National Institute for Health and Care Excellence
Centre for Health Technology Evaluation

Pro-forma Response

Executable Model

Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262) [ID695]

The economic model enclosed and its contents are confidential and are protected by intellectual property rights, which are owned by **School of Health & Related Research University, University of Sheffield (ScHARR)**. It has been sent to you for information only. It cannot be used for any other purpose than to inform your understanding of the appraisal. Accordingly, neither the model nor its contents should be divulged to anyone other than those individuals within your organisation who need to see to them to enable you to prepare your response. Those to whom you do show the documents must be advised they are bound by the terms of the Confidentiality Acknowledgement and Undertaking Form that has already been signed and returned to the Institute by your organisation.

You may not make copies of the file and you must delete the file from your records when the appraisal process, and any possible appeal, are complete. If asked, you must confirm to us in writing that you have done so. You may not publish it in whole or part, or use it to inform the development of other economic models.

The model must not be re-run for purposes other that the testing of its reliability.

Please set out your comments on reliability in writing providing separate justification, with supporting information, for each specific comment made. Where you have made an alteration to the model details of how this alteration was implemented in the model (e.g. in terms of programme code) must be given in sufficient detail to enable your changes to be replicated from the information provided. Please use the attached pro-forma to present your response.

Please prepare your response carefully. Responses which contain errors or are internally inconsistent (for example where we are unable to replicate the results claimed by implementing the changes said to have been made to the model) will be rejected without further consideration.

Results from amended versions of the model will only be accepted if their purpose is to test robustness and reliability of the economic model. Results calculated purely for the purpose of using alternative inputs will not be accepted.

No electronic versions of the economic model will be accepted with your response.

Responses should be provided in tabular format as suggested below (please add further tables if necessary).

July, 2014

Issue 1 The lower acquisition cost of biosimilar infliximab (Remsima™) has not been taken into account in the economic modelling

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
The report mentions and recognises biosimilars as part of the evidence base for infliximab. But, fails to include the anticipated lower cost of biosimilar infliximab (Remsima) in the health economic model. We believe that a lower price for biosimilar infliximab may have a significant effect on the ICERs which in turn will help the appraisal committee in their decision. Where colectomy is not considered to be an acceptable option the Assessment Group suggest that infliximab and golimumab are expected to be ruled out due to dominance. Applying the lower cost of biosimilar infliximab is likely to change this position.	We suggest the assessment group should include an analysis based on the lower acquisition cost of biosimilar infliximab (Remsima). We realise that this is difficult without an agreed published NHS list price. However we propose that the Assessment Group could apply a lower price. We would suggest a range of discounts, 10-30%, and that these could be applied simply to the NHS list price of originator infliximab without having to rebuild the model. For example in order to account for biosimilar infliximab (Remsima) we have carried out analyses for various pricing scenarios and have used 500, 1000, 2000 and 5000 iterations with prices for biosimilar infliximab ranging from 10-30% of the NHS list price (£419.62[1]) for originator infliximab (Remicade) 1.BNF July 2014, accessed on-line	The preliminary analysis using the lower prices suggested and applied to the redacted model suggests ICERs for biosimilar infliximab (Remsima), when compared to conventional treatment, of approximately £48,800 - £61.300. The figures for adalimumab and golimumab when compared to conventional treatment are approximately £50,300 and £104,400 respectively.