Australian Government

Department of Health

Application 1523:

Transluminal insertion, management, repositioning and removal of an intravascular microaxial ventricular assist device (Impella®), for patients requiring mechanical circulatory support

Ratified PICO Confirmation

(To guide a new application to MSAC)

Summary of PICO/PPICO criteria to define the question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

POPULATION 1	
Component	**Description**
Patients	Patients undergoing high-risk percutaneous coronary intervention as defined as having: • comorbidities; and • left ventricular ejection fraction ≤35%; and • unprotected left main; or • last patent coronary vessel; or • three-vessel disease.
Intervention	Insertion and management of intravascular microaxial ventricular assist device
Comparator	Standard care (ie pharmacological therapy and/or intra-aortic balloon pump, and extra-corporeal membrane oxygenation, percutaneous ventricular assist devices).
Outcomes	Safety outcomes: • Major adverse events • Myocardial infarction • Stroke/ transient ischaemic attack • Repeat revascularisation • Vascular complications • Major bleeding • Other (eg acute renal dysfunction, cardiopulmonary resuscitation/ventricular arrhythmia, aortic valve damage/ increase in aortic insufficiency, severe hypotension requiring treatment) • Angiographic failure of percutaneous coronary intervention • Procedure complications (eg device malfunctions, high purge pressures, tube fracture/post-operative groin bleeding, gastrointestinal bleeding, other) Clinical effectiveness outcomes: • Mortality • Length of hospital stay • Haemodynamic results (ie cardiac power output) • Change in the New York Heart Association functional status • Rate of in hospital events • Quality of life • Repeat revascularisation • Rehospitalisation Procedural outcomes: • Number of lesions attempted • Number of stents placed • Use of adjunctive therapies (ie glycoprotein IIb/IIIa inhibitors, total contrast media, rotational atherectomy) • Saphenous vein graft treatment • Total support time • Discharge from catheterisation lab on device

POPULATION 1	
Component	**Description**
	Healthcare resources (eg time to implant device, hospital length of stay, rehospitalisation, specialist visits, repeat revascularisation, future interventions). Cost-effectiveness (eg incremental cost per quality-adjusted life year gained).

POPULATION 2	
Component	**Description**
Patients	Patients with cardiogenic shock, with no evidence of significant anoxic neurological injury
Intervention	Insertion and management of left intravascular microaxial ventricular assist device
Comparator	Standard care (ie pharmacological therapy and/or intra-aortic balloon pump, and/or extra-corporeal membrane oxygenation, ventricular assist devices).
Outcomes	Safety outcomes: • Major adverse events • Stroke/ transient ischaemic attack • Repeat revascularisation • Vascular complications • Major bleeding • Other (eg myocardial infarction, acute renal dysfunction, cardiopulmonary resuscitation/ventricular arrhythmia, aortic valve damage/ increase in aortic insufficiency, severe hypotension requiring treatment) • Procedure complications (eg device malfunctions, high purge pressures, tube fracture/post-operative groin bleeding, gastrointestinal bleeding, other) Clinical outcomes: • Mortality • Haemolysis • Median duration of support • Multiple organ dysfunction scores (Multi Organ Dysfunction Score and Sepsis-related Organ Failure Assessment) • Left ventricular ejection fraction • Transition to long term ventricular assist devices • Rate of in hospital events • Quality of life Haemodynamic outcomes: • Cardiac index • Cardiac power index • Mean arterial pressure • Serum lactate • Support time and dose of vasopressor/inotropic medications • Mechanical ventilation support time

POPULATION 2	
Component	**Description**
	Healthcare resources (eg hospital length of stay, rehospitalisation). Cost-effectiveness (eg incremental cost per quality-adjusted life year gained)

POPULATION 3	
Component	**Description**
Patients	Patients with right ventricular heart failure
Intervention	Insertion and management of right intravascular microaxial ventricular assist device
Comparator	Standard care (including medical and mechanical circulatory support)
Outcomes	Safety outcomes: • Major adverse events: • Stroke/ transient ischaemic attack • Repeat revascularisation • Vascular complications • Major bleeding • Other (eg myocardial infarction, acute renal dysfunction, cardiopulmonary resuscitation/ventricular arrhythmia, aortic valve damage/ increase in aortic insufficiency, severe hypotension requiring treatment) • Procedure complications (eg device malfunctions, high purge pressures, tube fracture/post-operative groin bleeding, gastrointestinal bleeding, other) Clinical outcomes: • Mortality • Rate of in hospital events • Quality of life Healthcare resources (eg time to implant device, hospital length of stay, rehospitalisation, specialist visits). Cost-effectiveness (eg incremental cost per quality-adjusted life year gained)

Population

The proposed medical service is for use in patients requiring mechanical circulatory support (MCS) of the native heart in reduced ventricular function, ie patients experiencing advanced heart failure (HF), acute myocardial infarction (AMI) complicated by cardiogenic shock, cardiogenic shock and undergoing high-risk cardiac interventional procedures.

The population can be broadly divided into three primary subgroups, based on the Therapeutic Goods Administration (TGA) proposed indication(s) presented in the Sponsor's Application Form, patients recruited into the pivotal clinical trials, and feedback from medical experts. The three populations were confirmed by the PICO Confirmation Advisory Sub-Committee (PASC).

1) ***High-risk percutaneous coronary interventions (HR-PCI)***
    a) As a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction (EF) with a high risk of postoperative low output syndrome.
    b) To provide support during HR-PCI.
    c) Post-PCI.
2) ***Cardiogenic shock***
    a) Reduced left ventricular function (eg postcardiotomy, low output syndrome, cardiogenic shock after AMI).
    b) As bridge to decision or bridge to next therapy (ie left ventricular assist device (LVAD) or transplant).
3) ***Right heart failure***
    a) Acute or transient reduction of the right ventricular function (eg postcardiotomy low output syndrome).
    b) In cardiogenic shock as a consequence of a posterior myocardial infarction with right ventricular HF.
    c) As right heart support during coronary beating heart bypass surgery, especially for patients with a reduced preoperative cardiac output or for patients having a high risk of developing a postoperative low output syndrome for other reasons.
    d) In right ventricular heart failure after implantation of an LVAD.
    e) In therapy unresponsive arrhythmias with a reduction of right ventricular output.

Coronary heart disease (CAD) is the leading cause of death in Australia, representing 13% (n = 19,800) of all deaths (1) The prevalence of CAD increases markedly with age and is higher in males than females (2); it is the leading cause of burden of disease for men aged 45 and over, and is among the top two causes of burden for women 65 years and over (1).

The two major clinical forms of CAD are AMI (heart attack) and angina. An AMI occurs when there is a sudden and complete blockage to the heart; it is an acute life threatening event requiring prompt treatment (1). Revascularisation treatments for CAD include open-heart surgery (ie coronary artery bypass graft (CABG)) and PCI, with PCI increasingly being offered (3).

Data on the epidemiology of advanced HF, including acute and chronic cases, is limited in Australia. Current estimates are that 30,000 patients are diagnosed with incident HF annually and 300,000 people are living with chronic HF in Australia (approximately 1.5 to 2.0% of the population). The

prognosis of patients with HF is poor with 5% in hospital mortality due to decompensated HF following admissions, and approximately 25 and 50 % having died within 1 year and 5 years of diagnosis(4). PASC noted the total eligible population is expected to range from 797 to 3,297 people. Based on global experience, estimated uptake in year 1 is expected to be 5%, resulting in total estimated Impella® use in approximately 40 to 165 patients.

Population 1 – High-risk percutaneous coronary interventions

PCI, also known as coronary angioplasty, is a nonsurgical technique for treating obstructive CAD, including unstable angina, and AMI. PCI is the most common revascularisation modality and is applied to patients with increased lesion complexity and comorbidities with 51% of all PCI performed in patients >65 years of age (5). In addition, the advent of transcatheter techniques for the treatment of patients with valvular heart disease has resulted in older patients with severe coronary disease and left ventricular systolic dysfunction undergoing HR-PCI. Patients with poor left ventricular function undergoing HR-PCI can develop myocardial ischaemia (inadequate blood supply). This can cause hypotension, and decreased cardiac output and can result in poor blood circulation in the heart (coronary hypoperfusion), HF, and haemodynamic collapse (6).

"Protected PCI" is a strategy that may reduce peri- and post-procedural adverse events. The Cardiac Society of Australia and New Zealand (CSANZ) currently endorses the guidelines developed by The Society for Cardiovascular Angiography and Interventions (SCAI), American College of Cardiology (ACC), Heart Failure Society of America (HFSA) and Society of Thoracic Surgeons (STS) guidelines for PCI (7) which state that although there is no single definition for 'high –risk' PCI, there are key variables that contribute to elevated risk during PCI:

- patient specific (eg increased age, impaired left ventricular EF (LVEF));
- lesion specific (eg unprotected left main stenosis, chronic total occlusions); and
- clinical presentation (eg acute coronary syndrome or cardiogenic shock).

PCI in patients with factors such as impaired left ventricular systolic function defined as EF <35%, unprotected left main disease, severe 3-vessel disease (SYNTAX score >33), or last patent vessel are associated with in-hospital mortality rates between 5% and 15% (8). Table 1 lists the variables used to define HR-PCI based on clinical presentation, hemodynamic status, electrical instability and end organ function (9). Based on advice from medical experts, these criteria can be used to guide a restriction in the MBS item descriptor.

Table 1 High-risk PCI

Clinical
LVEF <35% Electrical instability Congestive HF
Comorbidities
Severe aortic stenosis Severe mitral regurgitation Chronic obstructive pulmonary disease Chronic kidney disease Diabetes Cerebrovascular disease Peripheral vascular disease Age >75 years Acute coronary syndrome
Coronary anatomy

Clinical
Last patent vessel Unprotected left main coronary artery 3 vessel disease, SYNTAX score >33 Target vessel providing collaterals to a territory, which supplies >40% of the myocardium Distal left main bifurcation

Source: Atkinson et al, 2016 (8). *Abbreviations:* HF, heart failure; LVEF, left ventricular ejection fraction.

The primary randomised controlled trial of haemodynamic support with intravascular microaxial ventricular assist device (Impella 2.5) versus IABP in non-emergent HR-PCI (PROTECT-II) included patients who had an unprotected left main or last patent coronary vessel with an LVEF ≤35%. Patients with 3-vessel disease and LVEF ≤30% were also eligible for inclusion (9).

It is noted that the primary clinical studies used to inform the clinical effectiveness in HR-PCI are performed specifically in the non-emergent/elective, rather than the emergent/acute setting. This was also validated by medical experts who advised that HR-PCI almost always occurs in the elective or semi-elective setting. The Sponsor advised that the proposed medical service may also occur in the emergency/acute setting in the instance of HR-PCI however this may be based on experience in the USA and not necessarily reflective of the setting of use in Australia.

Taking into account clinical evidence, current clinical guidelines and expert feedback, the proposed definition of Population 1 is patients undergoing high-risk percutaneous coronary intervention as defined as having:

- **comorbidities; and**
- **left ventricular ejection fraction ≤35%; and**
- **unprotected left main; or**
- **last patent coronary vessel; or**
- **three-vessel disease.**

Population 2 – Cardiogenic shock

Cardiogenic shock occurs when the heart suddenly cannot pump enough blood. It is defined as a state of end-organ hypoperfusion caused by left ventricular, right ventricular, or biventricular myocardial injury resulting in systolic and/or diastolic myocardial pump failure (10). It is characterised by a self-propagating cascade of falling cardiac output, falling left ventricular end diastolic pressure, and reduced end-organ and coronary perfusion. These conditions most often present in patients with AMI, out-of-hospital cardiac arrest, and patients with a history of congestive HF and/or advanced valvular heart disease.

Cardiogenic shock is relatively rare occurring in about 7% of all AMI (8, 11, 12), however it is a fatal complication with mortality rates ranging from 30-50% even with prompt reperfusion therapy with primary PCI (13). Adverse outcomes, such as high mortality and morbidity, continue to drive demand for improved therapeutic options for patients with cardiogenic shock. Patients in profound cardiogenic shock might not respond to other usual treatment options such as increasing doses of inotropes or IABPs (10). Early identification and rapid intervention is critical to optimise treatment efficacy in this patient population, with the aim to reverse the cascade of cardiogenic shock.

The SHOCK (SHould we emergently revascularize Occluded Coronaries for cardiogenic shocK) trial (8) outlined clinical and hemodynamic criteria to define cardiogenic shock (Table 2).

Table 2 Haemodynamic criteria for cardiogenic shock

Clinical
SBP <90 mmHg for 30 minutes Supportive measures needed to maintain SBP >90 mmHg End organ hypoperfusion Cool extremities UOP <30 mL/hour HR >60 beats/minute
Haemodynamic
Cardiac index <2.2 mL/min/m^2 PCWP >15 mmHg

Source: Atkinson et al, 2016 (8). *Abbreviations:* HR, heart rate; PCWP, pulmonary capillary wedge pressure; SBP, systolic blood pressure; UOP, urine output.

Furthermore, the spectrum of cardiogenic shock can be described based on severity: Pre/Early Shock, Shock, Severe Shock. Characteristics of this spectrum are outlined in Table 3.

Table 3 Spectrum of cardiogenic shock

Pre/Early Shock	**Shock**	**Severe Shock**
Clinical		
SBP <100 mmHg HR 70-100 beats/min Normal lactate Normal mentation Cool extremities	SBP <90 mmHg HR >100 beats/min Lactate >2 Altered mental status Cool extremities	SBP <90 mmHg HR >120 beats/min Lactate >4 Obtunded Cool extremities
Haemodynamic		
CI 2-2.2 PCWP <20 LVEDP <20 CPO >1 W	CI 1.5-2.0 PCWP >20 LVEDP >20 CPO <1 W	CI <1.5 PCWP >30 LVEDP >30 CPO <0.6 W
Vasoactive medications		
0 or 1 low dose	1 moderate to high dose	2 or more

Source: Atkinson et al, 2016 (8). *Abbreviations:* CI, cardiac index; CPO, cardiac power; HR, heart rate; LVEDP, left ventricular end-diastolic pressure; PCWP, pulmonary capillary wedge pressure; SBP, systolic blood pressure.

Based on advice from medical experts the patient population presenting with cardiogenic shock is heterogenous and despite the haemodynamic criteria and spectrum of cardiogenic shock presented above, there is no definitive or clear-cut criteria to guide a restriction in the MBS item descriptor. Additionally, given the large element of clinical discretion associated with managing these patients, the proposed MBS item descriptor has been kept broad. The Applicant has suggested the proposed medical service is indicated for use in patients in cardiogenic shock with no evidence of significant anoxic neurological injury. It was noted during the PASC meeting that this occurs in the emergent/acute setting.

Therefore, the proposed definition of Population 2 is patients in cardiogenic shock with no evidence of significant anoxic neurological injury.

Population 3 – Right heart failure

Right heart failure is characterised by the inability of the right ventricle to generate enough stroke volume, thereby resulting in systemic venous congestion, underfilling of the left ventricle and, in the

most advanced cases, cardiogenic shock (14). Right heart failure could result from direct affection of myocardial disease by myocarditis, cardiomyopathy, ischaemia, or arrhythmia. Right ventricular infarction complicates 30 to 50% of inferior myocardial infarction and it is usually caused by occlusion of the proximal right coronary artery. Compared with the left ventricle, the right ventricle is more resilient in the face of ischaemia. This is due to less myocardial oxygen demand, coronary perfusion occurring throughout the cardiac cycle, and a dual blood supply - the left anterior descending artery supplies the anterior two thirds of the septum. So, in the majority of cases, the RV recovers within a few days. However, during the initial presentation profound hypotension and shock may be present (14).

Right heart failure generally occurs post cardiac surgery or post LVAD. Based on the patient population in the primary clinical study (15), the proposed definition of Population 3 is patients with isolated right heart failure after LVAD implantation or after cardiotomy.

Right heart failure as the primary presentation of acute decompensated HF and cause of hospitalisation is very rare. In one registry it accounted for 2.2% of HF admissions (14).

The proposed definition of Population 3 is patients with isolated right heart failure after LVAD implantation or after cardiac surgery or myocardial infarction.

Current management approach within the Australian healthcare system

Patients under cardiogenic shock, HR-PCI, and right heart failure represent a wide spectrum of disease that requires tailored therapy to improve individual haemodynamic derangements.

Population 1: High-risk percutaneous coronary interventions

The treatment of patients undergoing 'high-risk PCI' and/or with heart attack is complex. Based on advice from medical experts the decision to perform HR-PCI is primarily led by the treating interventional cardiologist and is usually based on an algorithm developed by a multidisciplinary heart team, which may differ from hospital to hospital. The multidisciplinary heart team is typically comprised of interventional cardiologists and cardiothoracic surgeons.

The need for MCS depends upon the haemodynamic condition of patient at time of PCI, the anticipated risk of haemodynamic compromise during procedure, and the need for haemodynamic support after revascularisation.

Population 2: Cardiogenic shock

First, prompt recognition of patients with cardiogenic shock is essential (8). A typical diagnostic workup that could assess for myocardial ischaemia could include blood examination (ie troponin levels), chest X-ray, electrocardiogram (ECG), echocardiography, computed tomography angiography, and angiography. Once diagnosed with angiography, a multidisciplinary heart team approach is typically used to determine the treatment strategy (8, 16).

The treatment of patients in cardiogenic shock is complex and time critical. Based on advice from medical experts and the Sponsor, it is typically based upon an algorithm developed by a multidisciplinary heart team comprised of interventional cardiologists and cardiothoracic surgeons, and is hospital specific. The multidisciplinary heart team expands to include advanced heart failure

and intensive care physicians who will play an essential role in the post-procedure management. Due to the emergent nature of cardiogenic shock and requirement for quick intervention, a heart team approach is not always feasible (8).

Early diagnosis, stabilisation, revascularisation, and assessment of myocardial recovery in patients with cardiogenic shock is vital. Based on advice from the Sponsor and medical experts, protocol development is increasing at institutions in the United States however it is difficult to protocolise in Australia due to heterogeneity in patients and in practice. Some hospitals have developed a coordinated strategy including "shock teams". These structures are being developed to mimic best practices in trauma, ST-Elevation Myocardial Infarction (STEMI), and acute pulmonary embolism care. If the hospital cannot provide early revascularisation for the cardiogenic shock patient, rapid transfer to a facility that can provide early revascularisation is recommended.

Population 3: Right heart failure

Although the aetiologies of right ventricular (RV) failure are diverse, treatment often involves simultaneous and timely execution of multiple strategies aimed at optimising RV preload, afterload, and contractility, including medical therapy such as diuretics and inotropes, as well as MCS of the right ventricle (eg right ventricular assist device (RVAD), extra-corporeal membrane oxygenation (ECMO)) which can offer a bridge to RV recovery or to definitive management of the underlying cause (17).

Consultation feedback

Four respondents provided consultation on Application form 1523. All respondents agreed with the definition of the proposed populations for the intravascular microaxial ventricular assist device. It was suggested that other indications would potentially include LV venting with VA-ECMO and bridge to recovery for fulminant myocarditis. There was disagreement by one respondent with the projection regarding HR-PCI as most cases are not high-risk.

Intervention

The proposed medical service is insertion and management of an intravascular microaxial ventricular assist device, which PASC and the Applicant agreed that for accuracy should be changed from 'microaxial blood pump'. Specifically, the Impella® Ventricular Support System consists of a family of percutaneous heart pumps. To accommodate a range of cardiac output requirements, different sized Impella® Support Catheters are available. The Impella® family consists of four models relevant to this application, including three left-ventricular devices (Impella® 2.5, CP, and 5.0), and one right-sided ventricular device (Impella® RP):

1. Impella® 2.5: a 12-Fr (French) catheter-based device with maximal flow rates of 2.5 L/min, placed through a femoral percutaneous approach – via a standard catheterisation procedure through the femoral artery, into the ascending aorta, across the valve and into the left ventricle.

2. Impella® CP (cardiac power): a 14-Fr catheter-based device maximal flow rates of 3.5 L/min, placed through a femoral percutaneous approach – via a standard catheterisation procedure through the femoral artery, into the ascending aorta, across the valve and into the left ventricle.

3. Impella® 5.0: a 21-Fr catheter-based device with maximal flow rates of 5.0 L/min; placed via femoral cut down or through the axillary artery and goes through the ascending aorta, across the valve and into the left ventricle.

4. Impella® RP: a 22 Fr catheter-based device with maximal flow rate up to 4.0L/min; placed through a femoral percutaneous approach - through a standard catheterization procedure via the femoral vein, into the right atrium, across the tricuspid and pulmonic valves, and into the pulmonary artery.

All of the Impella® catheters consist of a micro-axial rotary blood pump mounted on a drive catheter, which is connected to an external controller, the Automatic Impella® Controller (AIC). The Impella® 2.5 is shown as an example in Figure 1.

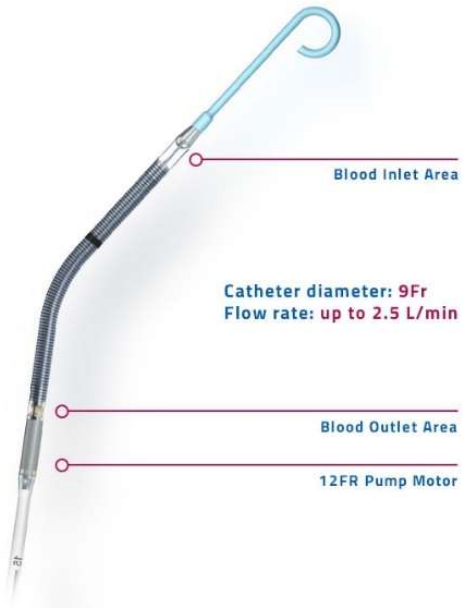

Figure 1 Example of Impella® Ventricular Support Catheter (Impella® 2.5)
Source: http://www.abiomed.com/Impella

The AIC generates signals required to power the drive motor of the Impella® Catheters and provides a user interface. The AIC also incorporates the disposable Impella® Purge Cassette system, which provides a fluid pressure barrier to prevent blood from entering the Impella® Catheters drive motor. A dextrose (5-40% with 50 Units/ml of heparin added) solution is used as a purge fluid. The AIC is portable and has been qualified for use for patient transport by trained healthcare professionals within healthcare facilities and during medical transport between hospitals (ie ambulance, helicopter or fixed-wing aircraft) in the US. The AIC and purge cassette are shown in Figure 2. The AIC is used by operators to monitor the correct positioning and functioning of the Impella®.

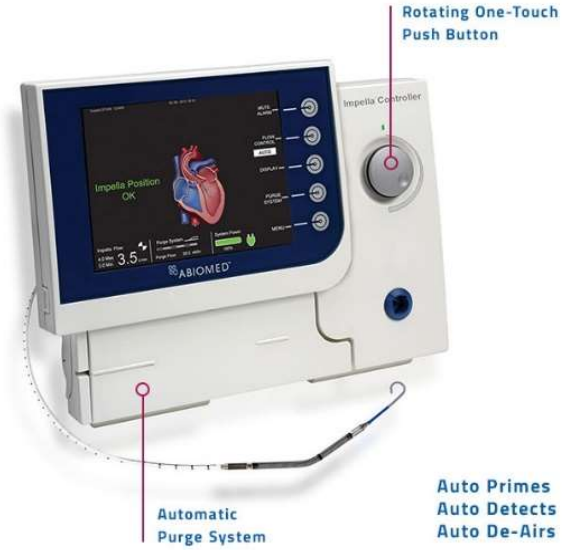

Figure 2 Automatic Impella® Controller and Impella® purge system
Source: http://www.abiomed.com/Impella

Impella® favourably alters the balance of myocardial oxygen demand and supply, improving myocardial ischaemic reserve. During normal physiological systole, blood is propelled by contraction of the left ventricle through the aortic valve to the systemic circulation via the ascending aorta, blood also enters the left and right coronary arteries via the coronary ostia to perfuse the heart. Impella® generates haemodynamic support by providing active forward flow that increases net cardiac output. By supplementing active forward flow and systemic aortic pressure there is an effective increase in mean arterial pressure and overall cardiac output. As a result, the Impella® devices can assist in maintaining end organ perfusion and facilitate myocardial recovery from insult. Figure 3 summarises the mechanism of action of Impella®.

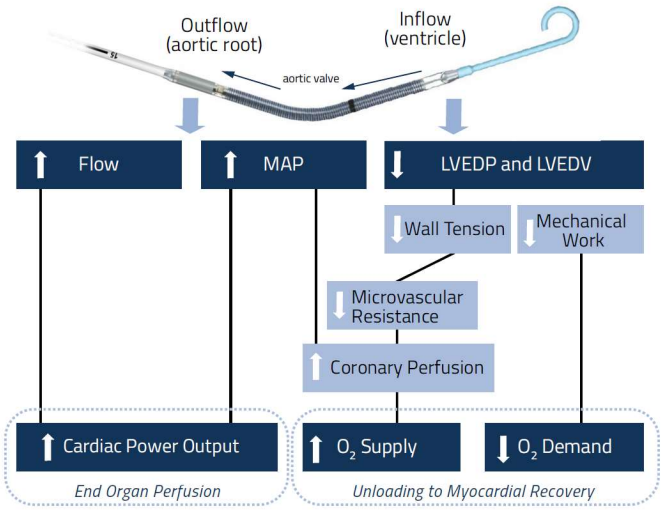

Figure 3 Mechanism of action of Impella®
Source: http://www.abiomed.com/Impella

The left sided Impella® devices are inserted retrogradely via a standard catheterisation procedure or cut down through the femoral artery (Impella® 2.5, CP, 5.0) or the axillary artery (Impella® 5.0) into the ascending aorta, across the aortic valve and into the left ventricle. The right sided Impella® RP is inserted retrogradely via a standard catheterisation procedure through the femoral vein into the right atrium, across the tricuspid and pulmonic valves and into the pulmonary artery.

PASC noted the three versions of Impella® – 2.5, 5.0 and CP – each of which have different flow rates and that the evidence relates primarily to Impella® 2.5. Whether comparative evidence for all models of Impella® for each respective indication, or comparative evidence for one type (eg 2.5) is enough to extrapolate to the other Impella® models should be factored into the assessment. It was noted by the Applicant that Impella® CP has similar haemodynamics and outcomes to Impella® 2.5. Results for Impella® 5.0 are from small numbers of patients.

PASC considered that Impella® would be unlikely to meet the definition of a prosthesis under the Prostheses List.

Provider type

Interventional cardiologists and cardiovascular surgeons will primarily deliver the proposed service and would be responsible for the implant and removal. General intensivists and advanced HF cardiologists would be responsible for ongoing care (18).

Operators of an intravascular microaxial ventricular assist device would require specific training to use and manage the devices. Abiomed Inc., the maker of the Impella®, offers a thorough training program for both physicians and hospital staff that are going to use the Impella® system. Training covers the full spectrum of therapy, from an overview of the technology, controller, and system set-up and insertion, through to patient management topics. In addition, local clinical support will be available.

Setting of use

The proposed setting of use of an intravascular microaxial ventricular assist device is as inpatient public or private hospital and will primarily be performed in hospital cardiac catheterisation laboratories. It can occur in both the elective/non-emergent setting (for HR-PCI) and the acute/emergent setting.

An intravascular microaxial ventricular assist device may also be delivered in operating theatres with imaging capabilities, it may be required in this setting if a patient is discovered to require additional cardiac support. It may also be delivered in intensive care (ICU) with medical imaging capabilities. It is unlikely that insertion of an intravascular microaxial ventricular assist device would occur in intensive care, however monitoring and repositioning of the device could be required in this setting.

Weaning of the intravascular microaxial ventricular assist device would be expected to occur in the cardiac catheterisation laboratories for HR-PCI and in the ICU setting for cardiogenic shock.

It is likely that any facility that meets the CSANZ guidelines for coronary angiography and PCI would be capable of inserting an intravascular microaxial ventricular assist device. The CSANZ guidelines on support facilities for coronary angiography and PCI (2016) (19) states that coronary interventional procedures (such as PCI) are preferably performed in hospitals with on-site surgical support.

However, the Society believes that centres without on-site surgical backup can provide coronary interventional procedures in accordance with the following standards for elective PCI:

- All operators and centres should meet the minimum requirements set in the Society's "Guidelines for competency in PCI"
- Hospitals should accredit cardiologists individually to perform PCIs
- Should be a minimum of two appropriately trained interventional cardiologists in centres providing elective PCI
- Facilities providing only elective PCI should have on-call team available to deal with post procedural complications
- There should be access to coronary care facilities for routine post procedure management and intensive care unit to facilitate management of mechanically ventilated patients. All units should have the ability to provide support IABP insertion
- Individual hospitals would have a written policy covering these issues
- The Society believes that under certain circumstances, coronary interventions can be performed as a day case procedure.

For primary (urgent) PCI, the Society believes that a policy of primary PCI should only be performed after an elective PCI program has been established and shown to perform with acceptable morbidity and mortality.

All variations of the proposed medical service (ie Impella® 2.5, CP, 5.0, RP) are intended for inclusion in the item descriptor.

Intravascular microaxial ventricular assist devices are not currently funded or reimbursed in the private or public setting in Australia for the proposed indication or any other clinical indication.

Consultation feedback

A list of benefits and disadvantages associated with the proposed medical service based on the Application form 1523 were provided by four respondents in response to a request for consultation. Impella® was described as providing good short term circulatory support that is less invasive compared with other methods or short term MCS, potentially has less complications, provides the possibility of mobilisation of patients while on support and is potentially life-saving. Disadvantages were related to the prohibitive cost and the need for highly trained multidisciplinary decision making.

Comparator

The intravascular microaxial ventricular assist device can replace current management and also be used in addition to current management options in HR-PCI (ie as an adjunct to help maintain haemodynamic stability in patients at high-risk), for cardiogenic shock (ie as a short term solution), and in the right ventricle for support in patients with right heart failure. Table 4 presents a summary of the currently available MCS comparators.

Table 4 Description of MCS comparator types (IABP, ECMO and pVAD)

Item	IABP	ECMO	pVAD
			
Cardiac flow	0.3-0.5L/min	3-7L/min	2.5-5L/min
Mechanism	Aorta	Right atrium-aorta	Left ventricle-aorta
Maximum implant days	Weeks	Weeks	2 weeks
Femoral artery size	>4mm	8mm	8mm
Cardiac synchrony/stable rhythm	7-8 Fr	15-17 Fr: arterial 21 Fr: venous	14-16 Fr: arterial 18-21 Fr: venous
Cardiac flow, power, MAP	↑	↑↑	↑↑
Myocardial oxygen demand	↓	↓↔	↔

Source: Atkinson et al, 2016 (8). *Abbreviations:* IABP, intra-aortic balloon pump; ECMO, extra-corporeal membrane oxygenation; MAP, mean arterial pressure; pVAD, percutaneous ventricular assist device; Fr, French.

The primary comparator differs based on the three population subgroups, as described below.

Population 1: High-risk percutaneous coronary intervention

The nominated comparator for HR-PCI is standard of care which includes a basket of therapies ie pharmacological therapy, and/or MCS including IABP, ECMO and ventricular assist devices (VADs). The latter two may be used if greater haemodynamic support is required. The intravascular microaxial ventricular assist device may replace current management and also be used alongside current management options in HR-PCI (ie as an adjunct to help maintain haemodynamic stability in patients at high-risk). Based on clinical trials, PASC agreed the comparator for HR-PCI is standard care (pharmacological therapy and/or IABP, and ECMO, pVADs), with the primary comparator being IABP.Pharmacological therapy

Inotropic therapy aims to improve pump function by acutely increasing contractility. Inotropic drugs acutely improve stroke volume, cardiac output, filling pressures and systemic and pulmonary vascular resistance, leading to some symptomatic improvement (20) . Commonly prescribed inotropes include dobutamine or milrinone. Vasopressor drugs are also used to provide positive inotropic effects. Commonly prescribed vasopressor drugs include norepinephrine, phenylephrine, or high-dose dopamine.

IABP

The IABP has been used to provide counterpulsation therapy, either with or without inotropes. The IABP is the most commonly used MCS device, although it provides minimal haemodynamic support. The main contraindications include aortic valve regurgitation of greater than mild degree, and severe peripheral arterial or aortic disease. Vascular complications can occur including stroke, limb ischaemia or vascular trauma. Anticoagulation can be given with IABP therapy; however, its use is variable and usually site specific (3).

ECMO

ECMO provides temporary cardiopulmonary support for patients whose heart and lungs can no longer provide adequate physiologic support. ECMO can be either veno-veno (VV) for oxygenation only or veno-arterial (VA) for oxygenation and circulatory support. The main contraindications include anticoagulation and severe peripheral arterial disease. Complications include bleeding and thromboembolic events, as well as haemolysis. Anticoagulation is essential to prevent thrombosis of the membrane oxygenator (3).

pVAD/LVAD

An example of a pVAD used in this setting is the Tandem Heart. This device is a percutaneously inserted circulatory assist device that pumps blood extra-corporeally from the left atrium to the iliofemoral arterial system via a trans-septally placed left atrial cannula, thereby bypassing the left ventricle. The main contraindications include severe peripheral arterial disease and contraindication to anticoagulation. Complications include vascular trauma and limb ischaemia. Anticoagulation with continuous infusion of heparinised saline is important to prevent thromboembolism or in situ thrombosis (3). This type of left pVAD, which is non-implantable, is typically used in the high-risk setting.

Population 2: Cardiogenic shock

The nominated comparator in patients with cardiogenic shock is standard of care again including a basket of therapies ie pharmacological therapy, and/or MCS including IABP and/or ECMO if greater haemodynamic support is required. The intravascular microaxial ventricular assist device may replace current management and also be used alongside current management options for cardiogenic shock (ie as a short term solution). The management algorithm in the Statement from the Interventional Council of the ACC (2016) (8) lists LVADs as a management option in this patient population however, based on advice from local medical experts this is not commonly used as standard care in cardiogenic shock due to the emergent nature of the condition and because patients in this state may not be able to tolerate the device. Medical experts suggest that LVADs are a part of the treatment strategy in more stable patients, eg as bridge to transplant in patients with chronic heart failure and no end organ damage. Based on clinical trials, PASC agreed the comparator for cardiogenic shock is standard care (pharmacological therapy and/or IABP, and ECMO, pVADs).

Pharmacological therapy

The use of intravenous inotropic drugs to treat cardiogenic shock remains a common practice. However, evidence suggests that in-hospital mortality increases with increasing number of inotropes. In one study of 3,462 patients who received open heart surgery, the hospital mortality for patients successfully separating from cardiopulmonary bypass on no inotropes, low-dose, moderate-dose, one high-dose, two high-dose, and three high-dose inotropes were approximately 2.0%, 3.0%, 7.5%, 21%, 42%, and 80% respectively (21).

IABP

Currently in Australia, IABP support is indicated in patients with acute left ventricular systolic failure and cardiogenic shock whose management remains partially complex and characterised by high mortality rates. Clinical practice guidelines have been interpreted to support IABP placement in

patients with acute myocardial infarction with cardiogenic shock (22). However, the benefits of IABP remain uncertain with the National Heart Foundation of Australia (NHFA) and CSANZ guidelines for acute coronary syndromes stating that routine IABP use in cardiogenic shock complicating STEMI treated by primary PCI has not been shown to reduce 30-day or 6-month mortality and should be avoided(7).

ECMO

In cases of biventricular failure, ECMO is the MCS of choice for patients in cardiogenic shock and impaired oxygenation, as it provides full cardiopulmonary support. ECMO may be used to provide circulatory support in acute or refractory cardiogenic shock or cardiac arrest. ECMO support may be continued until either the patient recovers or receives a long-term ventricular assist device as a bridge to orthotopic heart transplant. Whilst ECMO has been demonstrated to confer a survival benefit in both short and long term outcomes in applications such as cardiopulmonary resuscitation, survival rate in patients receiving ECMO for cardiac arrest, severe cardiogenic shock or failure to wean from cardiopulmonary bypass is approximately 20-30% (23). As described above, the main contraindications include anticoagulation and severe peripheral arterial disease.

pVADs/LVADs

Based on advice from medical experts pVADs are not commonly used as standard care in cardiogenic shock due to the emergent nature of the condition and because patients in this state may not be able to tolerate the device. There have been clinical trials of the Heartmate PHP, another type of pVAD, in cardiogenic shock (4).

Population 3: Right heart failure

There is minimal evidence on the current management algorithm and standard of care in patients with right heart failure. Based on advice from medical experts, treatment of right heart failure follows similar principles to treatment of HR-PCI and cardiogenic shock in terms of haemodynamic support. Patients are supported with pharmacological therapy (inotropes +/- vasopressors), nitric oxide and MCS. ECMO is the primary MCS option used with the current management of right heart failure, and IABP is not used in these patients. Medical experts have advised that in the absence of right-sided VADs, occasionally left-sided VADs are used off-label in the right ventricle. Therefore the nominated comparator in patients with right heart failure is standard of care including pharmacological therapy and/or MCS, primarily ECMO. The intravascular microaxial ventricular assist device may replace current management and also be used alongside current management options in supporting the right ventricle in patients with right heart failure. Based on clinical trials, PASC agreed the comparator for right heart failure is standard care (including medical and mechanical circulatory support).

Provider type and setting of use

There are limitations on the provider and setting in which the comparator (pharmacological therapy and/or IABP, ECMO, pVAD) can be provided. These have been described above under the subheadings Provider type and Setting of use.

Consultation feedback

Three of the respondents agreed with the proposed comparator in the Application form (1523). One respondent disagreed in that there are other VADs available.

Outcomes

Overall, the patient-relevant and healthcare resource outcomes crossover the three population subgroups. There is some specificity in haemodynamic and clinical effectiveness outcomes for the subgroups, which have been listed below. PASC noted that current randomised trial data and meta-analyses support the safety of IABP, but provide limited or no support for its efficacy, including 30-day mortality. PASC noted this is likely to complicate the analyses. The Applicant acknowledged the proposed populations are highly heterogeneous (which may affect clinical outcomes) and treatment involves complex clinical decisions.

PASC suggested the following outcomes:

Population 1: High-risk percutaneous coronary intervention

Safety outcomes:

- major adverse events
- myocardial infarction
- stroke/transient ischaemic attack
- repeat re-vascularisation
- vascular complications
- major bleeding
- other (e.g. acute renal dysfunction, cardiopulmonary resuscitation/ventricular arrhythmia, aortic valve damage/ increase in aortic insufficiency, severe hypotension requiring treatment)
- procedure complications (e.g. device malfunctions, high purge pressures, tube fracture/post-operative groin bleeding, gastrointestinal bleeding, other)
- angiographic failure of percutaneous coronary intervention.

Clinical effectiveness outcomes:

- mortality
- length of hospital stay
- haemodynamic results (i.e. cardiac power output)
- change in New York Heart Association functional status
- rate of in-hospital events
- quality of life
- repeat revascularisation
- rehospitalisations

Procedural outcomes:

- number of lesions attempted
- number of stents placed
- use of adjunctive therapies (i.e. glycoprotein IIb/IIIa inhibitors, total contrast media, rotational atherectomy)
- saphenous vein graft treatment
- total support time
- discharge from catheterisation lab on device

Healthcare resource outcomes:

- time to implant device
- hospital length of stay
- re-hospitalisation
- specialist visits
- repeat revascularisations
- future interventions

Cost effectiveness outcomes:

- incremental cost per quality-adjusted life year gained

Population 2: Cardiogenic shock

Safety outcomes:

- major adverse events
- myocardial infarction
- stroke/transient ischaemic attack
- repeat revascularisation
- vascular complications
- major bleeding
- procedure complications (e.g. device malfunctions, high purge pressures, tube fracture/post-operative groin bleeding, gastrointestinal bleeding, other)
- other (e.g. acute renal dysfunction, cardiopulmonary resuscitation/ventricular arrhythmia, aortic valve damage/ increase in aortic insufficiency, severe hypotension requiring treatment)

Clinical outcomes:

- mortality
- haemolysis
- median duration of support
- multiple organ dysfunction scores (multi organ dysfunction score and sepsis-related organ failure assessment)
- left ventricular ejection fraction
- transition to long term ventricular assist devices
- rate of in hospital events
- quality of life.

Haemodynamic outcomes:

- cardiac index
- cardiac power index
- mean arterial pressure
- serum lactate
- support time and dose of vasopressor/inotropic medications
- mechanical ventilation support time

Healthcare resource outcomes:

- hospital length of stay
- re-hospitalisation

Cost effectiveness outcomes:

- incremental cost per quality-adjusted life year gained

Population 3: Right ventricular heart failure

Safety outcomes:

- major adverse events
- myocardial infarction
- stroke/transient ischaemic attack
- repeat revascularisation
- vascular complications
- major bleeding
- procedure complications (e.g. device malfunctions, high purge pressures, tube fracture/post-operative groin bleeding, gastrointestinal bleeding, other)
- other (e.g. acute renal dysfunction, cardiopulmonary resuscitation/ventricular arrhythmia, aortic valve damage/ increase in aortic insufficiency, severe hypotension requiring treatment)

Clinical outcomes:

- mortality
- rate of in-hospital events
- quality of life

Healthcare resource outcomes:

- time to implant device
- hospital length of stay
- re-hospitalisation
- specialist visits

Cost effectiveness outcomes:

- incremental cost per quality-adjusted life year gained

Current and proposed clinical management algorithm for identified population

Currently, there are no standardised pathways for the treatment of patients requiring MCS in Australia. The current management algorithm involves a combination of treatment strategies ie pharmacological therapy, and/or MCS including IABP, ECMO and ventricular assist devices (VADs). The current clinical management algorithms may change with the addition of the proposed medical service however PASC noted that clarity is needed as to when the proposed medical service is likely to replace or be used in addition to current management options. The current and proposed clinical management pathway presented in the Application Form is from the Statement from the Interventional Council of the ACC (2016) (Figure 4).

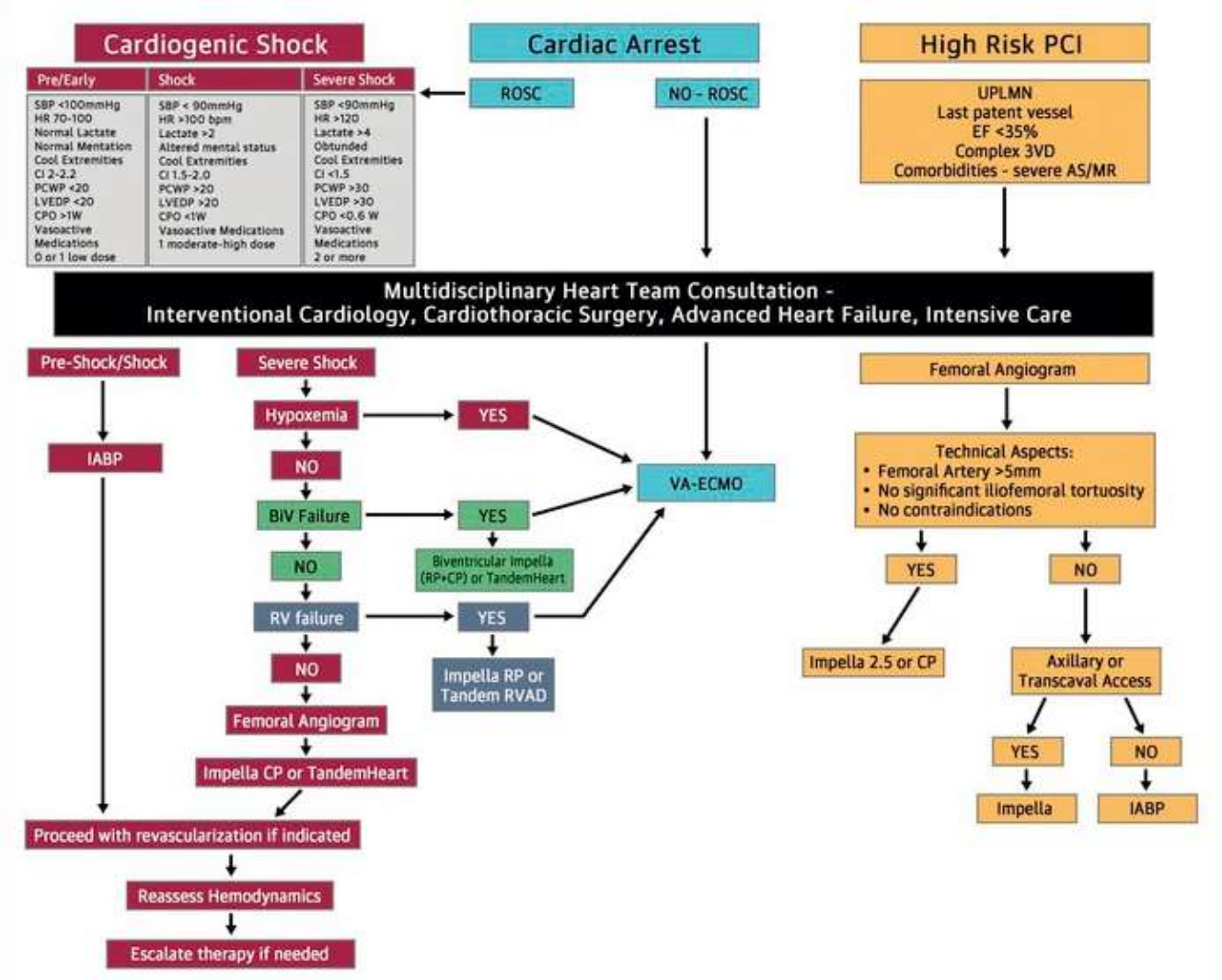

Figure 4 Current clinical management algorithm for percutaneous mechanical circulatory support device selection
Source: Atkinson et al, (2016) (8)
3VD = 3 vessel coronary artery disease; AS = aortic stenosis; BiV = biventricular; CI = cardiac index; CPO = cardiac power; EF = ejection fraction; HR = heart rate; HR-PCI = high-risk percutaneous coronary intervention; IABP = intra-aortic balloon pump; LVEDP = left ventricular end-diastolic pressure; MCS = mechanical circulatory support; MR = mitral regurgitation; PCI = percutaneous coronary intervention; PCWP = pulmonary capillary wedge pressure; ROSC = return of spontaneous circulation; RVAD = right ventricular assist device; SBP = systolic blood pressure; UPLMN = unprotected left main artery; VA-ECMO = venoarterial extracorporeal membrane oxygenation.
Red circles mark areas where Impella® would be implemented in the clinical management algorithm

Following use of MCS in either of the three population subgroups, arterial access is closed by the physician and the multidisciplinary team assess for myocardial and haemodynamic recovery, and the requirement for further revascularisation. Post procedural care is a critical aspect to MCS and could include hospital services performed in intensive care and coronary care units. Other considerations include anticoagulation management and haemolysis (8).

PASC noted the proposed clinical management algorithms required clarification whether Impella® is in addition to standard care or a replacement. In particular, PASC commented that Impella® is an alternative to ECMO and IABP, and the algorithm should reflect use of either Impella® or ECMO/IABP, not both.

Clinical management algorithms representing current practice as well as proposed practice have been developed for the three population subgroups. These are based on the current clinical management pathway suggested in the Statement from the Interventional Council of the ACC (2016) (Figure 4) and verification with a local medical expert, and advice from the Applicant. These algorithms may require further consensus from clinicians given that the proposed populations are highly heterogeneous affecting management approach, and treatment involves complex clinical decisions influenced by clinician discretion.

Population 1: High-risk percutaneous coronary intervention

Figure 5 presents the current clinical algorithm (in black) and proposed changes (in red) for patients with HR-PCI.

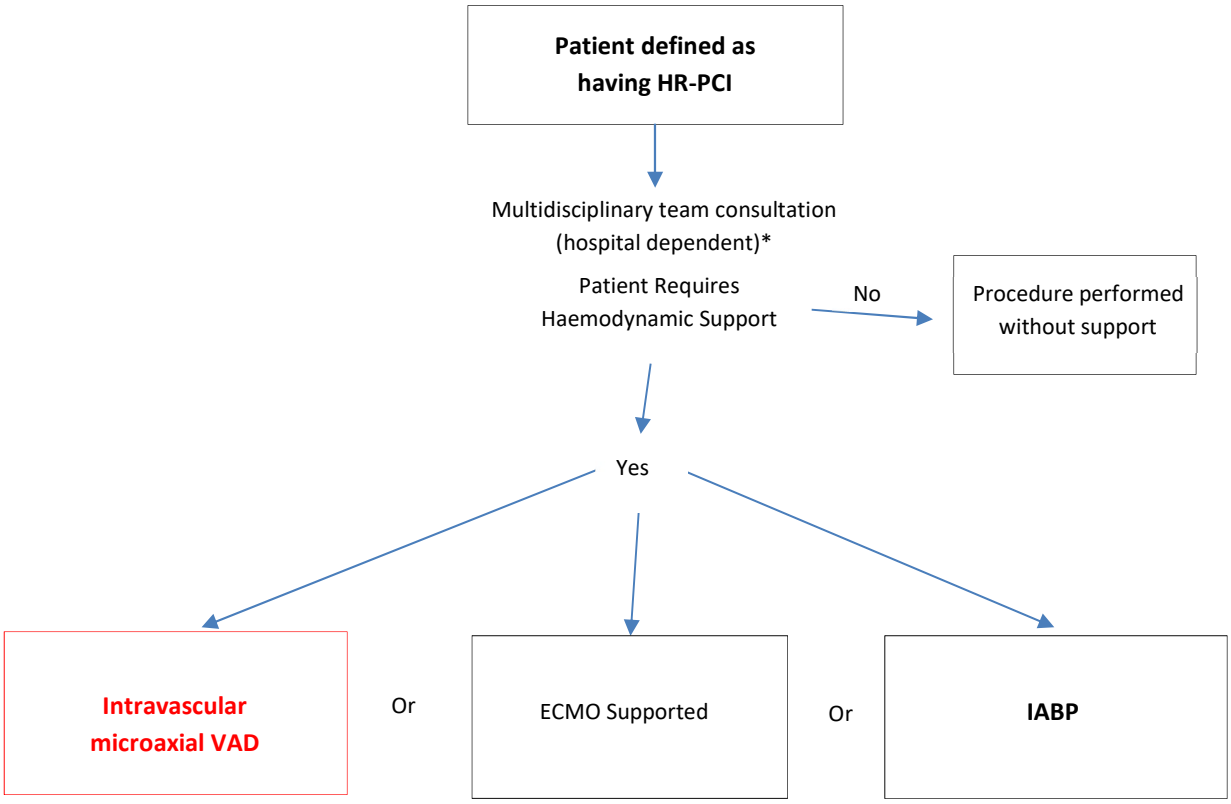

Figure 5 Current (in black) and proposed changes (in red) to clinical management algorithm for HR-PCI
Source: Based on advice from local medical experts and the Statement from the Interventional Council of the ACC (8).

Figure Note: *Based on the University of Washington Protected PCI decision algorithm, James McCabe, University of Washington, Seattle.
Abbreviations: ECMO, extra-corporeal membrane oxygenation; HR-PCI, high risk percutaneous coronary intervention; IABP, intra-aortic balloon pump; VAD, ventricular assist device.

Population 2: Cardiogenic shock

Figure 6 presents the current clinical algorithm (in black) and proposed changes (in red) for patients in cardiogenic shock. PASC noted that a multidisciplinary team consultation may not always be possible in the setting of cardiogenic shock.

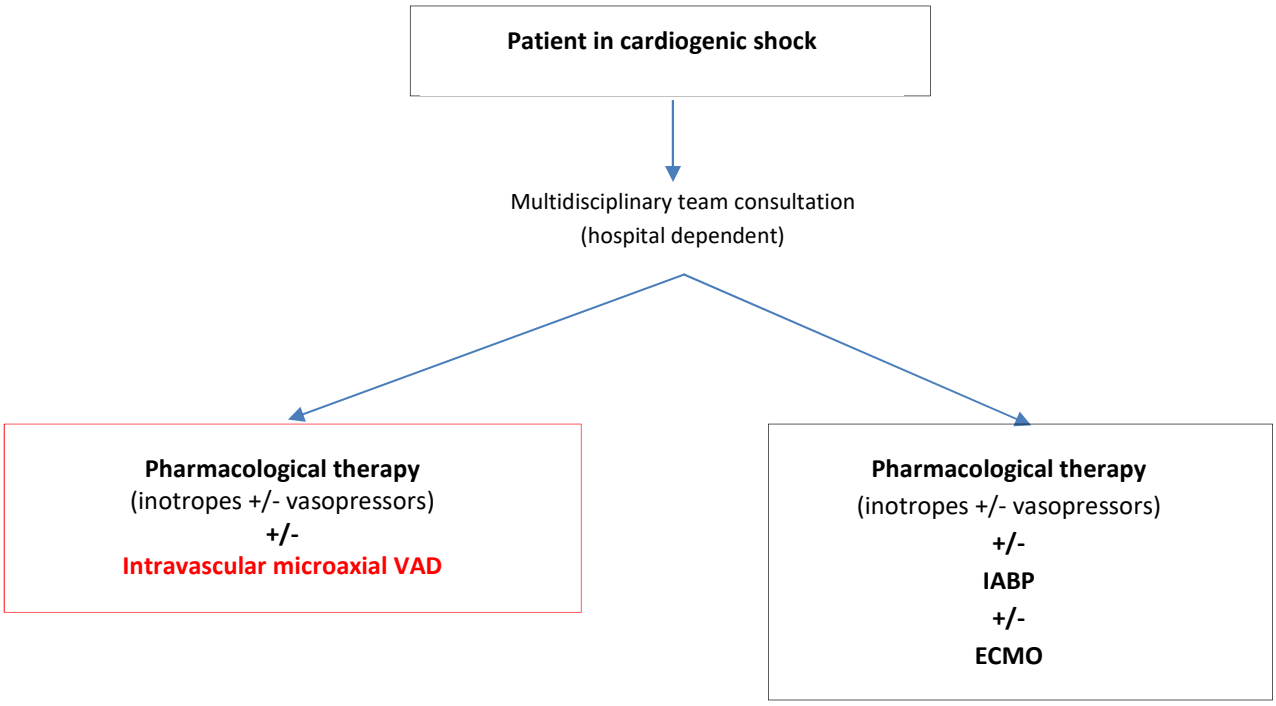

Figure 6 Current (in black) and proposed changes (in red) clinical management algorithm for cardiogenic shock
Source: Based on advice from local medical experts and the Statement from the Interventional Council of the ACC (8).
Abbreviations: ECMO, extra-corporeal membrane oxygenation; HR-PCI, high risk percutaneous coronary intervention; IABP, intra-aortic balloon pump.

Population 3: Right heart failure

Figure 7 presents the current clinical algorithm (in black) and proposed changes (in red) for patients with right heart failure. The Applicant noted that it is unlikely that ECMO and intravascular microaxial ventricular assist device can be used together in this indication.

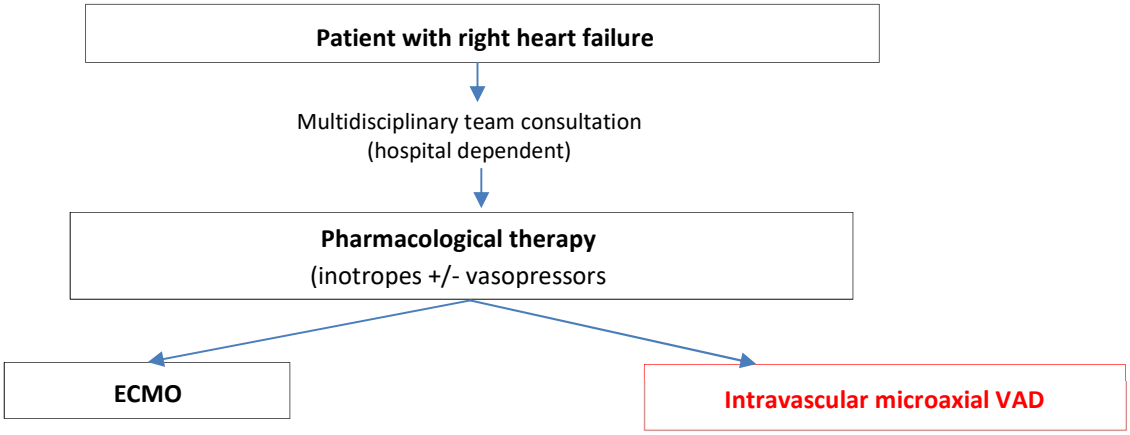

Figure 7 Current (in black) and proposed changes (in red) clinical *management algorithm in the treatment of right* heart failure

Source: Based on advice from local medical experts and the Statement from the Interventional Council of the ACC (8).

Abbreviations: ECMO, extra-corporeal membrane oxygenation; HR-PCI, high risk percutaneous coronary intervention.

Proposed economic evaluation

The overall clinical claim is that the proposed medical service (intravascular microaxial ventricular assist device) is superior in terms of comparative effectiveness and non-inferior in terms of safety versus standard of care in patients requiring MCS. This is based on reduced rates of major adverse cardiac and cerebral events (9), lower rates of acute renal dysfunction and reduced need for dialysis (24), improvement in LVEF (25), reduced HF symptoms and NYHA Class (26), reduced readmissions (27, 28), reduced length of stay in hospital (29), and improved survival and native heart recovery (27, 30).

Based on this a cost-utility model is appropriate, providing an incremental cost per QALY gained.

Consultation feedback

Two respondents to the consultation of Application Form 1523 agreed that intravascular microaxial ventricular assist device is superior in terms of comparative effectiveness and non-inferior in terms of safety versus standard of care in patients requiring MCS. Two respondents disagreed based on there being no evidence for improved 30-day mortality and not enough long-term evidence available to claim superiority.

Proposed item descriptor

There are six proposed MBS item descriptors as described below. The MBS item descriptors specific to surgical or percutaneous insertion of intravascular microaxial ventricular assist device were expanded since the Application form 1523 to include a restriction based on the definition of the patient population. PASC stated it is preferable to avoid the use of brand names in MBS item descriptors and if specific features of a product are needed, the features/specifications should be detailed and not the brand name. PASC also clarified that 'cardiotomy' should be changed to 'cardiac surgery' in the item descriptor.

PASC expressed concern about leakage, due to the brief item descriptors, and suggested the following revised descriptors.

Category 3 – Therapeutic Procedures	MBS 38XXX
Percutaneous insertion of a left or right intravascular microaxial ventricular assist device in patients with cardiogenic shock with no evidence of significant anoxic neurological injury, right heart failure or who are undergoing high-risk percutaneous coronary intervention. The criteria for high-risk percutaneous coronary intervention are: - comorbidities; and - left ventricular ejection fraction ≤35%; and - unprotected left main; or - last patent coronary vessel; or - three-vessel disease. The criteria for right heart failure is isolated right heart failure after LVAD implantation or after cardiac surgery or myocardial infarction. Fee: $(insert proposed fee here)	

Category 3 – Therapeutic Procedures	MBS 38XXX
Surgical insertion of a left or right intravascular microaxial ventricular assist device by arteriotomy in patients with cardiogenic shock with no evidence of significant anoxic neurological injury, right heart failure or who are undergoing high-risk percutaneous coronary intervention. The criteria for high-risk percutaneous coronary intervention are: - comorbidities; and - left ventricular ejection fraction ≤35%; and - unprotected left main; or - last patent coronary vessel; or - three-vessel disease.. The criteria for right heart failure is isolated right heart failure after LVAD implantation or after cardiac surgery or myocardial infarction.	

Fee: $(insert proposed fee here)

Category 3 – Therapeutic Procedures,
Initial and subsequent daily management and monitoring of parameters of the controller for a left or right intravascular microaxial ventricular assist device. Fee: $(insert proposed fee here)

Category 3 – Therapeutic Procedures,
Adjustment and repositioning, in patients supported by of a left or right intravascular microaxial ventricular assist device. Fee: $(insert proposed fee here)

Category 3 – Therapeutic Procedures,
Percutaneous removal of a left or right intravascular microaxial ventricular assist device. Fee: $(insert proposed fee here)

Category 3 – Therapeutic Procedures,
Surgical removal of a left or right intravascular microaxial ventricular assist device. Fee: $(insert proposed fee here)

PASC noted the Applicant has yet to formally propose MBS fees for the insertion, management, repositioning and removal of Impella®. PASC suggested the fees may be similar to comparable MBS items, and practitioners who provide the service should be consulted (interventional cardiologists, cardiovascular surgeons and intensive care specialists):

Proposed service	**MBS fee**
Percutaneous insertion of device	$384.95 – based on item 38362 (percutaneous insertion of IABP)
Surgical insertion of device	$1,480.00 – an amount $1,000 more than item 38609 (insertion of IABP via arteriotomy $479.15), but $50 less than item 38615 (insertion of VAD $1,532.00)
Surgical removal of device	$740.00 – based on item 38612 (removal of IABP), but the applicant stated removal of Impella® is more complex than IABP removal
Repositioning of device	$156.10 – based on item 13847* (IABP management on first day)

*The Intensive Care and Emergency Medicine Clinical Committee of the MBS Review Taskforce recommended item 13847 be deleted and combined with 13848 (management of IABP on subsequent days, MBS fee $131.05). This is because there is no significant

difference in clinical input required on the first and subsequent days of management, other than that already reflected in the separate item covering insertion of the IABP (item 38609).

PASC noted the large discrepancy in cost between percutaneous removal and surgical removal of Impella®, and recommended the evidence-based submission should consider how this might drive/influence practitioner behaviour and patient choice.

Consultation feedback

Consultation feedback was received from two individuals from intensive care, one individual from cardiology and one professional organisation (The Australian and New Zealand Society of Cardiothoracic Surgery).

The primary benefits associated with the proposed medical service listed by the respondents were that it provides good short term circulatory support and is less invasive compared with other methods or short term MCS, it can provide full LV support including LV decompression for patients in cardiogenic shock, it is more physiological than current alternatives, and provides the possibility of mobilisation of patients while on support. It was noted that there is no current suitable device available for the treatment of isolated RV failure, which is a benefit of the proposed medical service, specifically Impella® RP. From a clinical decision making process it was suggested that the proposed medical service may be a good short term solution in cases where ECMO has been used and the LV is not decompressed, and it buys time to consider other cares/support. It was described as potentially having less complications, reducing ICU stays and being life-saving.

The primary disadvantages listed by the respondents were based on cost of the device; specifically, that it is expensive for a short-term device and compared with ECMO. This prohibitive cost can be a disadvantage to institutions. Furthermore, it needs highly trained multidisciplinary decision making, can only be used for limited time period, and is invasive. One respondent noted that there is no down side given the patients requiring the proposed medical service are in cardiogenic shock and dying.

All respondents agreed with the proposed populations for the intravascular microaxial ventricular assist device. One respondent suggested that other indications could include LV venting with V-A-ECMO and bridge to recovery for fulminant myocarditis. The Applicant endorsed this and believes they should be taken into consideration. In addition it was agreed for use in acute heart failure but not a useful device in advanced/chronic HF. One respondent disagreed with the HR-PCI projection of use as most cases of PCI are not high-risk; use in the USA is based on the designation of Impella has led to marked, inappropriate overuse of the device.

Three of the respondents agreed with the proposed comparator. One respondent disagreed in that there are other VADs available.

In terms of the clinical claim, two respondents agreed with intravascular microaxial ventricular assist device is superior in terms of comparative effectiveness and non-inferior in terms of safety versus standard of care in patients requiring MCS. Two respondents disagreed since there is no evidence for improved 30-day mortality and there is not enough long-term evidence available to claim superiority. Further experience and studies need to be done.

All respondents agreed with the proposed MBS item descriptor.

One respondent suggested that reimbursement for the device should be limited to designated public hospitals who generally treat high-risk patients, cardiogenic shock and cardiac arrest patients so that the device is not used inappropriately.

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