National Institute for Health and Clinical Excellence

Centre for Health Technology Evaluation

Pro-forma Response

Executable Model

Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events (review of Technology Appraisal No. 90)

The economic model enclosed and its contents are confidential and are protected by intellectual property rights, which are owned by **Liverpool Reviews and Implementation Group (LRiG).**. 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. 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 2010

Issue 1   Risks of bleeding in patients on clopidogrel who need surgery

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
We are concerned about the risks of bleeding in patients taking clopidogrel therapy who require elective, or urgent surgery.	Please detail what happened to these patients in the studies, and it would be very helpful if guidelines on management could be included	This has the potential to affect a large number of patients and make particularly urgent surgery more liable to bleeding complications.

Issue 2   Clopidogrel after stenting in the femoropopliteal segment

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
An increasing number of patients are having a stent inserted for peripheral arterial stenoses	Although there is little current evidence, this issue should be highlighted, and it seems logical to recommend a similar regimen to coronary stents.	This will at least put down a marker for future potential studies.

Issue 3

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Give full details of the problem detected, if necessary, with explanation of why the issue is considered to be a problem.	Give details of any amendments/corrections made in sufficient detail to allow these to be reproduced	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)