National Institute for Health and Care Excellence

Centre for Health Technology Evaluation

Pro-forma Response

Executable Model

TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of technology appraisal 143 and technology appraisal 233)

The economic model enclosed and its contents are confidential and are protected by intellectual property rights, which are owned by **TNF-alpha inhibitors for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (including a review of technology appraisal 143 and technology appraisal 233)**. 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 Agreement 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).

January, 2015

Issue 1 The mean cost of infliximab is based on a fixed weight of 73kg

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
The mean drug acquisition cost of infliximab has been calculated using a fixed weight of 73kg (4 vials).	AbbVie considers that the mean cost for infliximab should be amended to take account of the distribution in patient weight of AS patients and resulting mean number of vials required. Applying the mean number of vials per infusion required based on the full range of baseline weights from the ATLAS trial gives a mean of 4.501 vials per infusion . Cell G10 of the costs worksheet should be updated with this mean number of vials.	The deterministic ICER resulting from this amended model is £45,222 for infliximab versus conventional therapy using the rebound to gain modelling assumption.