Ustekinumab

_for the treatment of chronic plaque psoriasis and psoriatic arthritis_

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendation

The Ministry of Health’s Drug Advisory Committee has not recommended ustekinumab to be listed on the Medication Assistance Fund (MAF) for the treatment of chronic plaque psoriasis and psoriatic arthritis.

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Factors considered to inform the recommendation for subsidy

Technology evaluation

1.1 The MOH Drug Advisory Committee (“the Committee”) considered the evidence presented for the technology evaluation of ustekinumab for the treatment of chronic plaque psoriasis and psoriatic arthritis. The Agency for Care Effectiveness conducted the evaluation in consultation with clinical experts from the public healthcare institutions.

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
   - 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 subsidy considerations.

Clinical need

2.1 The Committee recognised that ustekinumab is a biological interleukin (IL) 12/23 inhibitor. There are currently three biological tumour necrosis factor (TNF) inhibitors listed on the MAF for the same indications as those considered for ustekinumab in this evaluation. Therefore, there is no therapeutic gap in local clinical practice.

2.2 The Committee also noted that in line with international clinical guidelines, both biological IL 12/23 and TNF inhibitors are used in Singapore as treatment options in patients with psoriatic arthritis or chronic plaque psoriasis who have an inadequate response to, or who are intolerant of, conventional DMARDs.
Clinical effectiveness and safety

3.1 The Committee agreed that etanercept and adalimumab (which are both listed on the MAF) were the appropriate comparators for ustekinumab for chronic plaque psoriasis and psoriatic arthritis.

3.2 The Committee noted that in the pivotal trial for plaque psoriasis,
- Ustekinumab was superior to etanercept at week 12 in achieving a PASI75 response and cleared, or minimal disease based on the Physician’s Global Assessment (PGA) score; and
- Ustekinumab was comparable to adalimumab for PASI75 response based on indirect treatment comparisons.

3.3 In psoriatic arthritis, trials showed that ustekinumab was inferior to the TNF inhibitors for ACR20 response in patients who had not previously received treatment with a biologic based on indirect treatment comparisons; and superior to placebo in patients who have had prior biologics.

Cost effectiveness

Cost-effectiveness of ustekinumab versus etanercept/adalimumab

4.1 The Committee considered the cost-effectiveness of ustekinumab from published studies, and noted that there were no local economic evaluations available. It acknowledged that economic evidence from overseas showed that ustekinumab was dominant (that is, more effective and less costly) over etanercept for treating chronic plaque psoriasis. However, the Committee did not consider that the results would be generalisable to the Singapore context due to the differences in drug costs.

4.2 The Committee concluded that at the price proposed by the manufacturer, ustekinumab was unlikely to be a cost effective treatment option in Singapore for chronic plaque psoriasis or psoriatic arthritis, given that the price was higher than other TNF inhibitors on the MAF list.

Estimated annual technology cost

5.1 The Committee estimated that around 55 people in Singapore would benefit from Government assistance for ustekinumab. The cost impact was estimated to be less than $1 million per year in the near term.
Additional considerations

6.1 The Committee noted that there are patient assistance programs operating in the main public healthcare institution using ustekinumab in Singapore through support from the manufacturer which can provide considerable savings to eligible patients, and make access to ustekinumab more affordable.

Recommendation

7.1 On the basis of the evidence available, the Committee did not recommend ustekinumab for listing on MAF for the treatment of chronic plaque psoriasis or psoriatic arthritis due to unacceptable cost-effectiveness (based on the price proposed by the manufacturer) relative to available treatment alternatives and limited clinical need.