CONFIDENTIAL

Extra analyses for Ischaemic Heart Disease – Coronary Artery Stents– ACD meeting

Date: February 2006

Project Number	
Appraisal title	**Coronary artery stents for the treatment of ischaemic heart disease (review of NICE technology appraisal guidance no. 71)**
Synopsis of the technical issue	At the Appraisal Committee meeting to discuss the development of the Appraisal Consultation Document a number of issues with the economic evaluation were raised. Most notably: ➢ The Appraisal Committee was aware that no statistically significant differences for mortality or morbidity were found in the trials for DES versus BMS, however the Committee was mindful that although the trial data showed no statistical significance, there was a difference in AMI in favour of DES and that this should be taken account of in the economic evaluation. The Committee was also mindful of data in the literature regarding mortality and morbidity of CABG and repeat angiography. ➢ After reviewing the utility values in the Assessment Group's model the Committee was mindful of the possibility that there could be an additional disutility associated with CABG during the initial six weeks following the procedure compared with PCI. ➢ The Committee was persuaded that neither the Liverpool (CTC) and the Leicester registry data or the randomised controlled trial data were representative of repeat revascularisation rates in patients and as the BASKET trial and the Scottish Registry data had used methods that were likely to collect follow-up data from all patients, these data would therefore be more representative. ➢ The Committee heard that there was no consensus in the trials or registries regarding which risk factors would put an individual at a high risk of revascularisation. They were persuaded that the Assessment Group's risk factors used in the current assessment report, based on the CTC registry data were one possibility, however risk factors which had been used in the previous appraisal should also be included in the current model. The Committee also heard that diabetes should be considered as an independent risk factor for restenosis too. ➢ The Committee discussed the significance of the price premium (difference between DES and BMS price) and were mindful of the possibility that the price premium used in

	the Assessment Group's model was possibly too high (£560), given the procurement deals that took place in certain areas that brought the price premium down to less than £300. As a result of these points, further work was requested to be undertaken.
Question(s) to be answered by the Assessment Group	What is the cost effectiveness of DES in the treatment of ischaemic heart disease? The base-case scenario should be updated and if data allows should include: ➢ the risk of AMI ➢ the mortality risk associated with CABG ➢ the mortality risk associated with angiography ➢ the disutilities associated with CABG versus PCI immediately (in the 6 week period) following the procedure ➢ the absolute risk of revascularisation of BMS taken from the Scottish registry data ➢ the relative risks of the independent risk factors (small vessel and long lesion) taken from the trials ➢ if it is identified from the clinical evidence to be an independent risk factor, diabetes as another risk factor Sensitivity analysis should be carried out on the above estimates if appropriate and around: ➢ the price premium ranging from £255 (based on a cost used in Scotland) to £1000 (list price) for stents ➢ the stent wastage rates at 1% and 5%
How will these questions be addressed in an addendum?	The Assessment Group will be asked to: ➢ identify data in the literature regarding mortality and morbidity of CABG and repeat revascularisation. ➢ identify additional utility values in the first six weeks following CABG or PCI. ➢ identify the parameter values for the base-case scenario accordingly using data from the Scottish registry for absolute risks, relative risks for the two sub-groups (small vessels and long lesions) from the trial data, additional utility values and price premium.

	➢ identify from the literature and review whether diabetes is an independent risk factor for restensosis. ➢ develop a model, containing these new parameters with an appropriate time horizon, for example 12 months ➢ synthesise the available information and calculate the degree of uncertainty around the cost effectiveness estimate using sensitivity analysis.
Relevant new evidence requested	➢ Data in literature regarding mortality and morbidity of CABG and angiography ➢ Data on absolute risk of revascularisation from the Scottish registry data ➢ Clinical evidence regarding whether diabetes is an independent risk factor for restenosis