NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA120) [ID481]

Specification of further work following the Appraisal Committee meeting on 23 April 2013

Suggested presentation of analyses

- Please combine the ischaemic and non-ischaemic patient groups together, therefore presenting results for 24 subgroups rather than 48 in the original submission. For these subgroups, for each of the different scenarios presented, please present tables with fully incremental cost-effectiveness results as previously presented in tables 70-71 of the submission.

- Please also present a summary of the most optimal strategies at different cost-effectiveness thresholds, for example, at £20,000, £25,000 and £30,000 per QALY gained.

Specification of further work

1. The manufacturers' base case assumes a constant duration of effect of 7.5 years for all-cause mortality, followed by linear tapering over 20 years. Sensitivity analyses were also provided assuming life-long constant treatment effects without any tapering (MS page 194) as a more optimistic scenario, and assuming a constant duration of effect for 5 years as a more conservative scenario (Appendix 15 page 72-73). Please provide these analyses for the 24 subgroups outlined above, combining the ischaemic and non-ischaemic patient groups.

   In addition, please also provide a sensitivity analysis assuming a constant duration of effect up to the *average* duration of follow up in the trials, followed by linear tapering thereafter?

2. The effect of CRT-D devices on all-cause hospitalisation for NYHA III and IV class patients estimated in the IPD network meta analysis (HR; [redacted]) was not incorporated in the model and the value estimated for CRT-P ([redacted] for NYH III and [redacted] for NYHA IV) was used instead. The manufacturers' stated that it is unlikely that the use of CRT-D will result in a smaller treatment effect than the use of CRT-P in a given patient group, as both include CRT therapy.

   However, the Committee would like to see the effect on the ICERs of a more conservative estimate of effect of CRT D for all cause hospitalisation estimated in the IPD network meta-analysis (that is, HR [redacted])?

3. The Committee heard that defibrillating devices can increase anxiety in some patients. The manufacturers' model does not account for any additional cost of counselling apart from the bi-annual device related outpatient visits for ICD patients and quarterly visits for CRT (CRT-D or CRT-P) patients.

   Given the feedback from experts on the importance of counselling, particularly for patients receiving defibrillator devices, what is the impact of this additional resource use on the ICERs?

4. The manufacturer's model excludes the possibility of crossover or device upgrades, which are possible in clinical practice. Please comment on the likelihood of device upgrades in clinical practice.

   In particular, the Committee heard that there may be a subgroup of people indicated for CRT-P who are also likely to need a defibrillator in the near future, so that cardiologists would choose to implant a CRT-D in which the ICD function could be switched on when needed, rather than to implant a CRT-P device which would have to be upgraded to CRT-D at full cost at a later date. Please provide comment on experience with this situation in clinical practice, and on identification of a subgroup of patients for which this situation applies.

5. The Committee considered that further deterministic sensitivity analyses were required for resource use and cost parameters. Please provide such sensitivity analyses, as implementable within the current model structure.