The Australian and New Zealand Society of
Cardiac and Thoracic Surgeons
ABN 44 503 186 462

12 March 2015

Dr Megan Keaney
A/g Assistant Secretary
Medical Specialist Services Branch
Canberra ACT

Dear Dr Keaney

Re: MSAC review of LVAD MBS Item numbers – March 2015
(Your letter – 15 January 2015 - Potential amendments to Medical Benefits Schedule Items for Left Ventricular Assist Devices)

The Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) wish to thank the Department of Health for the opportunity to provide comment.

Expert opinion has been sought from transplant and non-transplant centres and includes both Cardiothoracic Surgeons and Cardiologists. Those providing opinion include:

Prof. Peter Macdonald	(PM)	Cardiologist	St Vincent's Hospital – Sydney
Mr Paul Jansz	(PJ)	Surgeon	St Vincent's Hospital – Sydney
Prof. David McGiffin	(DM)	Surgeon	The Alfred – Melbourne
Dr Peter Bergin	(PB)	Cardiologist	The Alfred – Melbourne
Prof. Paul Bannon	(PB2)	Surgeon	Royal Prince Alfred – Sydney
A/Prof. Jayme Bennetts	(JB)	Surgeon	Flinders Medical Centre - Adelaide

Consensus opinion agreed the review was comprehensive but some issues were raised regarding current literature and technical aspects of the available devices (Heartmate II and HeartWare).

1. Devices / Technical

- Neither device drain from the left atrium.
- The HeartMate II does not sit external to the body, it is implanted and the inflow and outflow cannulas are internal and don not traverse the skin.
- Neither device utilise an implantable power source and induction coils as a form of recharging are yet to become a reality in the clinical setting.
- Neither device pumps blood in 'pulses' - they are continuous flow. There is a slight pulsatility to the device but that's another topic in itself. The total artificial heart is pulsatile and utilise a pneumatic drive but this device is not TGA approved and is not included in the scope of this discussion.
- Neither device (HeartMate II or Heartware HVad) is pneumatic.

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2. Current Literature / Evidence

- I don't agree with the reviewers' conclusions regarding the available evidence ie. while there is more published data regarding bridge to transplant (BTT) LVAD implants, the quality of the studies in relation to DT is much higher with two prospective randomised controlled trials. While there was no sham procedure in the original Rose NEJM study, this hardly matters given that the primary endpoint of the trial was death – unless the reviewers strongly believe that placebo can improve long-term survival in advanced heart failure. DT is now an approved indication for LVAD implantation in the US and I think it is only a matter of when rather than if that DT is approved here.
- The Rematch trial is of historical interest (23% 2 year survival in the LVAD group which used a currently discontinued device). For that matter, so is the Slaughter study (HMII vs HMXVE). In the VAD technology world , 2007 is historical.
- The distinction between BTT and DT is becoming increasingly blurred and I think is to the point where these categories should perhaps be discontinued. From the INTERMACS registry, 43% of patients who were implanted with a BTT intent were no longer listed for transplant 2 years after VAD implant. 15% of patients implanted with a VAD with a DT intent were being considered for transplantation 2 years after VAD implantation.
- There is an important piece of information that was not referenced in the MSAC document and that relates to the comparison of the survival of VAD patients and cardiac transplant patients (Kirklin, JTCVS, 2012)
- Using the ISHLT registry the current 2 year survival after heart transplantation is 80%.
- A multivariable equation for death within 2 years of VAD implantation as DT was developed from INTERMACS and a solution nomogram produced a predicted survival based on certain risk factors in the model.. For patients less than 60 years of age without prior cardiac surgery their survival was at least as good as that of cardiac transplantation over 2 years.

3. General Comments

- An analogy to this situation is end-stage renal disease. Currently in Australia there are about 11000 Australians on dialysis (not sure about the exact figures). Only about 10% of these will ever undergo kidney Tx – the rest are destination dialysis patients. The current 2 year survival rate for >65 year olds receiving DT LVADs in the US is the same as the 2 year survival rate for > 65 year olds being started on dialysis.
- …a substantial proportion of patients undergoing LVAD implantation are not listed for HTx at the time of implant. Some do not meet eligibility criteria for HTx at the time of LVAD implant and the aim of the implant is to improve their condition to a point where they do meet eligibility criteria – so called bridge to decision or bridge to candidacy. ….Some of these patients particularly those presenting in acute cardiogenic shock will subsequently improve to a point where the VAD can be removed. It is not really possible to determine this at the time of implant.
- Encouragingly the review seems to acknowledge that the criteria for application of VAD technology is blurred. The review does how over, I feel, overstate the impact of

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the post VAD complications given that most patients that are receiving a LVad (or BiVad), in our experience are critically ill with a high short term mortality.

- Pt's come to VAD from a variety of pathways including:
  - Cardiogenic shock
  - Deterioration on current transplant waiting list
  - Indeterminate – "bridge to candidacy"

  And may or may not progress to being suitable for transplant candidacy (waiting list)
- In MBS 38615, a Right Ventricular Assist device is never used in isolation as a bridge to transplant. It is almost invariably used either as a temporary device in isolation or in conjunction with an LVAD or as a permanent device in conjunction with an LVAD.
- The word "ventricular" be removed because some patients have other mechanisms for their heart failure.
- the cardiology proposal to include "grey zone" patients who may become eligible for transplant does not recognise currently utilised surgical pathways (albeit small numbers I would believe) for which these codes are the only available CMBS items – namely post cardiotomy support, either VAD, BiVAD, or more likely ECMO currently. In addition, there are an increasing number of patients who are being supported on ECMO for acute conditions (with likely recovery and wean from ECMO), but who potentially may progress to longer term support on VAD and potentially need for transplant. I am unaware of any CMBS code for these patients except for central (38600) and peripheral (38603) cannulation options, but these are specific for cardiopulmonary bypass. It would seem the 38618 code (L+R support) is reasonable to use for ECMO.

4. Current CMBS Descriptors

38615	*LEFT OR RIGHT VENTRICULAR ASSIST DEVICE, insertion of* *(Anaes.) (Assist.)* *(See para T8.68 of explanatory notes to this Category)* *Fee: $1,532.00 Benefit: 75% = $1,149.00*
38618	*LEFT AND RIGHT VENTRICULAR ASSIST DEVICE, insertion of* *(Anaes.) (Assist.)* *(See para T8.68 of explanatory notes to this Category)* *Fee: $1,909.60 Benefit: 75% = $1,432.20*

Both codes are covered by the following caveat (Jan 2015 CMBS)

T.8.68. CARDIAC AND THORACIC SURGICAL ITEMS - (ITEMS38470TO38766)

Items 38470 to 38766 must be performed using open exposure or minimally invasive surgery which excludes percutaneous and transcatheter techniques unless otherwise stated in the item.

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5. MSAC Proposed Changes

38615
Insertion of LEFT OR RIGHT VENTICULAR ASSIST DEVICE, for use as a bridge to cardiac transplantation in patients with refractory ventricular heart failure and who are currently on a transplant waiting list,
(Anaes.) (Assist.)
Fee: $1532.00
Benefit: 75% . $1149.00

38618
Insertion of LEFT AND RIGHT VENTICULAR ASSIST DEVICE, for use as a bridge to cardiac transplantation in patients with refractory ventricular heart failure and who are currently on a transplant waiting list,
(Anaes,) (Assist.)
Fee: $1909.60
Benefit: 75% = $1432.20

6. Limitations of MSAC Proposed changes

While it was generally acknowledged the need to provide a framework around the implantation of VAD exists, the indications for current practice most often occur in supporting acutely unwell patients, either post cardiac surgery or acute cardiac failure, when the ability to determine suitability for transplant is not possible. Most frequently these patients may be supported with short-term measures, such as ECMO, while co-morbidities are assessed and the multi-organ failure resolves. Such patients may:

- Recover completely without further support (Bridge to Recovery)
- Recover to allow a decision regarding long term support. These patients may progress to be suitable for wait listing for transplant (Bridge to Transplant)
- Recover to be considered suitable for transplant but need ongoing support with longer term device (Bridge to Bridge)

Thus **unanimous opinion** was the proposed wording is **too** restrictive and not reflective of current best practice. Additionally it is suggested:

- Recognition of the need for short term support in the acute setting be included
- This support may include the use of ECMO
- No current code recognises ECMO specifically except for 38627 for cannulae repositioning

7. ANZSCTS Proposed CMBS codes

The suggested wording is designed to recognize current practice (Bridge to recovery, bridge to transplant, bridge to bridge), include ECMO as an appropriate means of support, and provide limitation around implantation of VADs for DT until further evidence (specifically cost effectiveness and outcomes) for this indication exists.

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38615
Insertion of LEFT OR RIGHT VENTICULAR ASSIST DEVICE, for use as

1. a bridge to cardiac transplantation in patients with refractory heart failure, and who are currently on a transplant waiting list, or are expected to be suitable candidates for cardiac transplantation following a period of support on the VAD
2. Acute post cardiotomy support for failure to wean from cardiopulmonary bypass following cardiac surgery or cardiopulmonary transplantation
3. cardiorespiratory support for acute cardiac or respiratory failure which is likely to recover with short term support (<6 weeks)

(Anaes.) (Assist.)

38618
Insertion of LEFT AND RIGHT VENTICULAR ASSIST DEVICE, for use as

1. a bridge to cardiac transplantation in patients with refractory ventricular heart failure and who are currently on a transplant waiting list, or are expected to be suitable candidates for cardiac transplantation following a period of support on the VAD
2. Acute post cardiotomy support for failure to wean from cardiopulmonary bypass following cardiac surgery or cardiopulmonary transplantation
3. cardiorespiratory support for acute cardiac or respiratory failure which is likely to recover with short term support (<6 weeks)

(Anaes,) (Assist.)

NEW
Insertion of ECMO, for use as

1. Acute post cardiotomy support for failure to wean from cardiopulmonary bypass following cardiac surgery or cardiopulmonary transplantation
2. cardiorespiratory support for acute cardiac or respiratory failure which is likely to recover with short term support (<6 weeks)

Via open, minimally invasive, or percutaneous techniques.
(Anaes.) (Assist.)

Alternatively, it would be possible for ECMO to be added into the header line for 38618 thus not creating the need for a new code. Point 3 indication for 38615 / 38618 could be the relevant caveat for ECMO usage.

38615 Insertion of LEFT OR RIGHT VENTICULAR ASSIST DEVICE, for use as

38618 Insertion of LEFT AND RIGHT VENTICULAR ASSIST DEVICE or ECMO, for use as

Given a code (CMBS 38627) currently exists for cannula/cannulae repositioning including ECMO no change to this code wording is required.

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38627
EXTRA-CORPOREAL MEMBRANE OXYGENATION, BYPASS OR VENTRICULAR ASSIST DEVICE CANNULAE, adjustment and re-positioning of, by open operation, in patients supported by these devices (Anaes.) (Assist.)
(See para T8.68 of explanatory notes to this Category)

Fee: $669.60 Benefit: 75% = $502.20

Two codes also exist for removal of VAD/s not recognising ECMO specifically. ECMO will also need a code for removal should a new code for insertion be recommended. Alternatively, ECMO needs to be added to 38624 (as per 38618 above) if it is decided to include ECMO within the current 38618 code.

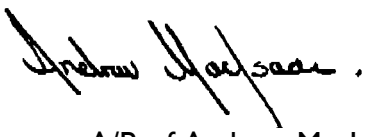
NEW
EXTRA-CORPOREAL MEMBRANE OXYGENATION, removal of, as an independent procedure (Anaes.) (Assist.)

or

38624
LEFT AND RIGHT VENTRICULAR ASSIST DEVICE or ECMO, removal of, as an independent procedure (Anaes.) (Assist.)
(See para T8.68 of explanatory notes to this Category)
Fee: $856.65 Benefit: 75% = $642.50

T8.68 caveat require these be by open techniques under current guidelines.

Thank you for considering our expert opinion regarding the proposed changes.
We look forward to further engagement in review of other CMBS codes relevant to the practice of Cardiothoracic Surgery in Australia.



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