

Treatment Appraisal: Decision Summary

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| Date | 10 th July 2012 |
| Appraisal | Left atrial appendage occlusion devices (Watchman™ and Amplatzer™ cardiac plug) for stroke prevention in patients with non-valvular atrial fibrillation |
| Details | <p>The NHS North East Treatment Advisory Group considered an appeal from the Clinical Advisory Group of the North of England Cardiovascular Network of its recommendation regarding the left atrial appendage occlusion Watchman™ device (ref WTM-LAA-JUL10), with an increased scope to also consider the Amplatzer™ Cardiac Plug, for the prevention of stroke in patients with non-valvular atrial fibrillation.</p> <p>The group conducted an updated appraisal of the evidence for the relevant devices.</p> |
| Recommendation | <p>The NHS North East Treatment Advisory Group recommends left-atrial appendage occlusion (LAAO) with approved devices in the management of non-valvular atrial fibrillation for patients with a proven bleeding risk which contraindicates anticoagulation therapy.</p> <p>The group recommends that LAAO devices should only be used by clinical teams with the appropriate specialist skills, and that enhanced measures for clinical governance and audit are implemented.</p> |
| Clinical evidence summary | The group was disappointed that the nature of clinical evidence relevant to the specific patient group identified by the appellants was generally poor. Nonetheless, the group was satisfied that LAAO devices could deliver meaningful clinical benefits to a robustly selected patient group. |
| Cost analysis summary | A new cost analysis was presented which estimated a lower cost per procedure of about £9,000 per operation compared with more than £11,000 in the initial appraisal. The mean cost per patient will be greater due to the treatment of complications and possible subsequent device implantation procedures. The group considered that LAAO devices would be cost-effective if applied to specific patient groups. |
| Financial impact | The total number of procedures within NHS North East was estimated at up to 60 per annum, most likely shared evenly between two specialist centres. This corresponds to a mean of up to five patients per NHS North East PCT. The maximum mean financial impact per PCT is therefore estimated at about £50,000 per annum. |
| Further research or information | The group recommends; that clinical expertise is developed within a single clinical team potentially operating across multiple sites; that a dual-operator model of delivery is applied until individual clinical competence has been acquired; and that comprehensive treatment and outcome data is routinely recorded and shared with local and national commissioners to ensure that the treatment and the associated resources are used for the maximum benefit of all patients. |

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