Golimumab

for treating rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and ulcerative colitis

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendations

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ Golimumab 50 mg/0.5 ml and 100 mg/ml pre-filled syringes in line with their registered indications for treating adults with moderately to severely active rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and ulcerative colitis.

Subsidy status

Golimumab 50mg/0.5ml and 100 mg/ml pre-filled syringes are recommended for inclusion on the Medication Assistance Fund (MAF) for the abovementioned indications.

Golimumab should be used in line with the clinical criteria in the checklists for MAF applications for anti-TNFα biologics.

MAF subsidy **does not** apply to golimumab 12.5mg/1ml concentrate solution for infusion formulation.

Updated on 18 January 2021

Factors considered to inform the recommendations for subsidy

Technology evaluation

1.1 The MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of golimumab 50 mg/0.5 ml pre-filled syringe for treating adults with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and ulcerative colitis in November 2016. The Agency for Care Effectiveness conducted the evaluation in consultation with clinical experts from the public healthcare institutions. Published clinical and economic evidence for golimumab was considered in line with its 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 subsidy considerations.

1.4 In September 2020, the Committee considered a request from the public healthcare institutions to also include golimumab 100 mg/ml pre-filled syringe formulation on MAF for patients who require higher doses.

Clinical need

2.1 Golimumab is a biological TNF inhibitor. At the time of evaluation, there were three other biological TNF inhibitors (that is, adalimumab, etanercept and infliximab) listed on the MAF for the same or similar indications to those considered for golimumab. Therefore, the Committee considered that there was no therapeutic gap in local clinical practice.

2.2 In line with local and international clinical guidelines, biological TNF inhibitors are used in Singapore as second or subsequent-line treatment options for patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or ulcerative colitis, and other inflammatory diseases.

Clinical effectiveness and safety

3.1 The Committee noted that published clinical evidence demonstrates that golimumab leads to significantly more favorable outcomes than placebo across all indications under evaluation.

3.2 While there were no published head-to-head trials comparing golimumab with any of the other biological TNF inhibitors at the time of evaluation, indirect analyses suggested that they all have comparable efficacy and safety for the indications under evaluation.

Cost effectiveness

4.1 The Committee considered the cost-effectiveness of golimumab and noted that there were no local economic evaluations available. It acknowledged that published economic evidence from the UK showed that the cost effectiveness of golimumab varied across the indications. However, all incremental cost-effectiveness ratios (ICERs) were within the range which would normally be considered an acceptable use of healthcare resources in the UK.

4.2 In November 2016, the Committee considered that at the price proposed by the manufacturer, golimumab 50 mg/0.5 ml pre-filled syringe was likely to be cost effective in Singapore compared to the other subcutaneous biological TNF inhibitors, adalimumab and etanercept, which were listed on the MAF at the time of evaluation.

Estimated annual technology cost

5.1 The Committee acknowledged that at the price proposed by the manufacturer, approximately 50 people would benefit from Government assistance for golimumab 50 mg/0.5 ml pre-filled syringe across all registered indications. The annual cost impact was estimated to be less than SG$1 million in the first year of listing on the MAF.

5.2 The Committee was mindful that although current usage of golimumab was relatively low in November 2016, subsidy would likely increase its use and potentially drive switching from other biological TNF inhibitors, which could lead to cost savings.

5.3 In September 2020, the Committee noted that no additional subvention was required to list golimumab 100 mg/ml pre-filled syringe on the MAF at the price proposed by the manufacturer.

Additional considerations

6.1 In November 2016, the Committee noted that there were a number of patient assistance programs operating in major public hospitals in Singapore, through support from the manufacturers, which can provide considerable savings to patients through bonusing schemes. The Committee acknowledged that the manufacturer of golimumab had committed to continuing these programs for patients who are not eligible for subsidy through the MAF but still meet the manufacturer's eligibility criteria for the existing patient assistance programs.

Recommendation

7.1 Based on the available evidence considered in November 2016, the Committee recommended golimumab 50 mg/0.5 ml pre-filled syringe for listing on the MAF for treating adults with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and ulcerative colitis who meet the clinical criteria in the checklists for MAF application for anti-TNFα biologics.

7.2 In September 2020, the Committee recommended golimumab 100 mg/ml pre-filled syringe be listed on the MAF in view of favourable cost effectiveness compared to alternative anti-TNFα biologics at the price proposed by the manufacturer.

VERSION HISTORY

Guidance on golimumab for treating rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis

This Version History is provided to track any updates or changes to the guidance following the first publication date. It is not part of the guidance.

1. **Publication of guidance**

Date of Publication	3 May 2017

2. **Guidance updated to include golimumab 100mg pre-filled syringe formulation on MAF**

Date of Publication	18 Jan 2021

Principal Head (HTA)
Agency for Care Effectiveness
Email: ACE_HTA@moh.gov.sg