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

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Mayo Score versus Truelove and Witts scoring will cause an issue correctly identified in the report. Currently the NHS would not have the capacity to do repeat endoscopies to support frequent Mayo scoring. This may cause an issue when trying to distinguish between patients with response and pat in remission after induction.	Consider using the Partial Mayo scoring as assessment tool .	Insert ICER resulting from amended model. If the model has not been re-run, if appropriate, describe your expectations of how the problem might have an impact on the result

Issue 2

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
In view of the new NICE recommendations it needs to be made clear what acceptable or preferable option for biologics instead of surgery involves.(7.1) Surgery may be considered as an option for patients with UC for a number of indications including due to complications of disease, perceived risk of or identified dysplasia/neoplasia or due to lack or loss of efficacy of medical treatments. For a proportion of patients without emergency symptoms, surgery may not represent an	need clear criteria what influences choice. As this is a change from previous guidance. (Patients are very reluctant to choose surgery until necessary).	Insert ICER resulting from amended model. If the model has not been re-run, if appropriate, describe your expectations of how the problem might have an impact on the result

acceptable treatment option		

Issue 3

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
From the 5.3 discussion it is difficult to distinguish between the effects of the biologics. The text is slightly confusing as multiple parameters discussed a short paragraph. i.e. pt in remisson after induction seem to adalimumab has the highest probability for staying in remission, but this may be irrelevant if only a small number of patients respond to adalimumab in the first place.	clarify in a simple table effectiveness and clearer recommendations. Appendix 9 would be useful start to understand and maybe interpret the findings. Clinicians dealing with the guidance would like to have clear description and interpretation of the different results and options.	Insert ICER resulting from amended model. If the model has not been re-run, if appropriate, describe your expectations of how the problem might have an impact on the result

(please cut and paste further tables as necessary)