30 June 2005

Maria Gibson/Emily Marschke
National Institute of Clinical Excellence
MidCity Place
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London
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Dear Maria/Emily,

Review of NICE Technology Appraisal Guidance No 71: the use of coronary artery stents

Please find attached the submission from Guidant Ltd. for above appraisal.

I hope that this information is adequate, please do not hesitate to contact me should you have any further queries.

Yours sincerely

UK Country Manager
Vascular Intervention

Submission from Guidant Ltd for the Review of NICE Technology Appraisal Guidance No 71: the use of coronary artery stents

The Technology

XIENCE ™ is a drug eluting stent based on the same design principle and materials as the MULTI-LINK VISION ™ stent that has been CE marked and commercially available in Europe since January 2003.

The XIENCE ™ stent has a drug eluting coating consisting of two layers:

- a primer layer CiC removed
- a drug reservoir layer CiC removed

These components have been used in CE marked and FDA approved products:

CiC removed

The antiproliferative drug on XIENCE ™ , Everolimus, is closely related to Sirolimus (Rapamune®) which is antiproliferative agent used in the CE marked and FDA approved Cypher ™ stents.

Treatment Aim

CE mark for XIENCE ™ Everolimus Eluting Coronary Stent System is pending. The proposed license indications are for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete *de novo* native coronary artery lesions, adequately covered by a 28mm stent, with a reference vessel diameter of 2.5 to 4.0mm.

Clinical Effectiveness

There are currently four clinical trials underway or planned for XIENCE ™ A summary of the clinical trials, their design endpoints and status is provided in Table 1. For those studies planned or underway (SPIRIT II, III and IV) the actual study end dates will be confirmed on enrolment of the last patients. Consideration should also be given to the Future I and Future II trials that assessed the safety, performance and efficacy of the CHAMPION ™ stent as this provides additional data on Everolimus. The results of these trials are also summarised in Table 1.

Impact on the NHS

Current NICE guidance for the use of drug eluting stents is consistent with the weight of evidence reviewed in the BCIA and BCS submissions.

Additional evidence for patient groups (e.g. diabetes, in-stent restenosis) warrants consideration for this review as it may determine optimal treatment but because of the small patient populations involved it is unlikely to have a significant impact on the NHS.