard that the safety profiles of dupilumab, mepolizumab and omalizumab were well-established for other indications, with no new safety concerns identified.

Cost effectiveness

4.1. The Committee agreed that a cost-minimisation approach was appropriate to evaluate the cost effectiveness of the biologics, given they were considered clinically comparable to each other for treating CRSwNP.

4.2. The Committee noted that omalizumab biosimilar (Omlyclo) had been recommended for listing on the Standard Drug List (SDL) and remained available as a funded treatment option for patients with CRSwNP. Overall, the Committee considered that dupilumab, mepolizumab and omalizumab reference biologic (Xolair) did not represent a cost-effective use of healthcare resources given their higher treatment costs versus Omlyclo.

Recommendations

5.1. Based on available evidence, the Committee recommended not listing dupilumab, mepolizumab and omalizumab reference biologic (Xolair) on the MOH List of Subsidised Drugs for treating CRSwNP, as they were unlikely to represent a cost-effective use of healthcare resources.