

CPAG Summary Report for Clinical Panel – 1692 Left Atrial Appendage Occlusion for patients with atrial fibrillation and relative or absolute contraindications to anticoagulation

The Benefits of the Proposition			
<i>No</i>	<i>Outcome measures</i>	<i>Grade of evidence</i>	<i>Summary from evidence review</i>
1.	Survival	Not measured	There is a survival benefit among patients having Left Atrial Appendage Occlusion (LAAO) who are able to take warfarin for Atrial Fibrillation (AF), but this has not been directly examined yet in patients who are unable to take anticoagulation.
2.	Progression free survival	There is a survival benefit [A]	The number needed to treat to prevent one stroke/thromboembolic event is 3.
3.	Mobility	Not measured	N/A
4.	Self-care	Not measured	But would be maintained in patients who avoided a stroke.
5.	Usual activities	Not measured	
6.	Pain	Not measured	
7.	Anxiety / Depression	Benefit determined [A]	The Commissioning through Evaluation (CtE) results showed that the greatest benefit from the procedure that was seen was a reduction of anxiety and depression with a non –significant improvement in QOL.
8.	Replacement of more toxic treatment	Benefit determined [A]	Patients unable to tolerate the standard treatment of oral anticoagulation therefore they remain unprotected from risk of stroke by virtue of having no treatment (a “more toxic” option).
9.	Dependency on care giver / supporting independence	Not measured	N/A
10.	Safety	Adverse events identified [B]	There were 25 deaths during the course of the CtE Registry. 19 of the 25 were unrelated to the procedure or its indication.

			Ten studies reported periprocedural death rates of 0.0% to 0.9%
11.	Delivery of intervention	Benefit determined [A]	<p>Procedural success of LAAO was high and ranged from 88.3% to 100%. Overall, procedural success and safety increased with operator and centre experience.</p> <p>There were no significant differences seen between the devices (Watchman with the Amplatzer amulet) in terms of superior technical or procedural success or neurological events.</p>

Other health outcome measures determined by the evidence review			
No	Outcome measure	Grade of evidence	Summary from evidence review
1.	Incidence of thromboembolic event (a blood clot forming and breaking loose causing a blockage of another vessel. A stroke can occur if the blood clot blocks a vessel in the brain)	Grade A	The CtE evidence showed that there was a lower incidence rate 2.6% (2.2% from Evidence Review). of a thromboembolic event for patients fitted with an LAAO compared to a predicted risk of 6.8% -9.8% (reference needed) per year.
2.	Quality of life (QoL) i.e. The patient's ability to enjoy normal life activities	Choose an item.	QoL was measured at baseline and at follow up (6 weeks, 6 months, 1 year and 2 years) using the EuroQol system (EQ-5D-5L), converted to utility scores. The median baseline utility was 0.82. This improved to 0.85 at both 6 weeks and 6 months and reduced slightly to 0.84 at one and two years. Improvements were not statistically significant. However, it should be noted that LAAO is not a treatment for symptoms. It is a secondary prevention therapy to protect against future harm. The CtE results showed that the greatest benefit

			from the procedure that was seen was a reduction of anxiety and depression.
3.	Ischaemic event (an inadequate supply of blood to an organ or part, as from an obstructed blood flow)	Choose an item.	The observed CtE 'any ischaemic event' rate was 2.6 per 100 patient years (see No. 1). This represents a relative risk reduction of 40 to 70% compared to medical therapy alone expected from historical data
4.		Choose an item.	
5.		Choose an item.	