

**Cost-effectiveness of golimumab (Simponi®) in the treatment of
moderate to severe rheumatoid arthritis**



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Summary

1. In November 2009 Schering Plough submitted an economic dossier on the cost effectiveness of golimumab (Simponi®) to the National Centre for Pharmacoeconomics. Golimumab is licensed for the treatment of moderate to severe rheumatoid arthritis, in combination with methotrexate (MTX), when the response to disease modifying anti-rheumatic agents including MTX has been inadequate. Additional information was submitted as an amendment on 24th January 2010.
2. Two scenarios were considered; golimumab plus MTX as compared with MTX alone and golimumab in comparison to other anti-TNF agents. The Birmingham rheumatoid arthritis model was chosen and data from the GO-FORWARD trial was used for the initial comparison and meta-analysis was used for the comparison with alternative anti-TNF agents. There was considerable uncertainty around the estimates of efficacy produced by the indirect comparison. The model was run over a lifetime time horizon, costs and consequences were discounted at an annual rate of 4% and the perspective was that of the Health Service Executive (HSE).
3. The review group had a number of concerns including the sequence of treatments chosen for the comparison with other anti-TNF agents which included non biological disease modifying agents (DMARDs) only. A sequence of biologic therapies would likely be used in the Irish healthcare setting.
4. Data chosen for the indirect comparison may have produced a higher efficacy estimate for golimumab, particularly the TEMPO trial and could have been omitted from the base case. In light of uncertainty surrounding the indirect comparison estimates the meta-analysis estimates were used for the model.
5. In relation to the HAQ progression rate on discontinuation of golimumab therapy, the assumption that the HAQ score will decrease at a rate at which it was gained “equal to gain” was noted. There was considerable uncertainty

around the assumption that any benefit as regards HAQ progression while on anti-TNF treatment is maintained for 2 years.

6. The estimates for efficacy, adverse effects and withdrawal were accompanied by a large degree of uncertainty and perhaps this could have been explored in greater detail in the submission. Particular concerns existed in relation to the estimates used for withdrawal rates for the anti-TNF agents.
7. The incremental cost-effectiveness ratio (ICER) for golimumab therapy was presented for both scenarios. The ICER for golimumab plus MTX versus MTX alone was estimated at €31,212/QALY. This ICER was sensitive to parameters such as time horizon and assumptions around the HAQ score. Probabilistic sensitivity analysis (PSA) demonstrated that the probability of golimumab plus MTX being cost effective as compared with MTX alone was 26.7% at the €20,000/QALY threshold level and 64.3% at a threshold of €45,000/QALY.
8. When compared with other anti-TNF agents golimumab was dominated by infliximab. Although less costly it was also less effective than adalimumab and etanercept with ICERs of €50,619/QALY and €12,062/QALY respectively. The PSA indicated that the probability of golimumab being cost effective as compared with the other anti-TNF drugs at the €20,000/QALY and €45,000/QALY thresholds was 1% and 3% respectively.
9. Budget impact was estimated from the percentage of market share envisaged for golimumab over the first five years following its introduction. Total annual direct costs ranged from approximately €1 million in year one to €13 million in year five.
10. The review group was not convinced of the cost effectiveness of golimumab for the treatment of rheumatoid arthritis in patients who failed MTX. Despite considerable uncertainty there was no evidence to suggest that golimumab was cost effective as compared with other available anti-TNF agents. We do not recommend reimbursement of golimumab at the submitted price.

