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

Pro-forma Response

Executable Model

Vedolizumab for treating moderately to severely active ulcerative colitis [ID691]

The economic model enclosed and its contents are confidential and are protected by intellectual property rights, which are owned by Takeda UK. 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).

November 2014

Issue 1 PAS price for golimumab

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Golimumab: PAS price not applied in model.	Change number of vials of golimumab required for induction from 6 to 3.	Total drug price for induction period with golimumab is expected to decrease.

Issue 2 Number of infusions of vedolizumab in induction period

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
The number of induction doses for vedolizumab was set to **two** in the model**.** The EMA marketing licence for vedolizumab states **three** doses for induction at weeks 0, 2 and 6.	Change number of doses of vedolizumab and number of infusions for induction from 2 to 3.	The drug acquisition cost for the induction period is expected to increase.

Issue 3 Incorrect transition state probabilities used for conventional therapy

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Transition state probabilities for infliximab for the maintenance period applied to	Source of error: worksheet 'Data Store' array D354:G356. In each array, change the rows 371, 372 and 373 with 395,	Unknown.

conventional therapy.	396 and 397, respectively.	

Issue 4 Formula error for cost of serious infection

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Formula error cost of serious infection '#DIV/0!' Source: worksheet 'Data Store', cell C238. =AVERAGE(E17,E24,E34,E42,E49) refers to blank cells.	Correct error.	Unknown.