



**Australian Government**

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**Medical Services Advisory Committee**

**Public Summary Document**

***Application No. 1330 – Transcatheter closure of patent ductus arteriosus***

**Sponsor/Applicant/s:**                      **Cardiac Society of Australia and New Zealand**

**Date of MSAC consideration:**    **1 August 2013**

**1. Purpose of application**

An application requesting Medicare Benefits Schedule (MBS) listing of transcatheter closure of patent ductus arteriosus (PDA) was received from the Cardiac Society of Australia and New Zealand (CSANZ) by the Department of Health and Ageing in September 2012.

Identifying patients suitable for transcatheter closure of PDA involves transthoracic echocardiography to determine whether the patent duct is suitable to be closed with a coil or occluding device.

Transcatheter closure of PDA is achieved by one of two methods and the choice of method of transcatheter closure appears to be based primarily on the shape of the PDA and minimal ductal diameter.

In the first method, a platinum coil is deployed via a catheter through the femoral artery or femoral vein. This causes thrombosis leading to closure of the open duct. Coils tend to be used in smaller PDAs as the larger PDAs do not always have a significantly constricting neck to trap the body of the coil. In addition, larger PDAs are likely to require multiple coils which may potentially protrude into the lumen of the left pulmonary artery.

In the second method, an occluder device is deployed via a catheter through the pulmonary artery through the PDA. One end of the device hugs the walls of the PDA while the other rests on the aortic side to close the duct. More recent iterations of occluder devices have smaller retention discs than the older versions. The design of such devices is under constant review to maximise the benefit of closure and to minimise protrusion of the device into the adjacent pulmonary artery and aorta.

Transcatheter closure of PDA has been established in the Australian health system, predominantly in the public sector, since the 1990s. The applicant indicated that transcatheter closure is standard therapy for treatment of PDA.

During foetal life, the ductus arteriosus is a normal structure which allows most of the blood leaving the right ventricle to bypass the pulmonary circulation and pass into the aortic arch. Normally, functional closure of the ductus arteriosus occurs by about 15 hours of life in

healthy infants born at term. This occurs by abrupt contraction of the muscular wall of the ductus arteriosus, which is associated with increases in the partial pressure of oxygen coincident with the first breath.

The failure of the ductus arteriosus to close is a congenital disorder referred to as PDA and is either an isolated lesion or may be present in association with other defects. When the ductus arteriosus fails to close there is a persistent shunt from the aorta to the pulmonary artery which results in increased pulmonary blood flow and volume loading of the left atrium and left ventricle.

Transcatheter closure of PDA is proposed as a direct substitute for surgical closure of PDA without cardiopulmonary bypass. Surgical division or ligation of PDA, without cardiopulmonary bypass, for congenital heart disease is currently funded under MBS item 38700.

Additionally, the determination of suitability will depend on various clinical and echocardiographic characteristics of the patient.

According to the applicant, patients weighing less than six (6) kilograms are usually considered unsuitable for the procedure in Australia. However, parental preference for surgery versus device closure, or cardiologist preference where the duct is large and the baby is small may factor into the decision making. Other factors of clinical significance (other than weight) are also important in making the decision to close the PDA via a transcatheter or surgical route.

## 2. Background

The intervention has not previously been considered by the Medical Services Advisory Committee (MSAC). There are no MBS items available for transcatheter closure of PDA.

## 3. Prerequisites to implementation of any funding advice

The Therapeutic Goods Administration (TGA) has provided regulatory approval for a range of trademarked PDA closure devices. Details regarding the listings on the Australian Register of Therapeutic Goods (ARTG) are provided in the following table. The devices currently listed on the ARTG include the Flipper coil (FC), the Amplatzer Duct Occluder (ADO), the ADO II, and the ADO II-Additional Sizes (AS).

Table 1 ARTG listing of devices associated with PDA closure

ARTG number	Registered	Details
<b>St Jude Medical Australia Pty Ltd</b>		
134070	20 Dec 2006	ADO
154956	5 Sept 2008	ADO II
162137	1 June 2009	AMPLATZER Cardiac Plug
191422	2 Nov 2011	ADO II AS
162140	1 June 2009	AMPLATZER TorqVue 45 X 45 degree Delivery Sheath
134074	20 Dec 2006	AMPLATZER TorqVue Delivery System
134075	20 Dec 2006	AMPLATZER TorqVue Exchange System
134076	20 Dec 2006	AMPLATZER TorqVue Delivery System with Pusher Catheter
191136	27 Oct 2011	AMPLATZER TorqVue LP Catheter
<b>William A Cook Australia Pty Ltd</b>		
188074	18 Aug 2011	Flipper 35 PDA Closure Detachable Coil Delivery System
194131	24 Jan 2012	MReye Flipper PDA Closure Detachable Coil

#### 4. Proposal for public funding

The applicant indicated that the technique involved in the procedure and the devices utilised most closely resemble MBS item 38272 transcatheter closure of atrial septal defect (ASD). MBS item 38272 has a schedule fee of \$912.30 as of 1 November 2012.

Table 2 Proposed MBS item descriptor for transcatheter closure of PDA

<b>Category 3 – Cardio-Thoracic</b>
PATENT DUCTUS ARTERIOSUS, Transcatheter closure of (Anaes.) (Assist.) Fee: \$912.30 Benefit: 75% = \$684.25

The proposed MBS item for transcatheter closure of PDA does not restrict the service by the age of the patient or the type of the defect and does not restrict patients due to prior interventions.

The applicant indicated that the procedure should be performed by a credentialed paediatric interventional cardiologist or adult interventional cardiologist. In the guidelines for paediatric cardiac catheterisation, closure of an uncomplicated PDA is classified as a level 2 procedure, while closure of a PDA in a patient of less than 10kg is classified as a level 3 procedure. The guidelines categorise paediatric cardiac catheterisation according to levels varying from simple to complex procedures similar to the classification of surgical procedures for congenital heart disease and can be viewed at [www.csanz.edu.au](http://www.csanz.edu.au).

The applicant recommended that cardiothoracic surgical back up should be available to the catheter laboratory where these procedures are performed in case surgical intervention is needed and that this procedure should only be funded for services delivered by the designated provider.

The applicant also indicated that current staffing numbers and skill sets within cardiac catheter laboratories are appropriate for these procedures. The catheter equipment required to perform this procedure is standard equipment present in all cardiac catheter laboratories.

#### 5. Consumer Impact Statement

Transcatheter closure of PDA is already available through the public healthcare system. It is anticipated that there will be no potential advantages (or disadvantages) to consumers should the procedure be explicitly funded under the MBS given it is a procedure that requires the proximity of cardiothoracic surgical backup in the event of complications.

#### 6. Proposed intervention's place in clinical management

Transcatheter closure of PDA is proposed as a direct substitute for surgical closure of PDA.

Following diagnosis of PDA, some patients (usually neonates) may have medication with the aim to close their ductus. However, some patients at the point of diagnosis may immediately proceed to transcatheter or surgical intervention if there is evidence of haemodynamic overload. Additionally, other patients who have previously trialled medication without success or were unable to receive medication due to a contraindication may also require intervention.

Three non-randomised studies comparing transcatheter closure with surgical closure (all published in 2009) were identified for inclusion in the assessment report. Additionally, the applicant provided an article for consideration by the MSAC titled "Transcatheter Closure of the Patent Ductus Arteriosus: An Intention to Treat Analysis" which had been published in 2013 on behalf of ANZSCTS and the CSANZ.

The outcomes from the “Multicenter USA Amplatzer Patent Ductus Arteriosus Occlusion (ADO) Device Trial”, conducted from September 1999 to June 2002, was also included in the assessment report. Given this was simply a device efficacy trial (without comparison to surgery) the relevance of this trial is limited.

The body of evidence is limited by a number of factors. For example, the medical devices and services for transcatheter closure of PDA have been available for decades with incremental improvements to the established devices creating little incentives for large scale clinical trials. Additionally, the devices are used for a limited population i.e. those patients with clinically significant PDA who are suitable for transcatheter closure of the congenital defect.

## **7. Other options for MSAC consideration**

Nil

## **8. Comparator to the proposed intervention**

Surgical ligation of PDA without cardiopulmonary bypass (MBS item 38700) has been identified as the appropriate comparator for transcatheter closure of PDA, in particular an isolated PDA that is not associated with co-existent congenital cardiac abnormalities.

Surgical ligation of PDA with cardiopulmonary bypass (MBS item 38703) is a more complex procedure usually performed with other cardiac procedures in association with co-existent congenital cardiac abnormalities.

MSAC agreed that the comparison of surgical versus transcatheter closure of PDA is appropriate.

Australian Institute of Health and Welfare (AIHW) hospital data is available for closure of PDA. However, the split for transcatheter versus surgical closure of PDA was not identified. AIHW data for 2010-11 indicated that for closure of PDA, of a total of 559 hospital separations, there were 66 admissions to a private hospital and 493 admissions to a public hospital of which 119 were for private patients. The data also indicated that there were 60 same day patient separations for the public hospital admissions. There were no same day patient separations for the private hospital admissions.

In 2011-12, there were 41 services for item 38700 with benefits paid of \$19,839, and 95 services for item 38703 with benefits paid of \$41,038. It should be noted that transcatheter closure of PDA is proposed as a direct substitute for surgical closure of PDA without cardiopulmonary bypass (item 38700).

MBS funding for open heart surgery for congenital heart disease can be found on the 1974 Schedule. The original generic MBS item covered operations for congenital PDA. Two specific MBS items for division or ligation of PDA for congenital heart disease were introduced on the Schedule on 1 November 1992. The current MBS item descriptors for surgical closure of PDA are presented in the following table.

Table 3 MBS item descriptors for 38700 and 38703 as at 1 November 2012

<b>Category 3 – Cardio-Thoracic</b>
<p><b>38700</b>            PATENT DUCTUS ARTERIOSUS, shunt, collateral or other single large vessel, division or ligation of, without cardiopulmonary bypass, for congenital heart disease (Anaes.) (Assist.)  <b>Fee:</b> \$1,067.40 <b>Benefit:</b> 75% = \$800.55</p>
<p><b>38703</b>            PATENT DUCTUS ARTERIOSUS, shunt, collateral or other single large vessel, division or ligation of, with cardiopulmonary bypass, for congenital heart disease (Anaes.) (Assist.)  <b>Fee:</b> \$1,924.10 <b>Benefit:</b> 75% = \$1,443.10</p>

## 9. Comparative safety

A systematic search was undertaken to identify the best available evidence for the assessment of the safety, effectiveness and cost-effectiveness of transcatheter closure of PDA compared to surgical closure of PDA.

No randomised controlled trials (RCTs) comparing transcatheter closure of PDA with surgical closure (without cardiopulmonary bypass) were identified for inclusion into the assessment report.

Three non-randomised comparative studies of transcatheter closure versus surgical closure (all published in 2009) were identified for inclusion in the assessment report. Two of the articles were based on studies at the Union Hospital in China:

- A prospective non-randomised study reported by Chen et al (Chin Med J 2009); and
- A retrospective study reported by Chen et al (Pediatr Cardiol 2009).

Chen et al (Chin Med J 2009) reported on a non-randomised study of 255 patients having isolated PDA with a minimal diameter of  $\geq 4$  mm. The patients were assigned to either the device or surgical closure group according to the patients' and/or their parents' preference with post procedural follow up of at least five years. The study concluded that transcatheter Amplatzer occlusion was less invasive and associated with fewer complications and residual shunt, and as effective in the regression of pulmonary hypertension and left ventricular dilation.

Chen et al (Pediatr Cardiol 2009) reported on a retrospective study of 181 patients aged  $\geq 6$  months with a PDA of 4-16 mm. A total of 130 patients underwent surgical closure for PDA, whereas 51 patients underwent Amplatzer occlusion. There were no deaths and no residual left-to-right shunting in either group at last follow-up. The study concluded that, although transcatheter Amplatzer device occlusion is as effective as and less invasive than surgical closure for PDA, surgical closure is less costly.

The third article was based on a retrospective study (with historical controls) at the Veterans General Hospital in Taiwan. Lin et al (2009) reported on 20 infants born full-term and aged  $\leq 3$  months with a PDA  $\geq 3$  mm. The data were compared with a historical control group of young infants with large, symptomatic PDA in whom surgical ligation was performed previously at the hospital i.e. a non concurrent group of patients who received surgery during a different time period. The study reported that transcatheter implantation of the ADO is more cost effective than surgery for young infants, with significantly less length of stay in the hospital, length of intensive care, and hospital charges. However, the report notes that the implantation of the ADO is more expensive than coils.

The Queensland Paediatric Cardiac Service, at the Mater Children's Hospital in Brisbane, established a cardiac catheterisation registry in 2003 which provided the dataset for analysis

of all patients undergoing cardiac catheterisation with the intent to perform transcatheter closure of a PDA.

The registry included analysis of 228 children with an isolated PDA who were admitted to the catheter laboratory at a single institution from January 2003 to December 2011. Of the 208 patients selected for transcatheter closure, all were followed through in the analysis. It should be noted that this registry compared the relative merits of the two commercially available devices predominantly used in Australia for transcatheter closure of PDA. The relative merits of transcatheter closure of PDA versus surgery (in those patients who were potentially candidates for either approach) was not considered.

The literature search retrieved a citation for the Multicenter USA Amplatzer Patent Ductus Arteriosus Occlusion (ADO) Device Trial. This trial was conducted from September 1999 to June 2002, with 484 patients enrolled in 25 centres. Forty-five (9%) of 484 patients did not have ADO implantation, because the PDA was too small or because of elevated pulmonary resistance. The median age of the patients at catheterisation was 1.8 years (range 0.2 to 70.7 years), and weight was 11 kg (range 4.5 to 164.5 kg) (Pass et al 2004).

The ADO was implanted successfully in 435 (99%) of 439 patients. At the last evaluation, PDA closure was documented in 428 (98%) of patients. There have been two cases of partial left pulmonary artery occlusion after ADO implantation and no cases of significant aortic obstruction. Conclusions were that moderate to large PDAs can be effectively and safely closed using the ADO device, with excellent initial and one-year results. This device should obviate the need for multiple coils or surgical intervention for these defects.

The recent studies indicate that closure of PDA can be achieved safely by transcatheter techniques.

Sheridan et al (2013) concluded that ADO I is the current device of choice, resulting in complete closure of all patients with no significant complications. The article also indicated that the development of devices with different design characteristics is likely to result in improved outcomes, particularly in the patient group weighing <6 kg with clinically significant PDA.

In the comparative study of long-term clinical outcome between ADO and surgical closure of PDA (Chen et al Chin Med J 2009), there were no cardiac deaths or significant complications in the transcatheter closure group. Acute major complications such as obstruction of the aorta and left pulmonary artery, embolisation, and haemolysis were not encountered in the study. The surgical group recorded more acute procedure-related complications as compared with the transcatheter closure group. Other complications associated with ADO, such as infective endocarditis, device integrity problems and deformations, were not reported in the 5 year follow-up period of the study.

Transcatheter closure of PDA is reported to have a high degree of safety and efficacy. The evolution of devices utilised has included the Raskind PDA Occluder, Gianturco and Flipper coils, Nit-occlud coils and the ADOs. In the current era FC and the ADO are the devices which are predominantly used (Sheridan et al 2013).

Both transcatheter and surgical treatment choices appear to be the main stay of curative treatment for PDA. One is not intending to entirely substitute the other at a global level, rather decision on treatment is heavily dependent on individual factors and whether the anatomical and physiological characteristics of the patent ductus is amenable to transcatheter closure.

## **10. Comparative effectiveness**

All of the studies comparing transcatheter closure with surgical closure have reported comparative effectiveness in terms of residual shunting. The assessment report did not pool the results of the three studies to statistically test the assertion around the clinical claim of non-inferiority.

The prospective study by Chen et al (Chin Med J 2009), the highest quality study identified for analysis, found that there was no statistically significant difference between the baseline characteristics of the transcatheter group and the surgical group (noting that the ratio of patients in the surgical group versus the transcatheter group in this study was 2.5:1). During long term post-procedural follow up, this study suggested that the rate of persistent residual shunt (PRS) free survival was slightly lower in the surgical group (91.3%) compared to the transcatheter group (98.6%) (overall P = 0.037). On the other metrics of treatment success (both in the short and long term) both treatment choices were by and large indistinguishable.

However, given the potential for systematic error (bias) inherent with the methodology used in the study reported by Chen et al (Chin Med J 2009), the conclusion from this study, as well as the conclusions from other comparative studies, need to be interpreted with caution. Across the clinical parameters measured in the three comparative studies it is reasonable to infer that transcatheter closure is likely to be non-inferior (in terms of clinical effectiveness) to surgical closure of PDA.

Sheridan et al (2013) reported successful occlusion in 96.2% of 208 patients (with the device of first choice) when transcatheter closure was attempted. The study reported the use of FC and ADO with device selection evolving to ADO exclusively in 2011. This study looked at 'single arm' registry data – within that arm was simply a device comparison. There was no aggregate comparison of the transcatheter closure technique generically with surgical closure. Chen et al (Chin Med J 2009) reported a shorter recovery time in the ADO group than in the surgical group, which was mainly due to fewer general anaesthesia and no surgical-related issues and complications. Additionally, unlike the residual PDA after surgical ligation which persisted if untreated, residual shunt detected soon after ADO disappeared automatically during the follow-up, which may be partially attributed to the self-expanding design of ADO or clot formation. The conclusion was that ADO was less invasive and associated with fewer complications and residual shunt, and as effective in the regression of pulmonary hypertension and left ventricular dilation. The article indicated that surgical closure should be reserved for those in whom the PDA is too large for device closure or at centres without access to device closure.

The available information and evidence for the effectiveness of transcatheter occlusion of PDA indicate that the procedure is effective with a high degree of successful closure.

## **11. Economic evaluation**

A cost-minimisation analysis was presented, taking into account that the service is currently provided for a small numbers of patients and therefore the total government expenditure on the service is likely to be small.

The economic evaluation included:

- the intended population;
- the circumstances of use; and
- the variables used in the economic evaluation.

The cost-minimisation analysis of transcatheter versus surgical closure of PDA compared costs only. The analysis was presented as the transcatheter technique is current standard practice and proposed to be non-inferior to surgical ligation in terms of efficacy and safety, and may generate cost offsets from reduced use of health care resources.

The analysis did not restrict the service by the age of the patient or the type of the defect. Taking into account that the most commonly reported length of follow-up visits following transcatheter or surgical closure of PDA is periodic appointments over the next year, the follow-up period was not factored in to the analysis. The potential for use of the service in a wider population or setting than the target population and setting is unlikely. The time profile of costs and benefits of transcatheter or surgical closure of PDA were assumed to be similar post discharge from hospital. Therefore, discounting was not applied to the cost-minimisation analysis.

The health care resource items for which there would be a change in use associated with providing transcatheter closure of PDA include diagnostic and hospital services. The clinical outcome of the intervention is the successful delivery of the device with no residual shunt and complete regression of signs of volume overload.

Overall, the estimated cost per patient of transcatheter closure of PDA is more expensive relative to its comparator, surgical ligation (\$17,599 and \$15,833 respectively for 2012-13). The unit cost of the ADO device (\$10,200), which is included in the cost of the transcatheter closure procedure, is a significant component of the overall cost of the procedure. In terms of cost-effectiveness of health resources (excluding the device cost), transcatheter closure of PDA provides relative benefit, for example shorter recovery time with a significantly decreased length of hospital stay, at lower costs.

The applicant indicated that the technique involved in the procedure and the devices utilised most closely resemble those of MBS item 38272 which covers transcatheter closure of ASD. MBS item 38272 has a schedule fee of \$912.30 as of 1 November 2012. However, the applicant also provided a draft item descriptor including a proposed Schedule fee of \$963.90.

The cost-minimisation analysis accounted for the majority of procedures being performed on a small numbers of young infants in the public healthcare system with proximity of cardiothoracic surgical backup in the event of complications. Therefore, out of pocket costs were not factored into the analysis.

## **12. Financial/budgetary impacts**

The volume of use of transcatheter closure of PDA was estimated to be 55 procedures in the private setting for 2012-13. As the procedure is already performed in the public healthcare setting, only procedures performed in the private healthcare setting were included for the purposes of the financial analysis in the assessment report.

The rate of uptake for transcatheter closure of PDA was estimated at 1.8% per annum, in line with the average increase of births per year sourced from the Australian Bureau of Statistics. Based on AIHW data, approximately 29% of all patients are treated percutaneously, a third of which are performed in a private setting.

For the purposes of the financial analysis in the assessment report, transcatheter closure of PDA was a once-only procedure, i.e. successful insertion of the device will result in a resolution of the disease process.

The MBS cost was based on the 75% benefit of the MBS items associated with transcatheter closure of PDA. In 2013-14, for an estimated 56 patients treated in the private healthcare setting, the total cost of the intervention to the MBS is \$124,020. Taking into account that the estimated number of procedures for transcatheter closure of PDA is low, it is anticipated that the volume of services will remain constant.

The financial analysis used the ICU and ward costs sourced from the Victorian Government guide to fees for admitted patients 2012-13. The guide places a value of \$2,209 per day for ICU and \$774 for an overnight ward stay. It should be noted that the fees vary between hospitals, and are determined on either a Diagnosis Related Group (DRG) or bed day basis.

Catheterisation laboratory and theatre costs were derived from figures in Kramer et al (2000) and Gray et al (1993). These costs were then adjusted to reflect current prices. The catheterisation laboratory cost was estimated at \$3,641 while the theatre cost for surgical closure of PDA was estimated at \$1,790.

The analysis assumed a stay of 2 days in a ward for transcatheter patients, and for surgical patients, 3 days in the ICU and 6 in a ward, for a total stay of 9 days. This figure correlates with 2010-11 AIHW average length of stay of 10.5 days for closure of PDA. MSAC disagreed with the assessment report assumptions. MSAC considered that in contemporary practice a transcatheter patient is more likely to be in hospital as a day patient or for a one night stay. MSAC considered that surgical patients are more likely to have one night in ICU and four nights in a ward.

Overall, the estimated hospital cost per patient (excluding the cost of the device) was \$5,189 for transcatheter closure of PDA in comparison to \$13,061 for surgical closure of PDA. MSAC noted that the above scenario would reduce the difference in MBS cost associated with medical management for the surgical patients

The comparison of the MBS cost per patient for transcatheter versus surgical closure of PDA takes into account a number of factors. The consultation and diagnostic services prior to the procedure for closure of PDA are assumed to be similar for both types of intervention. The MBS items for the initiation of anaesthesia will be different i.e. anaesthesia for cardiac catheterisation versus open heart surgery.

The operating time reported in Chen et al (Chin Med J 2009) indicated an average of 55.4 minutes for transcatheter closure and 80.9 minutes for surgical closure of PDA. Therefore, MBS items based on the length of time for the anaesthesia have been included which align to these reported operating times i.e. MBS item 23042 for transcatheter closure of PDA and MBS item 23062 for surgical closure of PDA.

Lin et al (2009) reported an average ICU stay of 0.9 days for transcatheter closure and 3.4 day for surgical closure of PDA. Therefore, the cost of MBS items has been included in the financial analysis for the initial and subsequent medical management for the surgical patients following admission to an ICU unit.

In summary, for an estimated 56 patients treated in the private healthcare setting in 2013-14, transcatheter closure of PDA was estimated to provide a small saving to the MBS of \$31,578 over surgical closure of PDA.

### **13. Key issues for MSAC from ESC**

#### Main issues around the proposed eligible population for public funding and/or the proposed main comparator

ESC noted that leakage to patients outside of the intended population will be extremely unlikely. ESC also noted that in adult women, previously undiagnosed PDAs are most commonly diagnosed during the woman's pregnancy.

#### Main issues around the evidence and conclusions for safety

ESC accepted that, although the studies for transcatheter versus surgical closure of PDA were non randomised, the studies indicated an equivalent level of safety for both types of intervention.

#### Main issues around the evidence and conclusions for clinical effectiveness

ESC also accepted that there was never likely to be a randomised trial for transcatheter versus surgical closure of PDA due to the small number of patients and that transcatheter closure is now an established standard and preferred treatment of PDA.

#### Other important clinical issues and areas of clinical uncertainty

ESC accepted that there is rarely a need for cardiac catheterisation for the diagnosis of PDA. ESC agreed the clinical management algorithm outlined that clinically significant PDA is usually confirmed by echocardiography. Usually, infants have an initial trial of medical management whereas adults have interventional treatment for closure of PDA.

#### Main economic issues and areas of uncertainty

ESC discussed as to whether the MBS listing for transcatheter closure of PDA may result in an increase of services in the private healthcare setting. However, ESC accepted that the majority of procedures were likely to continue to be performed in the public hospital setting due to a number of factors including that patients may have comorbidities with a PDA; that the procedure is most commonly performed on children; that cardiothoracic unit backup support is always required; and that the number of paediatric private cardiothoracic units are very limited.

#### Any other important areas of uncertainty (e.g. budget impact, translation of clinical evidence into the economic evaluation, linkage between an investigative intervention and a subsequent therapeutic intervention and outcomes)

ESC noted that the choice of device is based on clinical judgement and that the article provided by the applicant (Sheridan et al 2013) concluded that the ADO may be the device of first choice in the current era. ESC agreed that the ADO is the appropriate device to be used in the cost analyses.

### **14. Other significant factors**

The applicant suggested that no restrictions should be placed on the size of the child for transcatheter closure of PDA. Chen et al (Chin Med J 2009) and Sheridan et al (2013) cite cases where PDAs have been closed using the transcatheter technique in infants down to 5.2kg and 5.5kg respectively. The applicant also advised that there are other case reports where PDAs have been closed using this technique in much smaller infants. Also improved device design into the future will allow closure of PDAs in smaller infants. ESC agreed that no restriction should be placed on the size of the patient and that appropriate management will be a clinical judgement.

ESC accepted the applicant's feedback that the catheter theatre cost of \$3,641 (derived from international literature) is high i.e. twice the estimate of \$1,790 for surgical theatre.

The applicant indicated that hospital charges at their place of work do not reflect this difference.

The applicant advised that anaesthesia is rarely used in the pre-operative echocardiogram. ESC accepted that the MBS cost for the anaesthesia, estimated for both transcatheter and surgical closure of PDA, can be removed from the cost estimates.

The post ESC amendments for the estimated cost per patient include:

- equal cost for theatre and catheter laboratory;
- removal of MBS cost for the anaesthesia for transthoracic echocardiography; and
- removal of MBS cost for cardiac catheterisation and transthoracic echocardiography associated with the delivery of the intervention.

Table 4 Post ESC: Comparison of cost per patient

	Transcatheter		Surgery	
	Units	Total	Unit	Total
<b>Consultation and diagnostic</b>				
Specialist consultation	1	\$64.20	1	\$64.20
Chest x-ray	2	\$70.80	2	\$70.80
ECG	1	\$23.45	1	\$23.45
Transthoracic echocardiography	1	\$173.00	1	\$173.00
<b>Both surgery and transcatheter</b>				
Operating Theatre / Catheter laboratory	1	\$1,790.00	1	\$1,790.00
Anaesthesia for patient less than 12 months	1	\$14.75	1	\$14.85
Ward stay	2	\$1,548.00	6	\$4,644.00
<b>Transcatheter closure of PDA</b>				
Device	1	\$10,200.00		
Initiation anaesthesia (cardiac catheterisation)	1	\$103.95		
Anaesthesia (55 mins)	1	\$59.40		
Transcatheter closure of PDA	1	\$684.25		
Assistant	1	\$182.46		
<b>Surgical closure of PDA</b>				
Initiation anaesthesia (open heart)			1	\$297.00
Anaesthesia (1.21 mins)			1	\$89.10
Surgical closure of PDA			1	\$800.55
Assistant			1	\$213.48
ICU stay			3	\$6,627.00
ICU initial attendance			1	\$271.60
ICU followup attendance			2	\$402.90
<b>TOTAL</b>		<b>\$14,914.36</b>		<b>\$15,481.93</b>

*MBS costs based on 75% benefit of the Schedule fee as at 1 November 2012*

The post-ESC comparison of estimated cost per patient indicated that transcatheter closure of PDA is less expensive compared to surgical ligation (\$14,914 and \$15,482 respectively for 2012-13).

The post-ESC estimated cost to the MBS for 2012-13 of transcatheter versus surgical closure of PDA is \$1,376 and \$2,421 respectively. As noted in the assessment report, one of the main differences in the MBS cost is the associated medical management for the surgical patients following admission to an ICU unit.

Post-ESC, for an estimated 56 patients treated in the private healthcare setting in 2013-14, transcatheter closure of PDA was estimated to provide a small saving to the MBS of \$58,496 over surgical closure of PDA.

It was noted by ESC that the proposed MBS item descriptor for transcatheter closure of PDA did not refer to any associated imaging or cardiac catheterisation that may be performed at the same time of the procedure. ESC considered the item descriptor should include the associated services such as imaging and cardiac catheterisation.

Table 5 Post ESC: Proposed MBS item descriptor for transcatheter closure of PDA

<b>Category 3 – Cardio-Thoracic</b>
PATENT DUCTUS ARTERIOSUS, Transcatheter closure of, including cardiac catheterisation and any imaging associated with the service (Anaes.) (Assist.) Fee: \$912.30 Benefit: 75% = \$684.25

## 15. Summary of consideration and rationale for MSAC’s advice

MSAC noted that transcatheter closure of PDA is a well-established intervention in the Australian health care setting. MSAC further noted that surgical closure (currently an MBS subsidised intervention) is also a viable option for curative treatment of PDA in some clinical circumstances.

MSAC agreed that the comparison of surgical versus transcatheter closure of PDA is appropriate.

MSAC noted that there are limited studies available to provide evidence for clinical effectiveness and safety of transcatheter closure of PDA. Furthermore, as transcatheter closure of PDA has been standard treatment for many years and the devices are used in a limited population, MSAC considered it unlikely that there would ever be any randomised comparative trials conducted in this area. Based on data from three non-randomised studies comparing transcatheter closure with surgical closure and local Queensland registry data, MSAC accepted that transcatheter closure of PDA is likely to be non-inferior to surgical ligation of PDA in terms of comparative effectiveness and safety.

MSAC noted the economic evaluation presented was limited to a simple cost comparison analysis due to insufficient evidence of comparative clinical effectiveness and safety. MSAC disagreed with the assessment report assumption in the cost analysis of two days in a ward for transcatheter patients, and three days in the ICU with six days in a ward for surgical patients. MSAC considered that in contemporary practice a transcatheter patient is more likely to be in hospital as a day patient or for a one night stay. MSAC considered that surgical patients are more likely to have one night in intensive care and four nights in a ward. MSAC noted that this scenario would reduce the difference in MBS cost associated with medical management for the surgical patients following admission to an ICU unit, which is a significant component of the overall cost of the procedure. For transcatheter patients, the cost of the ADO device (\$10,200) is the significant component of the overall cost.

MSAC considered that an MBS listing for transcatheter closure of PDA may result in increased services in the private healthcare setting. However, MSAC noted that the majority

of procedures for transcatheter or surgical closure of PDA are performed on young infants in major public hospitals. MSAC expects that the majority of procedures are likely to continue to be performed in the public hospital setting.

MSAC noted that the overall net financial cost/year to the MBS is estimated to be cost saving \$31,578 for transcatheter closure of PDA over surgical closure of PDA, for an estimated 56 patients treated in the private healthcare setting in 2013-14.

MSAC agreed that the technique involved in the procedure and the devices utilised most closely resemble those of MBS item 38272 which covers transcatheter closure of ASD. Therefore, the proposed MBS fee should be consistent with MBS item 38272 and the proposed descriptor should include associated services such as imaging and cardiac catheterisation which may be performed at the same time of the procedure.

#### **16. MSAC's advice to the Minister**

After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of transcatheter closure of PDA, MSAC supports public funding via a new MBS item, with an MBS fee of \$912.30 and an item descriptor of:

<b>Category 3 – Cardio-Thoracic</b>
PATENT DUCTUS ARTERIOSUS, Transcatheter closure of, including cardiac catheterisation and any imaging associated with the service (Anaes.) (Assist.) Fee: \$912.30 Benefit: 75% = \$684.25

#### **17. Applicant's comments on MSAC's Public Summary Document**

No comment.

#### **18. Context for decision**

This advice was made under the MSAC Terms of Reference.

MSAC is to:

Advise the Minister for Health and Ageing on medical services that involve new or emerging technologies and procedures and, where relevant, amendment to existing MBS items, in relation to:

- the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
- whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
- the proposed Medicare Benefits Schedule (MBS) item descriptor and fee for the service where funding through the MBS is supported;
- the circumstances, where there is uncertainty in relation to the clinical or cost-effectiveness of a service, under which interim public funding of a service should be supported for a specified period, during which defined data collections under agreed clinical protocols would be collected to inform a re-assessment of the service by MSAC at the conclusion of that period;
- other matters related to the public funding of health services referred by the Minister.

Advise the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.

MSAC may also establish sub-committees to assist MSAC to effectively undertake its role. MSAC may delegate some of its functions to its Executive sub-committee.

## **19. Linkages to other documents**

MSAC's processes are detailed on the MSAC Website at: [www.msac.gov.au](http://www.msac.gov.au).