1223

Final decision analytic protocol (DAP) to guide the assessment of the insertion, replacement or removal of a cardiac resynchronisation therapy device capable of defibrillation (CRT-D) for mild chronic heart failure (New York Heart Association Class II)

May 2013

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government Health Minister to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Ageing on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is intended to provide a draft decision analytic protocol that will be used to guide the assessment of an intervention for a particular population of patients. The draft protocol that will be finalised after inviting relevant stakeholders to provide input to the protocol. The final protocol will provide the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

Patients – specification of the characteristics of the patients in whom the intervention is to be considered for use;
Intervention – specification of the proposed intervention
Comparator – specification of the therapy most likely to be replaced by the proposed intervention
Outcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention

Purpose of application

A proposal for an application requesting Medical Benefits Schedule (MBS) listing of insertion, replacement, or removal of a cardiac resynchronisation therapy device capable of defibrillation (CRT-D) for mild chronic heart failure (New York Heart Association (NYHA) class II) was received from OptumInsight (working with Biotronik, Boston Scientific, Medtronic Australasia and St Jude Medical) by the Department of Health and Ageing in May 2012.

This intervention is already listed on the MBS for patients with moderate to severe chronic heart failure (NYHA class III or IV) (item numbers 38371, 38368, 38654), and was the subject of a previous MSAC assessment report in 2006 (MSAC Reference 32).

There have been two previous MSAC reports on this topic. In August 2005, MSAC Application 1042 reported on cardiac resynchronisation therapy for severe heart failure. This excluded CRT with an implantable defibrillator, although it did include evidence from the Companion trial which compared CRT with CRT-D. In March 2006, MSAC Reference 32 reported on implantable cardioverter defibrillators (ICD) for prevention of sudden cardiac death. This report included ICD with CRT capability, with evidence used from the Companion trial.

Intervention

Description

Chronic heart failure

Heart failure is a complex syndrome resulting from any structural or functional cardiac abnormality that reduces the ability of the heart to function as a pump (Cowie & Zaphiriou 2002), and is a major cause of morbidity and mortality in Western societies. The condition is characterised by dyspnoea, fatigue, and fluid retention (Cowie & Zaphiriou 2002). Patients with heart failure have limited exercise capacity, frequent need for hospitalisation, high rates of mortality and an impaired quality of life (Hare 2002). The most common cause of heart failure in the developed world is coronary heart disease although hypertension often co-exists (Fox et al. 2001). Many patients have had a previous myocardial infarction.

The National Heart Foundation estimates that 1.5%-2.0% of Australians suffer from chronic heart failure. The prevalence of heart failure increases with age such that 50% of people aged 85 years and older may have the condition (Kannel & Cupples 1988).

Some patients have heart failure with a preserved ejection fraction (HFPEF). Others have heart failure due to left ventricular systolic dysfunction (LVSD), which is associated with a reduced left ventricular ejection fraction (NICE 2010a). In some of these patients the left ventricle fails to pump in synchrony with some or all of the other chambers of the heart. This DAP is focused on patients with left ventricular systolic dysfunction who have ventricular dyssynchrony.

The effectiveness of cardiac muscle contraction is represented by the measurement of left ventricular ejection fraction (LVEF). This is calculated as the percentage of blood present in the heart that is ejected with each contraction. The fraction is normally greater than 50%. The effect to which the symptoms of heart failure affect functional capacity can be assessed using the New York Heart Association (NYHA) classification (Table 1). Under this system, subjective symptoms are used to rank patients according to their functional capacity into four classes.

Table 1: The New York Heart Association (NYHA) classification of functional class for heart failure (NHF/CSANZ, 2011)

Class I	No limitations. Ordinary physical activity does not cause undue fatigue, dyspnoea or palpitations (asymptomatic left ventricular dysfunction).
Class II	Slight limitation of physical activity. Ordinary physical activity results in fatigue, palpitation, dyspnoea or angina pectoris (mild chronic heart failure).
Class III	Marked limitation of physical activity. Less than ordinary physical activity leads to symptoms (moderate chronic heart failure).
Class IV	Unable to carry on any physical activity without discomfort. Symptoms of CHF present at rest (severe chronic heart failure).

Heart rhythm

Normally, the heart rate is dictated by a natural pacemaker, the sinus node, a structure residing within the right atrium. The ensuing physiological rhythm is known as 'normal sinus rhythm'.

Arrhythmia, an irregular or abnormal heartbeat, results from a problem with the electrical system of the heart. In some cases, this may cause the heart rate to

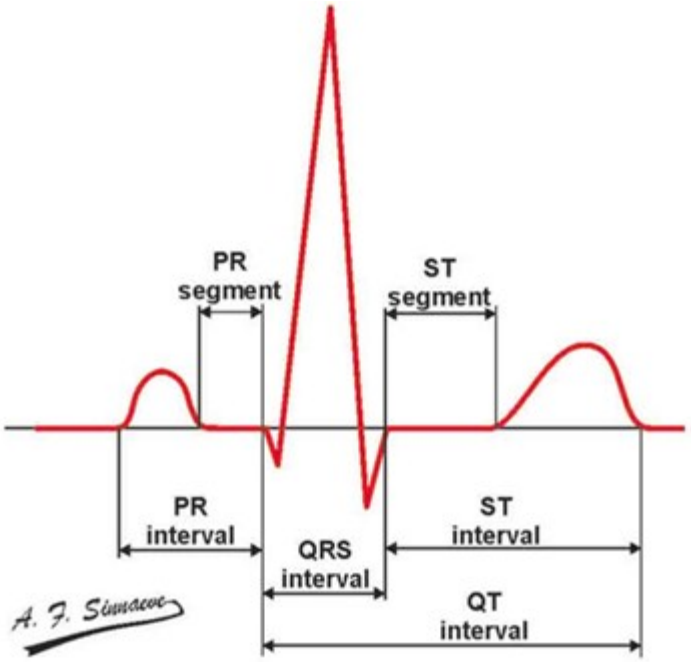
become very fast, unstable, or irregular. This can lead to sudden cardiac arrest which requires immediate treatment. An electrical shock administered to the heart can reset the heart's rhythm and restore normal blood flow throughout the body.

In atrial fibrillation (AF), the normal sinus node activity is suppressed by a pathological electrical hyperactivity within the atria, leading to an irregular and inappropriately fast heart rhythm. The condition can occur intermittently or remain chronic. It is the most common arrhythmia in clinical practice. The prevalence of AF is age-dependent and is present in 10% of octogenarians (Van Brabandt et al. 2010). In almost all trials on cardiac resynchronisation therapy, normal sinus rhythm was a prerequisite for enrolment. The presence of AF makes it difficult to ensure that there is consistent pacing of the ventricles that is required to benefit from CRT.

Intraventricular conduction delay

The electrocardiogram (ECG) is a graphical representation of the electrical activity of the heart as it can be derived from the surface of the body by means of electrodes. The QRS complex represents the electrical activity that gives rise to the contraction of the heart, and normally lasts 120 ms or less. In the diseased heart, the conduction of the electrical impulse through the ventricles can be delayed which can be recognised from the ECG by a prolonged QRS interval. The conduction delay can be predominantly located in the right or to the left side of the heart, and is then known as right or as left bundle branch block. The intraventricular conduction delay leads to a dyssynchronous contraction of the heart and in patients with a poor contractile function, worsening outcomes (MSAC 2006). By stimulating areas of the heart that would otherwise contract (too) late, the pumping function of the heart is improved by cardiac resynchronisation therapy, at least in patients with symptomatic HF. Echocardiographic studies suggest that resynchronisation of the heart's contraction improves remodelling of the heart's structure and morphology which occurs after injury to the myocardium. Accordingly, biventricular stimulation of the heart improves remodelling indices, specifically left ventricular diastolic and systolic volumes and the LVEF.

Figure 1: Normal electrocardiographic QRS complex (Van Brabandt et al. 2010)



Sudden cardiac arrest and sudden cardiac death

Patients with heart failure not only suffer from shortness of breath with or without exercise, shortness of breath at night, fatigue and weakness, and possibly dizzy spells and palpitations, but they are also at increased risk of sudden cardiac arrest (SCA) and sudden cardiac death.

Sudden cardiac death (SCD) is an abrupt loss of consciousness and unexpected death due to cardiac causes. It is a terminal event in approximately 35-50 per cent of patients with chronic heart failure (Packer 1992). Most SCDs are caused by acute, fatal arrhythmias; ventricular tachycardia (VT) and ventricular fibrillation (VF). Epidemiologic data indicate that structural coronary artery disease and their consequences are the cause of 80% of arrhythmias causing these SCD events (Huikuri et al. 2001, Myerburg et al. 1997). Dilated and hypertrophic cardiomyopathies account for the second largest number of sudden deaths from cardiac causes (Zipes & Wellens 1998). Other cardiac disorders, such as valvular or congenital heart diseases, acquired infiltrative disorders, and primary electrophysiological disorders account for only a small proportion of the sudden deaths that may occur in the general population (Huikuri et al. 2001).

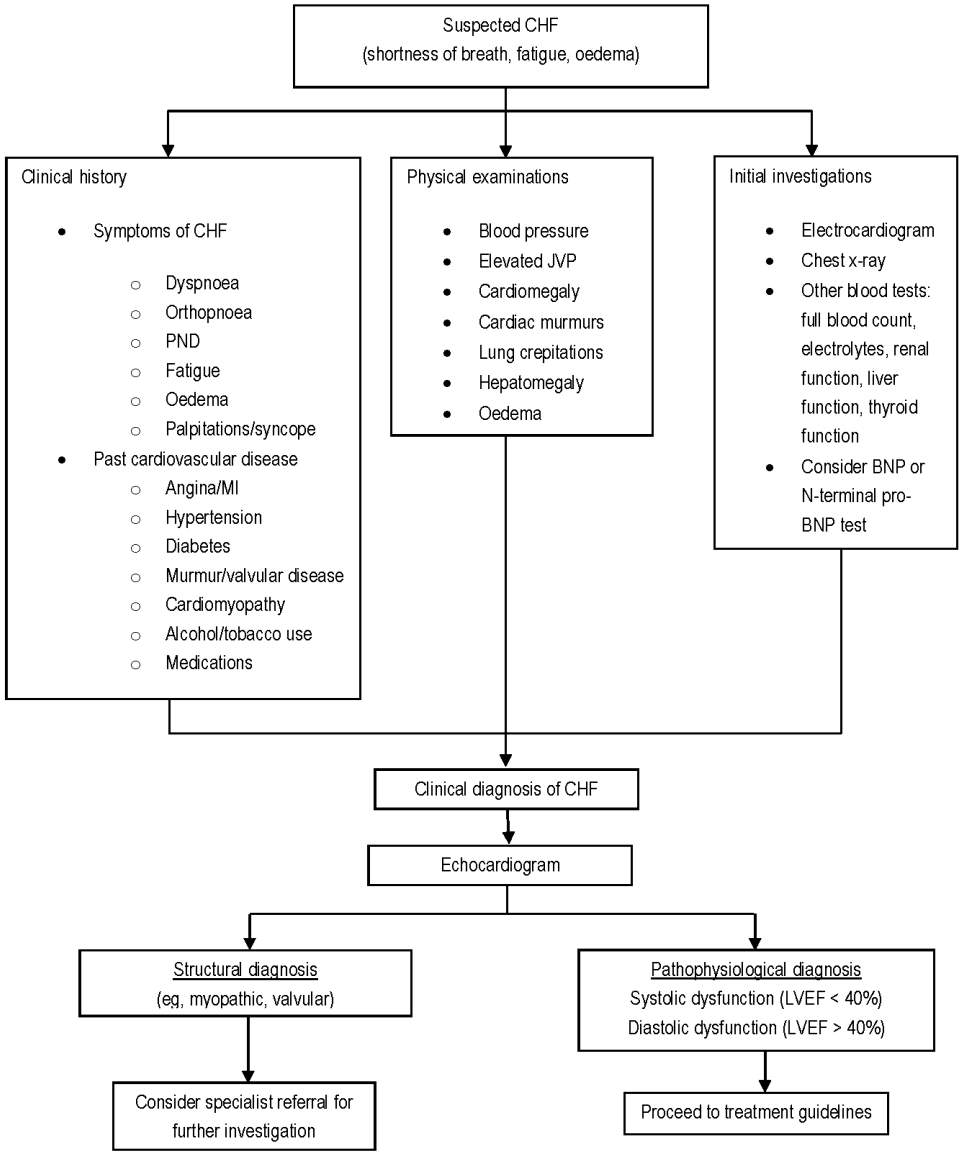
A patient with chronic heart failure is also susceptible to malignant ventricular arrhythmias. Further, the prevalence and complexity of ventricular arrhythmias such

as premature depolarisations and non-sustained ventricular tachycardia (NSVT) increases as left ventricular function deteriorates. In patients with LVEF less than 40%, the prevalence of NSVT rises from 15-20% in patients with NYHA class I-II symptoms of heart failure to 40-55% in patients with NYHA class II-III symptoms, and 50-70% in patients with NYHA class III-IV symptoms (Packer 1992). Therefore there is a complex interaction between electrical and mechanical performance of the heart, and it is impossible to determine which factor may play a primary factor in terminal heart failure (MSAC 2006). The risk of sudden death is higher in patients with chronic heart failure than in any other identifiable subset of patients in cardiovascular medicine and five times higher than in the general population (Packer 1992).

Australian pathway for diagnosis of chronic heart failure

The recommended diagnostic investigation pathway of CHF in Australia is shown in Figure 2 (CHFA and CSANZ 2011). This involves a comprehensive examination of the patient including a detailed physical examination and further diagnostic investigations. Following an initial diagnosis of CHF, trans-thoracic echocardiography is able to provide detail regarding the specific nature of the disease. It can distinguish between systolic dysfunction (typically an LVEF < 40%) and normal resting systolic function associated with abnormal diastolic filling, while also excluding correctable causes of CHF, such as valvular disease.

Figure 2: Diagnostic pathway for chronic heart failure (NHF/CSANZ guidelines 2011)



BNP, B-type natriuretic peptide; CHF, chronic heart failure; JVP, jugular venous pressure; LVEF, left-ventricular ejection fraction; MI, myocardial infarction; PND, paroxysmal nocturnal dyspnoea

Conservative and pharmaceutical treatments

Non-pharmacological strategies for CHF include physical activity, diet and risk factor modification (NHFA 2011). A number of pharmaceutical agents are recommended for the treatment of symptomatic systolic CHF (NHFA and CSANZ 2011, Krum et al 2011):

- Angiotensin-converting enzyme inhibitors (ACEIs)
- Beta-blockers
- Diuretics (for symptom control only)
- Aldosterone antagonists
- Digoxin
- Angiotensin II receptor antagonists
- Polyunsaturated fatty acids
- Direct sinus node inhibitors
- Iron

Although current pharmacological therapy can modify the natural history of heart failure, many patients remain symptomatic despite optimal medical therapy, and a high risk of death remains (Garg and Yusuf 1995, Dracup et al 1992, Cleland et al 1998, Goldman et al 1993). In addition, pharmacological therapy is not able to address the mechanical dysynchrony that reduces the effectiveness of cardiac contraction among a significant proportion of patients with CHF (Auricchio and Spinelli 2000).

A number of devices are available which have been developed to improve electrical dysfunction of the heart and to restore normal heart rhythm in patients with left ventricular systolic dysfunction. Note that pacemakers (MBS item 38353) are generally designed to correct bradycardia and are not relevant to this DAP.

In general, patients who receive an implantable cardiac device will continue with optimal medical therapy.

Implantable cardioverter defibrillators

An implantable cardioverter defibrillator (ICD) is a small battery-powered electrical impulse generator that is placed inside the chest or abdomen. The purpose of this device is to detect life-threatening irregular heartbeats (ventricular arrhythmias) in patients who are at risk of SCA. The ICD works by delivering an electrical pulse or shock to the ventricles in the heart to control the arrhythmia (National Heart, Lung and Blood Institute, 2012). Current ICDs have three main functions (Arrhythmia Alliance, 2012):

- If the heart rhythm is too slow, an ICD can work as a normal pacemaker to stimulate the heart (anti-bradycardia pacing).

- If the heart rhythm is too fast, an ICD can stimulate the heart to return it to a normal rhythm (anti-tachycardia pacing (ATP)).
- If the ATP is unable to bring the heart back to a normal rhythm or if the ICD detects a disorganised ventricular rhythm (VF) the ICD can then give a higher energy shock (defibrillation) to restore normal heartbeat.

ICDs may reduce mortality in patients with spontaneous or inducible life-threatening arrhythmias and in those with ischemic heart disease and severe left ventricular systolic dysfunction and no prior arrhythmias (Exner and Klein 2003). For the context of this DAP in the treatment of patients with chronic heart failure, the main function of the ICD is defibrillation and prevention of SCA.

The implantation of an ICD involves passing a lead or leads through a vein into the right atrium and right ventricle. The battery-powered generator is typically inserted under the skin in the upper chest near the left shoulder (NICE 2012). The ICD continually monitors cardiac rhythm to decide whether an arrhythmia episode merits treatment. If an abnormal or life-threatening ventricular arrhythmia is detected the device will automatically deliver bursts of anti-tachycardia pacing or one or more non-synchronised electric shocks to try and restore normal heart rhythm (defibrillation). Sensing heart rhythm and delivery of electric impulses and/or shocks is achieved by two leads positioned inside the heart that connect to the pulse generator. Although single lead RV chamber ICDs are available, these single chamber devices are not relevant to this DAP as they are only appropriate for patients who are in permanent atrial fibrillation or have good arrhythmia discrimination and have no indication for atrial pacing.

Although they last only a fraction of a second, these high-energy pulses can be painful. An ICD may be associated with increased morbidity due to inappropriate shocks as a result of system problems such as lead fracture or inappropriate detection of supra-ventricular arrythmias. This problem may be overcome by reprogramming the generator.

With all implantable cardiac devices there are considerable risks in removing the old leads, including perforation of either the heart or the vein through which the lead has been placed. New generation ICD devices are currently being designed where the leads are inserted subcutaneously, and are not implanted in the myocardial

tissue. These leads have the benefit of having less risk of displacement, but are not the subject of this DAP.

Cardiac resynchronisation therapy device

In patients with left ventricular systolic dysfunction and ventricular dyssynchrony, cardiac resynchronisation therapy (also known as biventricular pacing) device (CRT or CRT-P) aims to improve the pumping efficiency of the heart by resynchronising the pumping action of both right and left ventricles through continual pacing.

CRT involves implantation in the upper chest of a pulse generator from which three leads descend via veins into the heart. Leads are placed in the right atrium and the right ventricle (RV pacing lead), and a third lead (the left ventricular lead) is usually placed via the coronary sinus. CRT pacing (CRT-P) devices allow both regulation of atrioventricular delay and restoration of synchronous contraction by pacing the right atrium and both ventricles (NICE 2010b).

This device may be used to improve exercise capacity and quality of life in congestive heart failure patients who have left ventricular dysfunction and prolonged QRS interval despite optimal medical therapy.

Cardiac resynchronisation therapy devices capable of defibrillation

Clinical problems in patients suffering from heart failure, namely symptoms of shortness of breath and the risk of sudden death should an acute arrhythmic event occur, led to the development of a device that combines the cardiac resynchronisation function with that of an ICD (CRT-D). CRT-D therapy offers improved quality of life, together with a reduction in the risk of sudden cardiac death for patients with left ventricular systolic dysfunction and ventricular dyssynchrony.

Ultimately, the aim of CRT-D therapy is to improve symptoms and enable a reduction in mortality and hospitalisation due to heart failure. Specifically, CRT-D therapy may be able to slow the progression of heart failure (defined as a composite of all-cause mortality, hospitalisation for worsening HF, and ventricular arrhythmias requiring device therapy).

The choice of CRT-P or CRT-D may be patient-specific. Older patients may wish to have CRT to improve their quality of life, but may decide not to have CRT-D as the additional defibrillator function can cause painful electrical shocks.

Administration, dose, frequency of administration, duration of treatment

CRT-D therapy requires the insertion of a cardiac resynchronisation therapy pulse generator and three leads. All three leads are inserted into the heart via the subclavian, axillary, cephalic or internal jugular vein, and the generator is positioned in the infra-clavicular fossa. The defibrillation lead is placed in the right ventricle and the pacing lead is placed in the right atrium. The third lead, which is required to coordinate ventricular contractions, is placed at the coronary venous system of the left ventricle. This lead also enters the heart via the same veins, but it is then threaded through the coronary sinus and into a branch of the coronary sinus with the lead lying on the epicardial surface of the heart.

Due to the increased complexity, CRT-D implant requires more time than the implantation of an ICD, and slightly more time to implant than a CRT-P. The choice between general and local anaesthesia (with or without conscious sedation) is made with regard to local institutional practice, patient preference, and possibly whether ventricular fibrillation induction is to be performed (Daubert 2012). Current clinical practice does not require the patient to be placed into asystole, therefore the majority of patients who receive a CRT-D will not require an anaesthetist.

The staffing numbers required for the insertion, removal, or replacement of a CRT-D in patients with NYHA class II heart failure is the same as required for the placement of CRT-D in patients with NYHA class III and IV heart failure. MSAC Assessment Report 32 found that the same healthcare professionals were required for implanting CRT-D compared with ICD. The operating time required for implanting ICD is 60 minutes and 150 minutes is required for implanting CRT-D (MSAC 2005). The specific model of device is assumed to have no significant effect on the time requirements for implantation of the device.

In terms of how the service is to be provided, the applicant has stated that the insertion, removal, or replacement of a CRT-D will need to be performed by a surgeon, cardiologist or electrophysiologist. The reasoning for this is that the current listing for CRT-D in patients with NYHA class III and IV heart failure does not limit the insertion, removal, or replacement of the device to cardiologists. As those involved in the insertion, removal or replacement of CRT-D would be the same with the expanded listing, the proposed listing is not expected to lead to any incremental training requirements.

As stated in the MSAC Assessment Report 32, the average length of stay for implantation of the ICD device or the CRT-D device in Australia is likely to be the same as for implantation of a standard cardiac pacemaker (National Hospital Cost Data Collection Cost Weights for AR-DRG Versions 5.1 [private] and 5.2 [public] 2008-09, AR-DRG F12Z estimate this to be 4.65 days in public hospitals and 3.9 days in private hospitals), except in cases where there are complications associated with implantation of the device. The intensity of hospital care, and therefore the cost per day, is the same for patients implanted with an ICD or CRT-D device as for patients implanted with a standard cardiac pacemaker. However, patients indicated for an ICD or CRT device will have more severe cardiac problems than patients indicated for a pacemaker.

CRT-D implantation requires the correct positioning of the electrode that connects the device to the left ventricle. In approximately 10% of cases, several implantation sessions are required to place this electrode correctly, and sometimes this proves to be impossible (MSAC 2005, Tang et al., 2010).

- Failure to achieve left ventricular lead placement through a transvenous route would occur in 5-10% of patients
- Some of these patients would have the lead placed through the surgical route
- The remaining patients would revert to ICD therapy

Ordinarily, the CRT-D device will only require replacement when the battery expires. Implanted device batteries typically last between 4 and 8 years. Though lead dislodgement or failure of the implantation may also give rise to medical services being repeated more regularly, this is only expected in a minority of patients. The MSAC Assessment Report 32 discussed the incidence of lead dislodgement or failure for CRT-D implantation in NYHA III-IV patients.

It can be assumed that the likelihood of lead dislodgement in NYHA II patients is similar to that for NYHA class III-IV patients (MSAC 2006).

The provision of CRT-D to patients with NYHA class II CHF will be the same as for patients with class III and IV CHF currently available on the MBS. The facilities, equipment, location, and other aspects of service delivery will remain the same. The staffing numbers required for the insertion, removal, or replacement of a CRT-D in

patients with NYHA class II heart failure will be the same as required for the replacement of CRT-D in patients with NYHA class III and IV heart failure.

CRT-D devices are generally checked every 3-6 months (current MBS item 11727). This would be in addition to the routine clinical care of patients with heart failure.

Co-administered interventions

The diagnostic tests required to establish the existence and type of chronic heart failure is the same for all patients, as shown in Figure 2. These tests will provide the necessary information to quantify the parameters needed to show whether a patient is eligible for ICD, CRT or CRT-D. Optimal medical and pharmaceutical therapy for chronic heart failure would be provided in accordance with Australian clinical practice guidelines (NHF/CSANZ 2011).

CRT-D implantation is commonly provided under local anaesthesia.

In the majority of patients receiving a CRT-D device the pharmaceutical therapy would remain unchanged after implantation.

The main adverse event of CRT-D placement is infection. This is more common for replacement implantation than in the original placement.

The battery for a CRT device needs replacing more frequently than that for ICD, due to the continual pacing. Current data suggests a battery life for CRT of approximately 4-8 years. Current data shows that established leads are expected to last approximately 10 years. Longevity data is not yet available for some new types of lead.

Background

Current arrangements for public reimbursement

The CRT device was the focus of an MSAC review in 2006 (MSAC 2006). Consequently, CRT-D is available on the MBS for patients with NYHA class III and IV heart failure and ventricular dyssynchrony. The listings for CRT-D include items for the generator (38371, Table 3), and for left ventricular lead insertion for this population (38368, Table 2; 38654, Table 4). CRT-D also requires two additional leads inserted: ICD lead (right ventricle); this item is currently available for patients

with class II heart failure (38384, Table 12); pacemaker lead (right atrium) (38350, Table 6). Transvenous implantation is usually attempted first as the procedure has a lower morbidity, and all leads can be inserted at the same time. Current data suggest that surgical implantation only occurs in approximately 5-10 per cent of patients.

CRT-D generators and leads are also available on the Prosthesis list (Appendix 3, 4 and 5). The listing of these devices does not appear to be limited to specific patient populations or condition.

CRT (biventricular pacing with no ICD, 38365, Table 5) and ICD (38387, Table 13) are also listed on the MBS.

Appendices 3, 4 and 5 summarise the Prosthesis List items for CRT-D devices, ICD leads and pacemaker leads respectively. The benefits associated with the CRT-D devices start from $45,760 to $52,750. The benefit is $9,000 for ICD leads and from $3120 to $6,240 for left heart leads, and $1,215 to $2,600 for pacemaker leads. These differences reflect the variety of features/performance associated with different implantable devices.

Table 2: Current MBS item descriptor for transvenous left ventricular electrode for CRT

Category 3 – Therapeutic Procedures
MBS 38368
PERMANENT TRANSVENOUS LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of through the coronary sinus, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria:
- sinus rhythm
- a left ventricular ejection fraction of less than or equal to 35%
- a QRS duration greater than or equal to 120ms.
Where the service includes right heart catheterisation and any associated venogram of left ventricular veins. Not being a service associated with a service to which items 38200 and 35200 apply
Multiple Services Rule (Anaes.)
Fee: $1,224.60 Benefit: 75% = $918.45
(See para T8.66 of explanatory notes to this Category)
Item notes:
T8.66 Permanent Cardiac Synchronisation Device (Items 38365, 38368 and 38654)
Items 38365, 38368 and 38654 apply only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device replaced.

CRT: cardiac resynchronisation therapy; NYHA: New York Heart Association.

Table 3: Current MBS item descriptor for cardiac synchronisation device capable of defibrillation

Category 3 – Therapeutic Procedures
MBS 38371 PERMANENT CARDIAC SYNCHRONISATION DEVICE CAPABLE OF DEFIBRILLATION, insertion, removal or replacement of, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120ms. Multiple Services Rule (Anaes.) Fee: $287.85 Benefit: 75% = $215.90 85% = $244.70 (See para T8.68 of explanatory notes to this Category) Item notes: T8.68 Cardiac Resynchronisation Therapy - (Item 38371) Item 38371 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had an CRT device capable of defibrillation inserted and who prior to its insertion met the criteria and now need the device replaced. Related Items: 38371

MBS: Medicare Benefits Schedule; NYHA: New York Heart Association; CRT: cardiac resynchronisation therapy.

Table 4: Current MBS item descriptor for left ventricular electrode insertion via open thoracotomy for CRT

Category 3 – Therapeutic Procedures
MBS 38654 PERMANENT LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of via open thoracotomy, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120ms. Multiple Services Rule (Anaes.) (Assist.) Fee: $1,224.60 Benefit: 75% = $918.45 (See para T8.66, T8.70 of explanatory notes to this Category) Item notes: T8.66 Permanent Cardiac Synchronisation Device (Items 38365, 38368 and 38654) Items 38365, 38368 and 38654 apply only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device replaced. Related Items: 38365, 38368, 38654 T8.70 Cardiac and Thoracic Surgical Items - (Items 38470 to 38766) 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.

MBS: Medicare Benefits Schedule; NYHA: New York Heart Association; CRT: cardiac resynchronisation therapy.

Table 5: Current MBS item descriptor for cardiac synchronisation device

Category 3 – Therapeutic Procedures
MBS 38365 PERMANENT CARDIAC SYNCRONISATION DEVICE, insertion, removal or replacement of, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120ms. Multiple Services Rule (Anaes.) Fee: $255.45 Benefit: 75% = $191.60 (See para T8.66 of explanatory notes to this Category) Item notes: T8.66 Permanent Cardiac Synchronisation Device (Items 38365, 38368 and 38654) Items 38365, 38368 and 38654 apply only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device replaced. Related Items: 38365, 38368, 38654

MBS: Medicare Benefits Schedule; NYHA: New York Heart Association; CRT: cardiac resynchronisation therapy.

Table 6: Current MBS item descriptor for single chamber pacemaker lead insertion

Category 3 – Therapeutic Procedures
MBS 38350 SINGLE CHAMBER PERMANENT TRANSVENOUS ELECTRODE, insertion, removal or replacement of, including cardiac electrophysiological services where used for pacemaker implantation Multiple Services Rule (Anaes.) Fee: $638.65 Benefit: 75% = $479.00 (See para T8.63 of explanatory notes to this Category) Item notes: The fees for the insertion of a pacemaker (Items 38350, 38353 and 38356) cover the testing of cardiac conduction or conduction threshold, etc related to the pacemaker and pacemaker function. Accordingly, additional benefits are not payable for such routine testing under Item 38209 or 38212 (Cardiac electrophysiological studies). Related Items: 38209, 38212, 38350, 38353, 38356

MBS: Medicare Benefits Schedule.

Table 7: Current MBS item descriptor for dual chamber pacemaker lead insertion

Category 3 – Therapeutic Procedures
MBS 38356 DUAL CHAMBER PERMANENT TRANSVENOUS ELECTRODES, insertion, removal or replacement of, including cardiac electrophysiological services where used for pacemaker implantation Multiple Services Rule (Anaes.) Fee: $837.35 Benefit: 75% = $628.05 (See para T8.63 of explanatory notes to this Category) Item notes: The fees for the insertion of a pacemaker (Items 38350, 38353 and 38356) cover the testing of cardiac conduction or conduction threshold, etc related to the pacemaker and pacemaker function. Accordingly, additional benefits are not payable for such routine testing under Item 38209 or 38212 (Cardiac electrophysiological studies). Related Items: 38209, 38212, 38350, 38353, 38356

MBS: Medicare Benefits Schedule.

The utilisation of the current relevant MBS items is shown in Table 8.

Table 8: Number of services provided for MBS items relating to CRT-D and ICD

MBS Item number	Summary of descriptor	Number of services 2007-08	Number of services 2008-09	Number of services 2009-10	Number of services 2010-11	Number of services 2011-12
38371	Implantation of CRT-D generator	395	492	655	834	937
38368	Implantation of permanent left ventricular electrode via coronary sinus	585	668	747	894	1007
38654	Implantation of permanent left ventricular electrode via open thoracotomy	27	47	52	62	67
38384	Insertion of ICD leads (no proposed change required)	644	775	852	961	1085
38387	Insertion of defibrillator generator (ICD) (no proposed change)	444	562	612	623	755
38365	Implantation of a CRT generator (no proposed change)	227	269	234	219	320
11727	Implanted defibrillator testing (no proposed change required)	16,020	24,273	29,281	32,480	35,880
38350	Implantation of pacemaker lead (no proposed change required)	1,684	2,018	2,007	2,218	2,363

Note: Data retrieved from https://www.medicareaustralia.gov.au/statistics/mbs_item.shtml, 17 January 2013

MBS: Medicare Benefits Schedule; CRT-D: cardiac resynchronisation therapy device capable of defibrillation; ICD: implantable cardioverter defibrillator.

Regulatory status

CRT-D generator and lead listings on the Australian Register of Therapeutic Goods (ARTG) is shown in Appendix 1 and 2. According to the ARTG, all implantable CRT-D devices appear to be listed for a broad intended purpose: to detect and treat tachyarrhythmias and for the treatment of heart failure through cardiac resynchronisation therapy. The applicant has provided additional information for each device in terms of the registered indications for use in Australia. All devices are intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias. Specific device information follows:

Biotronik CRT-D devices are indicated for treating life-threatening ventricular arrhythmias with antitachycardia pacing and defibrillation. Triple-chamber devices are indicated for patients with risk of sudden cardiac death caused by ventricular arrhythmias and risk of congestive heart failure with ventricular asynchrony. They are also indicated for primary prophylaxis in congestive heart failure patients.

Boston Scientific CRT-D devices are indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy and have LVEF $\leqslant$ 35%) and QRS duration $\geqslant$ 120 ms. Boston Scientific is in the process of updating TGA labelling for CRT-D devices to include patients with mild heart failure (NYHA II) who remain symptomatic despite stable, optimal heart failure drug therapy and have LVEF $\leqslant$ 30% and QRS duration $\geqslant$ 150 ms.

Medtronic CRT-D devices are indicated for use in patients who are at high risk of sudden death due to ventricular tachyarrhythmias and who have heart failure with ventricular dyssynchrony. These devices are intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias.

St Jude Medical CRT-D devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening arrhythmias. CRT-D devices are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

In the United Kingdom, NICE guidance published in 2010 recommends that CRT-P is available to patients with NYHA class II-IV heart failure, with sinus rhythm and with a QRS duration of 150 ms or longer or with a QRS duration of 120–149 with mechanical dyssynchrony, with LVEF of 35% or less, despite being on optimal medical therapy (NICE 2010b). CRT-D may be considered for patients who fulfil the criteria for CRT-P and also fulfil criteria for the implantation of an ICD. ICDs are recommended for a range of patients for 'primary prevention' following a history of myocardial infarction, or 'secondary prevention' to treat sustained ventricular tachycardia or ventricular fibrillation (NICE 2007). Overall guidance for chronic heart failure is published in NICE clinical guideline 108 (NICE 2010a). A NICE review of ICD, CRT and CRT-D for the treatment of heart failure across a broad range of populations is currently underway (http://guidance.nice.org.uk/TA/WaveR/111); the expected date of issue is September 2013 (NICE 2012).

There are a number of CRT-D devices which have been provided with device approvals and clearance from the FDA. Many of these devices are limited to use in patients with class III or IV NYHA symptoms, or in patients for whom defibrillation therapy is useful. Certain devices are also approved for use in patients who receive prescription drug therapy for heart failure who have the symptoms of mild heart failure (NYHA class II) with a QRS duration greater than or equal to 130 ms and an ejection fraction of less than or equal to 30% (Medtronic CRDM CRT-D, P010031/S232). Other devices are approved for a broader population of patients who are indicated for an ICD, exhibit symptoms related to heart failure and receive optimised medical therapy (for example BIOTRONIK Kronos LV-T, P050023).

Clinical input has advised that it is appropriate for all current CRT-D devices to be grouped together for the purposes of the DAP.

Patient population

Proposed MBS listing

The proposed submission will request an expansion of three current items:

- insertion, removal or replacement of, a permanent cardiac synchronisation device capable of defibrillation (see MBS 38371 for full details)
- insertion, removal or replacement of a permanent transvenous left ventricular electrode (see MBS 38368 for full details)

- insertion, removal or replacement of a permanent left ventricular electrode via open thoracotomy (see MBS 38654 for full details).

The proposal is to expand these services to include patients with mild chronic heart failure (NYHA class II) despite optimised medical therapy and who meet the following criteria:

- sinus rhythm
- LVEF less than or equal to 30%
- QRS duration greater than or equal to 150 ms.

A change to all three item numbers is necessary, since all of the services required to perform the implantation. CRT-D implantation also requires the insertion of ICD leads, a procedure which is currently funded for NYHA II patients with LVEF of less than or equal to 35% (MBS number 38384). Extending CRT-D implantation to NYHA class II patients will not require any changes to this listing.

The use of CRT-D may be for two main patient populations:

- Primary prevention: In patients with low LVEF, and who are at risk of cardiac arrest;
- Secondary prevention: In patients who have already suffered a cardiac arrest where they have a ventricular problem.

Contra-indications for CRT-D implant:

- Patients with cardiac problems brought about as a result of reversible biochemical or metabolic abnormalities and drug toxicities which will not recur;
- Patients with ischaemic heart disease, revascularisation or other structural abnormalities that should be treated initially with surgical therapy.

Other contraindications provided by the applicant include tachyarrhythmia caused by temporary or reversible factors (including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis); incessant ventricular tachycardia or ventricular fibrillation; and patients who have a unipolar pacemaker implanted. Patients who

have had acute myocardial infarction within the preceding 3 months are not indicated for CRT-D.

Table 9: Proposed MBS item descriptor for CRT-D

Category 3 – Therapeutic Procedures
MBS 38371 proposed PERMANENT CARDIAC SYNCHRONISATION DEVICE CAPABLE OF DEFIBRILLATION, insertion, removal or replacement of, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120 ms. And for patients who have mild chronic heart failure (NYHA class II) despite optimised medical therapy who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 30% - a QRS duration greater than or equal to 150 ms. Fee: $276.95 Benefit: 75% = $207.75 85% = $235.45 Item 38371 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device capable of defibrillation inserted and who prior to its insertion met the criteria and now need the device replaced.

MBS: Medicare Benefits Schedule; NYHA: New York Heart Association; CRT: cardiac resynchronisation therapy.

Table 10: Proposed MBS item descriptor for transvenous left ventricular electrode

Category 3 – Therapeutic Procedures
MBS 38368 proposed PERMANENT TRANSVENOUS LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of through the coronary sinus, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120 ms. And for the purpose of cardiac resynchronisation therapy, for patients who have mild chronic heart failure (NYHA class II) despite optimised medical therapy and who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 30% - a QRS duration greater than or equal to 150 ms. Where the service includes right heart catheterisation and any associated venogram of left ventricular veins. Not being a service associated with a service to which items 38200 and 35200 apply. Multiple Services Rule (Anaes.) Fee: $1,178.20 Benefit: 75% = $883.65 Item 38368 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device replaced.

MBS: Medicare Benefits Schedule; NYHA: New York Heart Association; CRT: cardiac resynchronisation therapy.

Table 11: Proposed MBS item descriptor for left ventricular electrode

Category 3 – Therapeutic Procedures
MBS 38654 proposed PERMANENT LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of via thoracotomy, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120 ms. And for patients who have mild chronic heart failure (NYHA class II) despite optimised medical therapy who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 30% - a QRS duration greater than or equal to 150 ms. Fee: $1,178.20 Benefit: 75% = $883.65 Item 38654 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device capable of defibrillation inserted and who prior to its insertion met the criteria and now need the device replaced.

MBS: Medicare Benefits Schedule; NYHA: New York Heart Association; CRT: cardiac resynchronisation therapy.

The proposed eligibility for CRT-D implantation in NYHA II patients requires measurement of LVEF and QRS duration and determining the presence of sinus rhythm. However, as discussed above, echocardiogram or ECG assessments of LVEF, QRS duration and sinus rhythm is already part of standard practice for HF patients. The proposed restriction for the listing of CRT-D in NYHA II patients who have not responded to medical therapy prevents the potential for inappropriate medicalisation of a previously untreated condition. Moreover, these patients are currently eligible for implantation of an ICD device. Therefore, many patients receiving a CRT-D implant will receive it as an alternative to an ICD implant.

There can be some uncertainty in the diagnosis of HF, and diagnosis does involve clinical judgement. Nevertheless, the pre-requisites for CRT-D of presence of HF symptoms, LVEF, QRS duration and sinus rhythm ensures a consistent diagnosis.

Clinical place for proposed intervention

The two major barriers in accurately determining the incidence and prevalence of heart failure in Australia are the lack of a universally agreed definition and difficulties in diagnosis, particularly when the condition and symptoms are mild.

Impact of heart failure in Australia

Based on 2007-08 National Health Service self-reports, 277,800 Australians (1.4% of the population) had heart failure or oedema (swelling, which can be a sign of heart failure when it occurs in the lower legs; Australian Institute of Health and Welfare 2010). Around 64% of those with the disease were females, with a prevalence of 1.7% compared with 1.0% for males (Australian Institute of Health and Welfare 2010). The estimated prevalence of heart failure or oedema increased with age from 2.6% in people aged 55 to 64 years to 8.2% in those aged 75 years and over (Australian Institute of Health and Welfare 2010). An estimated 30,000 new cases of heart failure are diagnosed each year (National Heart Foundation of Australia and Cardiac Society of Australia & New Zealand, 2002).

Heart failure and cardiomyopathy accounted for 4,055 deaths in 2007. However, due to the nature of these diseases, they are more likely to be listed as an associated cause of death rather than an underlying cause (Australian Institute of Health and Welfare 2010). In 2007, heart failure or cardiomyopathy was the underlying or associated cause of death in 19,967 cases (Australian Institute of Health and Welfare 2010). Most of these occur among people aged 75 years and over. In 2007, heart failure was the second most common contributing cause of death in males (contributing to 9,125 deaths), and the third most common contributing cause of death in females (contributing to 10,973 deaths; Australian Institute of Health and Welfare 2010). The percentage of cardiovascular disease hospitalisations due to heart failure was 10.4% in 2007-08; Australian Institute of Health and Welfare 2010).

Information about the incidence and prevalence of specific types of heart failure in Australia is mainly derived from extrapolation from overseas studies (MSAC 2006; National Centre for Monitoring Cardiovascular Disease 2004). It is assumed that the epidemiology in Australia is similar to that in Europe and the United States. One large (n=3960) cross-sectional study of a random cohort, conducted in England, found 69% of all heart failure patients were NYHA class II, and 32% of all heart

failure patients had LVEF <40%, with sinus rhythm and no valve disease (Davies et al 2001).

MBS benefits are available to NYHA class II patients for the insertion of an ICD device. There were 1,085 services for ICD implantation processed by Medicare from July 2011 to June 2012. Among those currently eligible to receive an ICD implantation, there is a subpopulation of patients who would meet the requested NYHA class II restriction (that is who have sinus rhythm, LVEF ≤30%, QRS duration ≥150ms). Under the proposed changes to the MBS, it would be expected that many of the patients who meet these additional criteria would undergo a CRT-D implantation instead. This patient group would be expected to comprise the majority of CRT-D patient population if the expanded listing is accepted. In addition to this, there may be additional NYHA class II patients who would be eligible for CRT-D if the requested listing is accepted. For example, there may a group of patients who, though eligible, have not received an ICD implantation, though this population would be expected to be small.

The submission proposes that CRT-D will be a direct substitute for ICD in the defined population. Some patients will be eligible for ICD implantation but not eligible for CRT-D.

Broad clinical management algorithms for the current and proposed services are shown in Figure 3 and 4; these show how eligibility of patients with heart failure to CRT-D fits in with ICD and CRT. As noted by the applicant, not all eligible patients will receive CRT-D implantation; some patients will receive ICD and some will continue to receive optimised medical therapy if the implantation of a device is contraindicated by comorbidities.

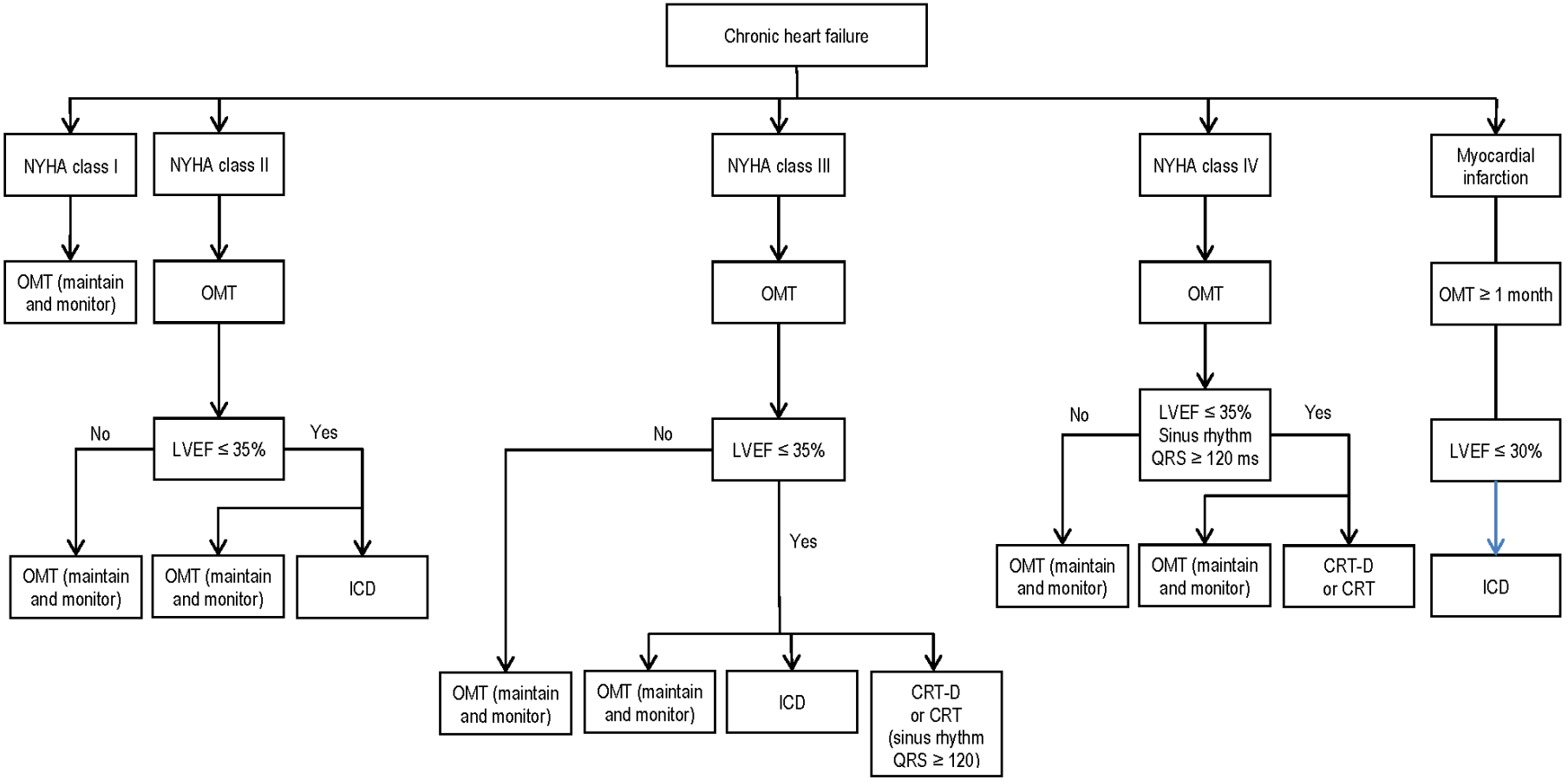
Issues:

- The majority of patients would have leads placed through the transvenous route.
- Due to blood vessel and coronary sinus anatomy, 5-10 per cent of patients will not be able to have the left ventricular lead placed through a transvenous route.
    - In some cases a transthoracic route may be attempted.
    - In other cases the patient would be provided with an ICD.

- Even with what appears to be correct placement of the left ventricular (CRT) lead, the response rate may only be approximately 60-70%. The vein is used to guide the lead to the correct position on the coronary sinus, but variability in patient anatomy may mean that the lead is not placed in exactly the correct location.
    - In this instance, the leads and the device are left in place and the patient is left with a functioning defibrillator function of the CRT-D in case of SCA.
    - Alternatively, some patients may have an attempt at secondary lead placement via a thoracotomy, but this is less common.
    - After successful implantation the device is very rarely removed.

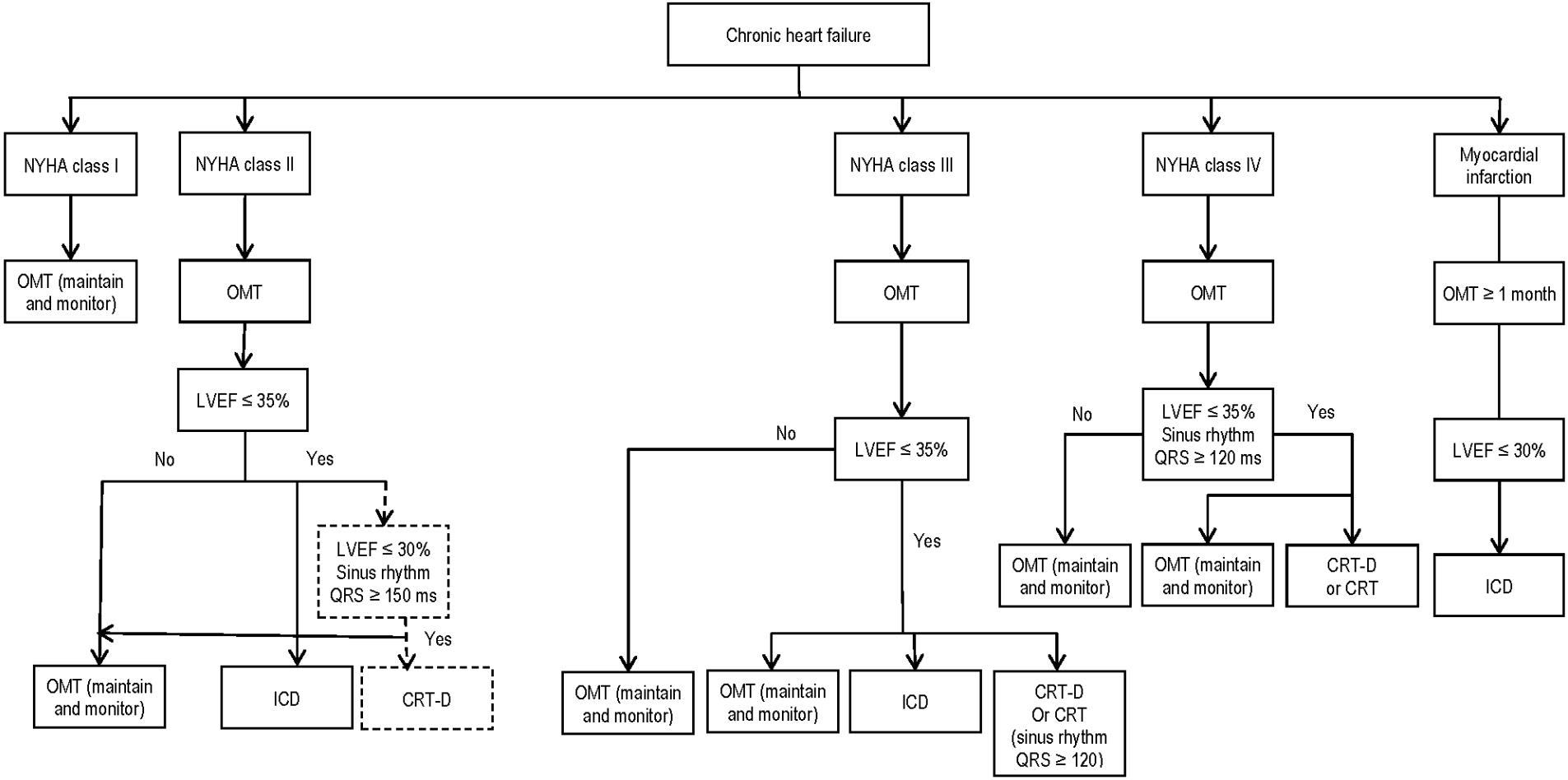
These issues should be accounted for in the final decision analytic and economic evaluation.

Figure 3 : Current clinical management algorithm



NYHA: New York Heart Association; OMT: optimal medical therapy; LVEF: left ventricular ejection fraction; ICD: implantable cardioverter defibrillator; CRT-D: cardiac resynchronisation device capable of defibrillation.

Figure 4: Proposed clinical management algorithm



NYHA: New York Heart Association; OMT: optimal medical therapy; LVEF: left ventricular ejection fraction; ICD: implantable cardioverter defibrillator; CRT-D: cardiac resynchronisation device capable of defibrillation.

Comparator

The comparator for CRT-D (with optimised medical therapy) in the proposed population is:

- ICD with optimised medical therapy

CRT-D is proposed as a direct substitute for ICD (without CRT). However, it is unclear if CRT-D will completely replace ICD as the eligible populations for both are slightly different. The final choice of cardiac device may to an extent depend upon patient and clinician preference.

ICD is currently listed on the MBS (item number 38387 and 38384) for primary prevention of sudden cardiac death in:

- patients with a LVEF of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or
- patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a LVEF less than or equal to 35% when the patient has received optimised medical therapy.

Table 12: Current MBS item for implantable cardioverter defibrillator – electrode insertion

Category 3 – Therapeutic Procedures
MBS 38384 AUTOMATIC DEFIBRILLATOR, insertion of patches for, or insertion of transvenous endocardial defibrillation electrodes for, primary prevention of sudden cardiac death in: - patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or - patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimised medical therapy. Not being a service associated with a service to which item 38213 applies Multiple Services Rule (Anaes.) (Assist.) Fee: $1,052.65 Benefit: 75% = $789.50 85% = $978.15

MBS: Medicare Benefits Schedule; NYHA: New York Heart Association.

Table 13: Current MBS item for implantable cardioverter defibrillator – generator implantation

Category 3 – Therapeutic Procedures
MBS 38387 AUTOMATIC DEFIBRILLATOR GENERATOR, insertion or replacement of for, primary prevention of sudden cardiac death in: - patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or - patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimised medical therapy. Not being a service associated with a service to which item 38213 applies, not for defibrillators capable of cardiac resynchronisation therapy Multiple Services Rule (Anaes.) (Assist.) Fee: $287.85 Benefit: 75% = $215.90 85% = $244.70 NOTE: T8.69 Implantable Cardioverter Defibrillator - (Items 38384 and 38387) Items 38384 and 38387 apply only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had an ICD device inserted and who prior to its insertion met the criteria and now need the device replaced.

MBS: Medicare Benefits Schedule; NYHA: New York Heart Association; ICD: implantable cardioverter defibrillator.

Clinical claim

CRT-D, compared with ICD, reduces mortality due to heart failure and significantly improves ventricular remodelling indices, specifically left ventricular (LV) diastolic and systolic volumes and LVEF and a reduced left ventricular size (Tang et al, 2010). The benefits of CRT may be due to a reduced LV filling pressure, which is reflected by improvements in atrial size, pulmonary pressures, or RV function (Solomon et al., 2010). In addition, there is some evidence to show that CRT may result in improved quality of life and exercise tolerance (Caseau et al, 2001).

Clinical practice guidelines

The 2006 assessment report of Implantable Cardioverter Defibrillators for Prevention of Sudden Cardiac Death (MSAC 2006) recommended the listing of CRT-D implantation on the MBS for NYHA class III and IV patients. Since then, a body of evidence has been growing that demonstrates that CRT-D significantly reduces mortality and hospitalisation due to heart failure compared with ICD in NYHA class II patients. This proposed indication will bring the MBS into line with the National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand Guidelines for the Prevention, Detection and Management of Chronic Heart Failure in Australia. These guidelines recommend considering CRT-D to reduce risk of death and heart

failure events for patients with NYHA class II HF despite optimised medical therapy and who have an LVEF ≤ 30% and a QRS duration ⩾ 150 ms (Krum et al 2011). European Society of Cardiology guidelines concluded that CRT-P or CRT-D may be considered to reduce morbidity in NYHA class II patients with LVEF ≤ 35% and QRS of greater than or equal to 150 ms (Dickstein et al 2010). Guidelines in the United States from the Heart Failure Society of America recommend that biventricular pacing therapy may be considered in patients with reduced LVEF and QRS≥150 ms who have NYHA class I or II symptoms (Lindfeld et al 2010).

In NYHA class II patients with an LVEF of 30% or less, there is randomised evidence demonstrating that CRT-D leads to a significant reduction in the risk of death and heart failure events compared to ICD (Tang et al 2010). The clinical efficacy of CRT-D was greatest in the subset of NYHA class II patients with QRS durations of 150 ms or more. Therefore, the current application proposes that the current MBS listing for CRT-D should be extended to include NYHA class II patients with LVEF ⩽ 30% and QRS duration ⩾ 150 ms. This is consistent with the advice provided in current clinical practice guidelines (Krum et al 2011), which recommend considering CRT-D in patients with NYHA class II HF despite optimised medical therapy and who have an LVEF ⩽ 30% and a QRS duration ⩾ 150 ms.

Table 14: Classification of an intervention for determination of economic evaluation to be presented

<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="4">Comparative effectiveness versus comparator</td></tr>
<tr><td colspan="2">Superior</td><td>Non-inferior</td><td colspan="2">Inferior</td></tr>
<tr><td rowspan="5">Comparative safety versus comparator</td><td rowspan="3">Superior</td><td colspan="2" rowspan="3">CEA/CUA</td><td rowspan="3">CEA/CUA</td><td>Net clinical benefit</td><td>CEA/CUA</td></tr>
<tr><td>Neutral benefit</td><td>CEA/CUA*</td></tr>
<tr><td>Net harms</td><td>None^</td></tr>
<tr><td>Non-inferior</td><td colspan="2">CEA/CUA</td><td>CEA/CUA*</td><td colspan="2">None^</td></tr>
<tr><td rowspan="3">Inferior</td><td>Net clinical benefit</td><td>CEA/CUA</td><td rowspan="3">None^</td><td colspan="2" rowspan="3">None^</td></tr>
<tr><td>Neutral benefit</td><td>CEA/CUA*</td></tr>
<tr><td>Net harms</td><td>None^</td></tr>
</table>

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable).

Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

^ No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

Outcomes and health care resources affected by introduction of proposed intervention

Outcomes

- Primary effectiveness outcomes
    - All-cause mortality
    - Sudden cardiac death
    - Quality of life
    - Rates of hospitalisation
- Secondary effectiveness outcomes:
    - Other clinical outcomes including:
        - Heart transplantation
        - Sustained ventricular tachycardia (VT), symptomatic VT
    - Other technical and device-related outcomes including:
        - Pharmaceutical therapy before/after implantation
        - Battery replacement
        - Magnetic resonance imaging (MRI) compatibility
        - Device or electrode failure
        - Device or electrode removal
        - Inappropriate shocks
        - Duration and type of previous optimised medical therapy
        - Lead placement through transvenous or transthoracic route
        - Successful LV lead placement
        - Successful LV lead function
        - Use of local or general anaesthesia
- All adverse events (frequency and severity), including but not limited to:
    - Additional procedures as a result of lead or device problems
    - Lead failure / lead dislodgement
    - Inappropriate shocks
    - Infection
    - Pneumothorax

- Outcomes for patients specifically reported as having left bundle branch block should be reported separately where possible.
- Outcomes for elderly patients (75 years and older) should be reported separately where possible.

Health care resources

The initial tests to establish the formal diagnosis of CHF will be unchanged.

Table 15: List of resources to be considered in the economic analysis

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt. budget	Private health insurer	Patient	Total cost
Resources provided to identify eligible population										
- No additional resources required	-	-	-	-	-	-	-	-	-	-
- Echocardiogram	-	-	-	-	-	-	-	-	-	-
- Electrocardiogram	-	-	-	-	-	-	-	-	-	-
- Chest X-ray	-	-	-	-	-	-	-	-	-	-
- Blood tests???	-	-	-	-	-	-	-	-	-	-
- Optimised medical therapy	-	-	-	-	-	-	-	-	-	-
Resources provided to deliver comparator 1 – ICD with optimal medical therapy										
- Insertion of ICD device	MBS	Surgical	-	1 service	MBS 38387	-	-	-	-	-
- Insertion of RA and RV leads	MBS	Surgical	-	1 service	MBS 38384	-	-	-	-	-
- ICD device	Other govt	Surgical	-	1 unit	-	-	-	-	-	-
- RA lead	Other govt	Surgical	-	1 unit	-	-	-	-	-	-
- RV lead	Other govt	Surgical	-	1 unit	-	-	-	-	-	-
- Hospitalisation for insertion of device	MBS/other govt	Public or private hospital	-	1 inpatient episode		-	AR-DRG item F12Z	-	-	-
Resources provided in association with comparator 1 (ICD)										
- Drugs TBC	-	-	-	-	-	-	-	-	-	-
- Tests TBC	-	-	-	-	-	-	-	-	-	-
- Hospitalisation for heart failure	MBS/other government	Public or private hospital	TBA	1 inpatient episode	-	-	AR-DRG item F62a	-	-	-
- Testing implanted device	MBS	Public or private hospital	100%	Every 3-6 months	MBS 11727	-	-	-	-	-
- Replacement of ICD device	-	-	-	Every 5-10 years?	-	-	-	-	-	-
- Replacement of leads	-	-	-	Every 10 years?	-	-	-	-	-	-

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt. budget	Private health insurer	Patient	Total cost
Resources provided to deliver proposed intervention – CRT-D										
- Insertion of CRT-D device	MBS	Surgical	-	1 service	MBS 38371	-	-	-	-	-
- Insertion of LV lead (transvenous)	MBS	Surgical	90-95%	1 service	MBS 38368	-	-	-	-	-
- Insertion of LV lead (thoracotomy)	MBS	Surgical	5-10%	1 service	MBS 38654	-	-	-	-	-
- Insertion of RA and RV leads	MBS	Surgical	-	1 service	MBS 38384	-	-	-	-	-
- Insertion of RA pacemaker lead	MBS	Surgical	-	1 service	MBS 38350	-	-	-	-	-
- Replacement of CRT-D device	-	-	-	Every 4-8 years?	-	-	-	-	-	-
- Replacement of leads	-	-	-	Every 10 years	-	-	-	-	-	-
- CRT-D device	Other govt	Surgical	-	1 unit	-	-	-	-	-	-
- LV lead	Other govt	Surgical	-	1 unit	-	-	-	-	-	-
- RA lead	Other govt	Surgical	-	1 unit	-	-	-	-	-	-
- RV lead	Other govt	Surgical	-	1 unit	-	-	-	-	-	-
- Hospitalisation for insertion of device	MBS/other govt	Public or private hospital	-	1 inpatient episode	-	-	AR-DRG item F12Z	-	-	-
Resources provided in association with proposed intervention										
- Drugs TBC	-	-	-	-	-	-	-	-	-	-
- Tests TBC	-	-	-	-	-	-	-	-	-	-
- Hospitalisation for heart failure	MBS/other government	Public or private hospital	TBA	1 inpatient episode	-	-	AR-DRG item F62a	-	-	-
- Testing implanted device	MBS	Public or private hospital	100%	Every 3-6 months	MBS 11727	-	-	-	-	-

MBS: Medicare Benefits Schedule; ICD: implantable cardioverter defibrillator; RA: right atrial; RV: right ventricular; CRT-D: cardiac resynchronisation therapy device capable of defibrillation; LV: left ventricular.

The current Australian pathway for diagnosis of chronic heart failure (Figure 2) would be used for all the populations above and would provide the necessary measurements to inform whether or not a patient would be indicated for ICD or CRT-D.

According to the applicant, current clinical practice does not require the patient to be placed into asystole, therefore the majority of patients who receive a CRT-D will not require an anaesthetist.

Tests involved in the current pathway of diagnosis may include the following MBS services:

- Echocardiogram: 55113, 55116, 55117, 55122, 55123.
- Electrocardiogram (ECG): 11700, 11708, 11713, 11701, 11708, 11709.
- Other blood tests: 66500, 11715, 66695.
- Full blood count: 65129, 65070
- Renal function: 12524, 12527
- Thyroid function: 66719
- BNP/ N-terminal pro-BNP test: 66830

Other costs may include:

- 38212; 38213; 38358 (extraction of leads)
- Cardiac MRI, coronary angiography.

Clinical advice has suggested that tests prior to CRT-D implantation are the same as those prior to ICD implant:

- Electrocardiogram and cardiac echocardiogram
- Possibly cardiac catheterisation, cardiac MRI, cardiac biopsy
- Patients with a cardiac device will require testing at least every 6 months
- In some cases testing may require echocardiographic optimisation of the CRT device
- ICD devices need replacing approximately every 5-8 years. CRT-D devices need replacing approximately every 4-6 years (a shorter time due to continual pacing). Leads have a lifetime of approximately 10 years.
- Overall, resources for the population with mild chronic heart failure will be the same as for those with moderate to severe chronic heart failure currently eligible for CRT-D on the MBS.

Device costs

The component costs of a CRT-D device include the generator, the right atrium lead, the right ventricular lead, and the left ventricular lead. For public hospitals, the device costs for the generator, the right atrium lead, the right ventricular lead, and the left ventricular lead are approximately $17,000, $475, $1,500, and $2,100 respectively (MSAC 2006); for private hospitals the device costs are $45,760 to $52,750, $1,215 to $2,600, $9,000 to $9,360, and $3,120 to $6,240 respectively (February 2012 Prosthesis List minimum benefit).

The equipment required for the implantation of an ICD includes the generator, the right atrium lead, and the right ventricular lead. For public hospitals the generator costs, right atrium lead costs, and right ventricular lead costs are approximately $13,000, $475, and $1,500 respectively (MSAC 2006); for private hospitals the device costs are $40,560 to $44,670, $1,144 to $2,600, and $9,000 respectively (February 2012 Prosthesis List minimum benefit).

Anaesthetist cost

As considered by MSAC previously in Report 32, an anaesthetist may be required to provide services for device implantation. However, current advice suggests that CRT-D implantation is commonly provided under local anaesthesia. The assessment should provide evidence regarding the use of local and general anaesthetic in CRT-D implantation and account for this in the economic analysis.

Proposed structure of economic evaluation (decision-analytic)

Table 14 shows the summary PICO criteria. The decision analytic model provided by the applicant is shown in Figure 5.

Table 16: Summary of extended PICO to define research question that assessment will investigate

Patients	Intervention	Comparator	Outcomes to be assessed	Healthcare resources to be considered
Patients with NYHA class II heart failure, despite optimised medical therapy who have all the following criteria: • Sinus rhythm • A left ventricular ejection fraction (LVEF) of less than or equal to 30% • A QRS duration greater than or equal to 150 ms. Sub-groups of interest: • Patients with the above criteria but with LVEF less than or equal to 35%. • Patients with atrial fibrillation (who fulfil the other criteria) where there is an indication for pacing.	CRT-D with optimised medical therapy	ICD with optimised medical therapy	All-cause mortality Sudden cardiac death Hospitalisation for heart failure Patient-related quality of life All adverse events (See above for complete lists of outcomes of interest)	Length of hospitalisation Initial and follow-up tests Use of pharmaceuticals before/after device implantation, including any definition of 'optical medical therapy' Use and type of anaesthesia or sedation Other resources as reported in 'Outcomes' above,

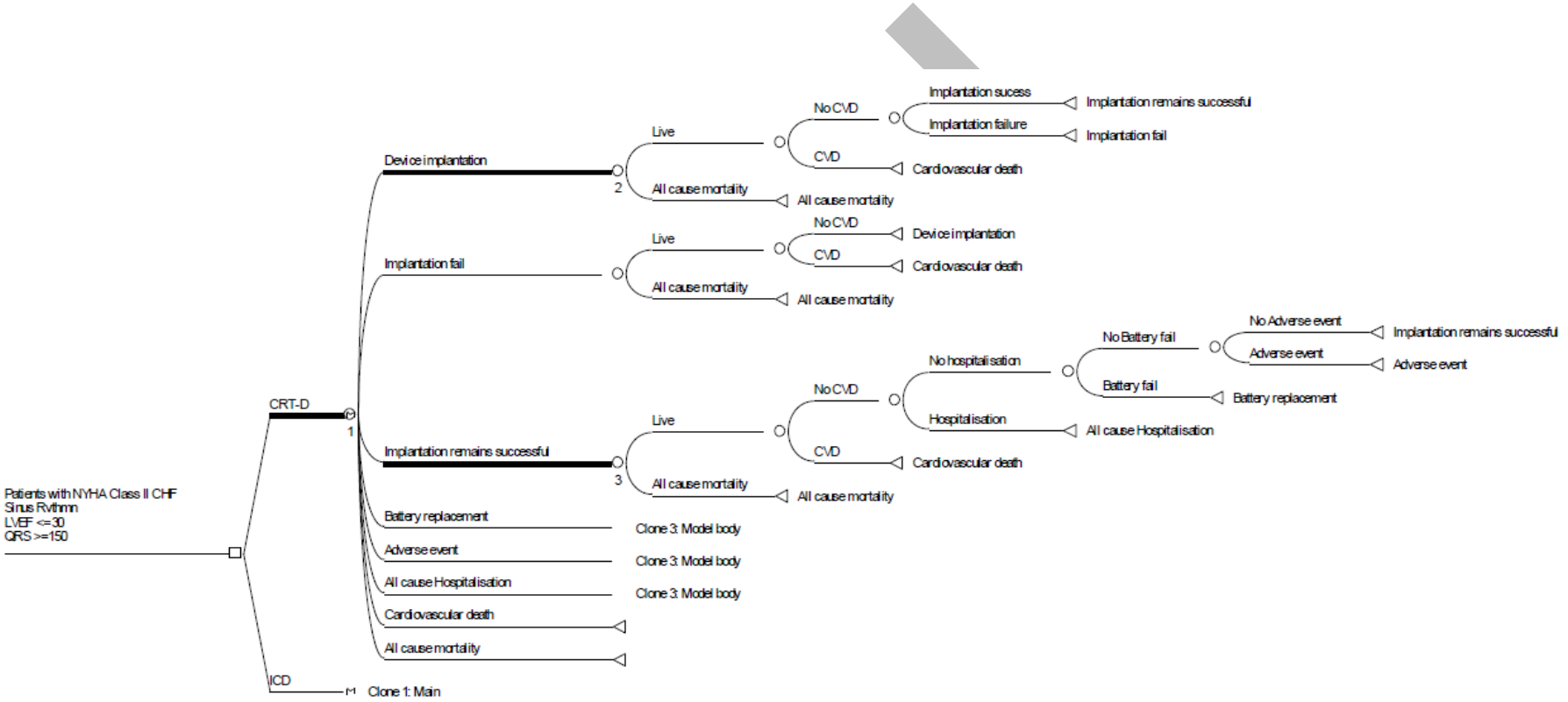
NYHA: New York Heart Association; LVEF: left ventricular ejection fraction; CRT-D: cardiac resynchronisation therapy device capable of defibrillation; ICD: implantable cardioverter defibrillator.

Subgroups have been identified following external stakeholder input and discussions at PASC.

Where possible, evidence regarding the nominated sub-populations should be reports separately. A sensitivity analysis should be undertaken for these populations.

PASC requested that non-response and adverse events be accounted for in the algorithm to identify downstream events and treatment costs.

Figure 5: Decision analytic model for the cost effectiveness of CRT-D compared with ICD in NYHA class II patients – as provided by the applicant



CRT-D: cardiac resynchronisation therapy device capable of defibrillation; ICD: implantable cardioverter defibrillator; NYHA: New York Heart Association; CHF: chronic heart failure; LVEF: left ventricular ejection fraction; CVD: cardiovascular disease.

Clinical research questions for public funding

- What is the safety, effectiveness, and cost-effectiveness of a CRT-D in NYHA class II HF patients (with sinus rhythm, LVEF of no more than 30%, and a QRS duration of 150 ms or greater) compared with ICD?
- What is the safety, effectiveness, and cost-effectiveness of a CRT-D in NYHA class II HF patients (with LVEF of no more than 30%, and a QRS duration of 150 ms or greater) with atrial fibrillation compared with ICD?
- What is the safety, effectiveness, and cost-effectiveness of a CRT-D in NYHA class II HF patients (with sinus rhythm, LVEF of less than or equal to 35%, and a QRS duration of 150 ms or greater) compared with ICD?

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Appendix 1 CRT-D devices on the ARTG

Sponsor's name	Manufacturers name	Device	ARTG number
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Lumax 540 HF-T	153974
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Lumax 740 HF-T	195225
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	COGNIS 100 HE DF1/IS1	154033
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	COGNIS 100 HE DF1/LV1	154034
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	COGNIS 100 HE GDT LLHH	154035
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	CONTAK RENEWAL 4 HE CRT-D Model H199	104676
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	CONTAK RENEWAL 4 CRT-D Model H195	104677
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	CONTAK RENEWAL 4 CRT-D Model H190	104678
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	CONTAK RENEWAL 4 HE CRT-D Model H197	104679
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	CONTAK RENEWAL 4 AVT CRT-D Model M175	114929
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	CONTAK RENEWAL 4 AVT HE CRT-D Model M177	114930
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	CONTAK RENEWAL 4 AVT HE CRT-D Model M179	114931
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	CONTAK RENEWAL 4 AVT Model M170	114932
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	ENERGEN CRT-D - Model N142	192553
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	ENERGEN CRT-D - Model N143	192554
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	INCEPTA CRT-D - Model N162	192555
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	INCEPTA CRT-D - Model N163	192556
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	INCEPTA CRT-D - Model N165	192557
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	LIVIAN Cardiac Resynchronisation Therapy Device (Standard Energy)	152951
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	LIVIAN Cardiac Resynchronisation Therapy Device (High Energy)	152952
Medtronic Australasia Pty Ltd	Medtronic Inc	Concerto C174AWK	126814
Medtronic Australasia Pty Ltd	Medtronic Inc	Concerto II CRT-D Model D294TRK	162425

Medtronic Australasia Pty Ltd	Medtronic Inc	Consulta CRT-D Model D234TRK	154089
Medtronic Australasia Pty Ltd	Medtronic Inc	Consulta CRT-D D 214TRM	185553
Medtronic Australasia Pty Ltd	Medtronic Inc	MAXIMO II CRT-D D264TRM	190851
Medtronic Australasia Pty Ltd	Medtronic Inc	Maximo II CRT-D Model D284TRK	154092
Medtronic Australasia Pty Ltd	Medtronic Inc	Protecta XT CRT-D D354TRM	181996
Medtronic Australasia Pty Ltd	Medtronic Inc	Protecta XT CRT-D D354TRG	176435
Progressive Medical	ELA Medical	Ovatio CRT 6750	132650
Sorin Group Australia	Sorin Biomedica Crm Srl	Paradym CRT 8750	163470
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Atlas II HF Model V-365	136216
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Atlas II+ HF Model V-367	136218
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Promote RF Model 3213	149308
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Promote Accel RF Model CD3215	158920
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Promote Accel Model CD3215-36Q	170537
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Promote Quadra CD3237-40	181842
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Promote Quadra CD3237-40Q	181843
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Promote Quadra CD3239-40	184879

St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Promote Quadra CD3239-40Q	184880
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Unify CRT-D CD3235-40Q	171540
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Unify CRT-D CD3235-40	171541

Appendix 2 ICD and pacemaker leads on the ARTG

Sponsor's name	Manufacturers name	Device	ARTG number
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Corox OTW xx-UP Steroid	119415
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Corox OTW (-S) xx-BP	142124
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Corox OTW -L BP	174958
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Dextrus Model 413x	140309
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Linox SD xx/yy	129076
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Linox TD xx/yy	132892
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Linox S xx	142174
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Linox T xx	142175
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Linox Smart SD xx/yy	167216
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Linox Smart TD xx/yy	167217
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Linox smart S DX - Lead,	191636
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Myopore Bipolar Sutureless Myocardial Pacing Lead	159391
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	MYOPORE Bipolar Sutureless Myocardial Pacing Lead	194595
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Selox SR xx	106564
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Selox ST xx	118361
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Selox JT xx	118362
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Siello S xx	170066
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Siello T xx	170067
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Siello JT xx	170068
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Safio S	188217
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Setrox S xx	129077
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	ACUITY Models 4554,4555,4556	126935

Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Acuity Spiral Lead	155274
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	EASYTRAK IS-1	112809
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	EASYTRAK 3	114811
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	EASYTRAK 3 IS-1	119321
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Easytrak 2	99579
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	EASYTRAK 2 IS-1	112810
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance G Passive Fixation Leads model 0174-0177	116534
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance SG Passive Fixation Leads models 0170-0173	116535
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	ENDOTAK RELIANCE SG LEADS	119322
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	ENDOTAK RELIANCE G LEADS	119328
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance Leads models 0147,0148,0149	128708
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance S Passive Fixation Implantable Lead	165638
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance Active Fixation Implantable Lead	165639
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance S Active Fixation Implantable Lead	165640
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance G Passive Fixation Implantable Lead	165641
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance SG Passive Fixation Implantable Lead	165642
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance Passive Fixation Implantable Lead	165643
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance G Active Fixation Implantable Lead	165644
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak Reliance SG Active Fixation Implantable Lead	165645
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Endotak SQ Array XP Model 0085	128625
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Fineline II Sterox Leads	128060
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Flextend Models 4086, 4087, 4088	129949
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Myopore Bipolar Sutureless Myocardial Pacing Lead	161123

Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Selute; Model 4185	128826
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Selute Picotip VDD	128827
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Selute Picotip Atrial J	128828
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	Selute Picotip; Model 4035	128965
Medtronic Australasia Pty	Medtronic Inc	5071 - Sutureless, unipolar, myocardial screw-in pacing lead	136181
Medtronic Australasia Pty	Medtronic Inc	Attain OTW Model 4194 Lead	120254
Medtronic Australasia Pty	Medtronic Inc	Attain StarFix Model 4195	131306
Medtronic Australasia Pty	Medtronic Inc	Attain Ability 4196	151600
Medtronic Australasia Pty	Medtronic Inc	Attain Ability Plus Model 4296	178071
Medtronic Australasia Pty	Medtronic Inc	Attain Ability Straight Model 4396	178072
Medtronic Australasia Pty	Medtronic Inc	Capsure Fix Novus Lead	134286
Medtronic Australasia Pty	Medtronic Inc	Capsure SP Novus Leads	134288
Medtronic Australasia Pty	Medtronic Inc	Capsure Sense Leads	134289
Medtronic Australasia Pty	Medtronic Inc	Capsure Sense Lead - Model 4074	134331
Medtronic Australasia Pty	Medtronic Inc	Capsure Sense Lead - Model 4574	134426
Medtronic Australasia Pty	Medtronic Inc	Capsure Z Novus Model 5554	142167
Medtronic Australasia Pty	Medtronic Inc	Capsure Z Novus Model 5054	142168
Medtronic Australasia Pty	Medtronic Inc	Capsure SP Novus Model 5092	142170
Medtronic Australasia Pty	Medtronic Inc	Capsure VDD-2 Model 5038	142171
Medtronic Australasia Pty	Medtronic Inc	Capsure Epi Lead - Model 4965	134427
Medtronic Australasia Pty	Medtronic Inc	Capsure Epi Leads	134287
Medtronic Australasia Pty	Medtronic Inc	CapsureFix Model 5568	142169
Medtronic Australasia Pty	Medtronic Inc	CapsureFix Novus Model 4076	159822

Medtronic Australasia Pty	Medtronic Inc	CapsureFix MRI Model 5086MRI	165256
Medtronic Australasia Pty	Medtronic Inc	SelectSecure Model 3830	131307
Medtronic Australasia Pty	Medtronic Inc	Sprint Quattro Secure	134290
Medtronic Australasia Pty	Medtronic Inc	Sprint Quattro Model 6944	142172
Medtronic Australasia Pty	Medtronic Inc	Sprint Quattro Secure S Model 6935	157536
Medtronic Australasia Pty	Medtronic Inc	SPRINT QUATTRO SECURE Model 6947M DSP	191092
Medtronic Australasia Pty	Medtronic Inc	SPRINT QUATTRO SECURE Model 6947M DXAC/DSP	191093
Pacing Importers Pty Ltd	Oscor Inc	Refino ER	196633
Pacing Importers Pty Ltd	Oscor Inc	Refino ERJU	196835
Pacing Importers Pty Ltd	Oscor Inc	Refino ERU	196836
Sorin Group Australia	ELA Medical	Petite ER	178088
Sorin Group Australia	ELA Medical	Petite ERJB	178409
Sorin Group Australia	ELA Medical	Physique ER	178090
Sorin Group Australia	ELA Medical	PY2 ERU	178083
Sorin Group Australia	ELA Medical	Refino ERU	178089
Sorin Group Australia	ELA Medical	Refino ERJU	178410
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead Model 7120	159843
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead Model 7171	159844
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead Model 7121	159845
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead Model 7122	159846
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead Model 7131	159847

St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead Model 7130	159848
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead Model 7170	159849
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead model 7120Q	170589
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead model 7121Q	170590
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead model 7122Q	170591
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead model 7170Q	170592
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead model 7171Q	170593
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead model 7172Q	170594
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	IsoFlex S Lead Model 1636T	120363
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	IsoFlex S Lead Model 1642T	120364
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	IsoFlex S Lead Model 1646T	120370
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	IsoFlex Lead Model 1944	159532

St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	IsoFlex Lead Model 1948	159533
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Myodex Lead Model 1084T	145900
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	OptiSense Model 1699T Lead	143294
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	OptiSense Model 1699TC Lead	143296
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	OptiSense Lead Model 1999	159534
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	QuickFlex Lead Model 1258T	161391
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	QuickSite Lead Model 1056K	120366
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Quartet Model 1458Q Lead	171332
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Riata ST Optim Lead Model 7021	142966
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Riata ST Optim Lead Model 7020	142967
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Riata ST Optim Lead Model 7070	142968
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Riata ST Optim Lead Model 7022	142970

St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Riata ST Optim Lead Model 7071	142972
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Riata ST Optim model 7022Q	170586
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Riata ST Optim model 7021Q	170588
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Riata ST Optim Lead model 7020Q	170597
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril SDX Pacing Lead Model 1688T	116569
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril SDX Pacing Lead Model 1688TC	116571
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril ST Model 1782TC Lead	143297
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril ST Model 1788T Lead	143298
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril ST Model 1788TC Lead	143299
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril ST Model 1882TC Lead	143300
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril ST Model 1888TC Lead	143301
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril STS Lead Model 1988TC	170585

St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Tendril STS Lead Model 2088TC	170587

Appendix 3 CRT-D devices on the Prosthesis list

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Biotronik Australia Pty Ltd	Lumax 540 HF-T	High Energy, Three Chamber ICD (Implantable Cardiac Defibrillator) with Advanced Patient Management Via unique Home Monitoring Technology incorporating Automatic RV/LV Threshold Monitoring and Extended Longevity.	47,840.00	
Boston Scientific Australia Pty Ltd	COGNIS 100 HE (DF-1/IS-1 & DF-1/LV-1)	CRT-D high energy with RF	47,840.00	
Boston Scientific Australia Pty Ltd	COGNIS 100 HE 4-SITE	CRT-D high energy with RF IS4	48,590.00	
Boston Scientific Australia Pty Ltd	ENERGEN CRT-D	High energy CRT-D with DF-1 RV connector and IS-1 LV connector	47,840.00	
Boston Scientific Australia Pty Ltd	ENERGEN DF-4 CRT-D	High energy CRT-D with DF-4 RV connector and IS-1 LV connector	48,590.00	
Boston Scientific Australia Pty Ltd	INCEPTA CRT-D	High energy CRT-D with DF-1 RV connector & IS-1 (N163) or LV-1 (N165) LV connector	47,840.00	
Boston Scientific Australia Pty Ltd	INCEPTA DF-4 CRT-D	High energy CRT-D with DF-4 RV connector and IS-1 LV connector	48,590.00	
Boston Scientific Australia Pty Ltd	LIVIAN CRT-D	CRT-D with RF	45,760.00	
Boston Scientific Australia Pty Ltd	LIVIAN CRT-D HE	CRT-D, high energy with RF	47,840.00	
Guidant Australia Pty Ltd	Contak Renewal 4 CRT-D Model H190, Model H195	CRT-D	45,760.00	
Guidant Australia Pty Ltd	Contak Renewal 4 HE CRT-D Model H197, Model H199	CRT-D high energy	47,840.00	
Guidant Australia Pty Ltd	Contak Renewal 4 AVT HE CRT - D - Model M177, M179	Implantable Cardioverter Defibrillator with cardiac resynchronisation Therapy	47,840.00	
Guidant Australia Pty Ltd	Contak Renewal 4 AVT CRT-D - Model M170 and M175	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation Therapy	45,760.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Medtronic Australasia Pty Ltd	Consulta CRT-D Model D234TRK	Fully Automatic, Wireless Implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT), and therapies for ventricular and atrial tachyarrhythmia	52,000.00	
Medtronic Australasia Pty Ltd	Consulta CRT-D Model D234TRM	Fully Automatic, Wireless Implantable cardioverter defribillator with cardiac resynchronization therapy (CRT), and therapies for ventrilcular and atrial tachyarrhythmia. DF-4 lead connector.	52,750.00	
Medtronic Australasia Pty Ltd	Protecta XT CRT-D D354TRG	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, SmartShock Technology, OptiVol 2.0 Fluid Status Monitoring and Complete Capture Management Specifications (DF-1)	52,000.00	
Medtronic Australasia Pty Ltd	Protecta XT CRT-D D354TRM	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, SmartShock Technology, OptiVol 2.0 Fluid Status Monitoring and Complete Capture Management Specifications (DF-4)	52,750.00	
Sorin Group	PARADYM CRT-D 8750	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, High Energy	47,840.00	
St Jude Medical Australia Pty Ltd	Atlas II+ HF V-367	Cardiac Resynchronisation Therapy Defibrillator with V-V Timing Programmability	47,840.00	
St Jude Medical Australia Pty Ltd	Promote RF CRT-D 3213	Cardiac Resynchronisation Therapy Defibrillator with RF Telemetry	47,840.00	
St Jude Medical Australia Pty Ltd	Promote Accel RF CD3215-36	Cardiac Resynchronisation Therapy Defibrillator with RF Telemetry	52,000.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
St Jude Medical Australia Pty Ltd	Promote Accel CD3215-36Q	Cardiac Resynchronisation Therapy Defibrillator with RF Telemetry and SJ4 connector	52,750.00	
St Jude Medical Australia Pty Ltd	Promote Accel CD3215-30	Cardiac Resynchronisation Therapy Defibrillator with RF Telemetry	49,760.00	
St Jude Medical Australia Pty Ltd	Promote Quadra CRT CD3239-40	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy and VectSelect Quartet Programmable LV pulse configuration	52,000.00	
St Jude Medical Australia Pty Ltd	Promote Quadra CRT CD3237-40	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy, VectSelect Quartet Programmable LV pulse configuration and Multisite Pacing	52,000.00	
St Jude Medical Australia Pty Ltd	Promote Quadra CRT CD3239-40Q	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy and VectSelect Quartet Programmable LV pulse configuration and SJ 4 connector	52,750.00	
St Jude Medical Australia Pty Ltd	Promote Quadra CD3237-40Q	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy and VectSelect Quartet Programmable LV pulse configuration plus Multisite Left Ventricular Pacing and SJ4 connector.	52,750.00	
St Jude Medical Australia Pty Ltd	Unify CRT CD3235-40Q	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy and SJ4 connector	52,750.00	
St Jude Medical Australia Pty Ltd	Unify Quadra CRT CD 3251-40	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered plus Quadripolar pacing	52,000.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
St Jude Medical Australia Pty Ltd	Unify Quadra CRT CD 3251-40Q	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy with quadripole pacing and SJ4 connector	52,750.00	

Appendix 4 ICD leads on the Prosthesis list

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Transvenous/steroid/passive leads				
Boston Scientific Australia Pty Ltd	Endotak Reliance S 4-SITE	Passive fixation single coil defibrillation leads & 4-SITE connector	9,000.00	
Boston Scientific Australia Pty Ltd	Endotak Reliance G 4-SITE	Passive fixation dual coil defibrillation leads with ePTFE covered coils & 4-SITE connector	9,000.00	
Boston Scientific Australia Pty Ltd	Endotak Reliance SG 4-SITE	Passive fixation single coil defibrillation leads with ePTFE covered coil & 4-SITE connector	9,000.00	
Boston Scientific Australia Pty Ltd	Endotak Reliance 4-SITE	Passive fixation dual coil defibrillation leads with 4-SITE connector	9,000.00	
Biotronik Australia Pty Ltd	Linox TD	Fractal and steroid coated passive fixation quadripolar ICD lead	9,000.00	
Biotronik Australia Pty Ltd	Linox T	Single-shock coil ICD lead with passive fixation	9,000.00	
Biotronik Australia Pty Ltd	Linox SMART TD	Dual-shock coil ICD lead with passive fixation and hydrophilic coating on lead body	9,000.00	
Guidant Australia Pty Ltd	Endotak Reliance Lead	Passive Dual Coil	9,000.00	
Guidant Australia Pty Ltd	Endotak Reliance SG Passive	Passive Single Coil with GORE ePTFE covered coil	9,000.00	
Guidant Australia Pty Ltd	Endotak Reliance G Passive	Passive Dual Coil with GORE ePTFE covered coil	9,000.00	
Medtronic Australasia Pty Ltd	Medtronic Sprint Quattro Lead Model 6944RV/SVC 65cm; Model 6944RV/SVC 75cm; or Model 6944RV/SVC 100cm; Medtronic Sprint Quattro Lead Model 6944RV/SVC 58cm	Silicone and polyurethane	9,000.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
St Jude Medical Australia Pty Ltd	Durata 7170, 7171	Passive fixation, true bipolar, dual coil, steroid eluting, endocardial defibrillation leads with Optium insulation overlay	9,000.00	
St Jude Medical Australia Pty Ltd	Durata 7170Q, 7171Q and 7172Q	7170Q/7171Q - passive fixation, bipolar, dual coil, 7172Q - passive fixation, bipolar - single coil steroid eluting endocardial defibrillation leads with Optim insulation overlay and SJ4 quadripolar lead connector	9,000.00	
St Jude Medical Australia Pty Ltd	Riata ST Optim 7070/1	Passive Fixation, True bipolar, Dual Coil, Steroid Eluting, Endocardial Defibrillation Leads with Optim insulation overlay	9,000.00	
Transvenous/steroid/active leads				
Biotronik Australia Pty Ltd	Linox SD	Fractal coated and steroid electrode, active fixation quadrapolar	9,000.00	
Biotronik Australia Pty Ltd	Linox S	Active fix RV bipolar fractal coated steroid IC lead	9,000.00	
Biotronik Australia Pty Ltd	Linox SMART SD	Dual-shock coil ICD lead with active fixation helix and hydrophilic coating on lead body	9,000.00	
Biotronik Australia Pty Ltd	Linox SMART SD X	LinoxSmart S DX pentapolar, singlecoil ICD lead with floating atrial dipole. Permanent, transvenous implantation in the right ventricle.	9,000.00	
Guidant Australia Pty Ltd	ENDOTAK RELIANCE G Active	Active Dual Coil with GORE ePTFE covered coils	9,000.00	
Guidant Australia Pty Ltd	ENDOTAK RELIANCE SG Active	Active Single coil with GORE ePTFE covered coils	9,000.00	
Medtronic Australasia Pty Ltd	Medtronic Sprint Quattro Secure Lead Model 6947 58cm; Model 6947 65cm; Model 6947 75cm; Model 6947 100cm	Leads, Defibrillator, Implantable, Silicone, polyurethane, platinised tantalum coils, steroid eluting tip	9,000.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Medtronic Australasia Pty Ltd	Sprint Quattro Secure S	Model 6935, Active Fixation Single Coil Defibrillation Lead	9,000.00	
Medtronic Australasia Pty Ltd	Sprint Quattro Secure 6947M Lead	Active fixation, true bipolar, dual coil defibrillation leads with silicone backfill and DF-4 connector	9,000.00	
Sorin Group	ISOLINE 2CR	Active fixation, steroid eluting, integrated bipolar, dual coil defibrillation lead	9,000.00	
St Jude Medical Australia Pty Ltd	Durata 7120, 7121, 7122, 7130, 7131	Active fixation bipolar, dual-coil/single coil Steroid-eluting Endocardial Defibrillation Leads	9,000.00	
St Jude Medical Australia Pty Ltd	Riata Transvenous tachyarrhythmia Leads Model 1582	Tri-polar Active - Fixation, Steroid Eluting, Single shock Coil Tachyarrhythmia; Lead	9,000.00	
St Jude Medical Australia Pty Ltd	Riata Transvenous Tachyarrhythmia Lead Model 1580, Model 1581	Quadripolar, dual-coil, steroid eluting, active fixation tachyarrhythmia leads	9,000.00	
St Jude Medical Australia Pty Ltd	Riata i Transvenous Tachyarrhythmia Leads Model 1590/1591	Active fixation leads, Steroid Eluting, Dual Shock Coil Defibrillation Lead	9,000.00	
St Jude Medical Australia Pty Ltd	Riata i Transvenous Tachyarrhythmia Lead Model 1592	Active Fixation, Steroid Eluting, Single Shock Coil Defibrillation Lead	9,000.00	
St Jude Medical Australia Pty Ltd	Riata ST 7000/7001/7002	Active-Fixation True-Bipolar, DualCoil, (7002 - Single-Coil) Steroid Eluting Steroid Eluting, Endocardial Defibrillation Leads	9,000.00	
St Jude Medical Australia Pty Ltd	Riata ST Optim 7020/1/2 and 7030/1	7020/1 - Active fixation, true bipolar, 7022 - Active fixation, true bipolar - single coil, 7030/1 - Active fixation, integrated bipolar, dual coil steroid eluting endocardial defibrillation leads with Optim insulation overlay	9,000.00	
Boston Scientific Australia Pty Ltd	Endotak Reliance SG 4-SITE	Active fixation single coil defibrillation leads with ePTFE covered coil & 4-SITE connector.	9,000.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Boston Scientific Australia Pty Ltd	Endotak Reliance 4-SITE	Active fixation dual coil defibrillation leads with 4-SITE connector	9,000.00	
Boston Scientific Australia Pty Ltd	Endotak Reliance S 4-SITE	Active fixation single coil defibrillation leads & 4-SITE connector	9,000.00	
Boston Scientific Australia Pty Ltd	Endotak Reliance G 4-SITE	Active fixation dual coil defibrillation leads with ePTFE covered coils & 4-SITE connector	9,000.00	
St Jude Medical Australia Pty Ltd	Durata 7120Q, 7121Q and 7122Q	7120/1Q - Adtive fixation, true bipolar; 7122Q - Active fixation true bipolar - single coil steroid eluting endocardial defibrillation leads with Optim insulation overlay and SJ4 quadripolar lead connector	9,000.00	
St Jude Medical Australia Pty Ltd	Riata ST Optim 7020Q, 7021Q, 7022Q	7020/1Q - Active fixation, true bipolar; 7022Q - Active fixation true bipolar - single coil steroid eluting endocardial defibrillation leads with Optim insulation overlay and SJ4 quadripolar lead connector	9,000.00	

Appendix 5 Pacemaker leads on the Prosthesis list

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Transvenous, multi-polar, passive, steroid, left ventricular				
Biotronik Australia Pty Ltd	Corox OTW BP; Corox OTW-S BP	Bipolar, steroid eluting coronary sinus pacing lead with fractal coating	6,240.00	
Biotronik Australia Pty Ltd	Corox OTW-L BP	Corox OTW-L BP is a bipolar coronary sinus lead, intended for permanent implantation in the venous system and left ventricular pacing with appropriate single or multi chamber cardiac pacemakers or ICDs as part of cardiac resynchornisation therapy (CRT)	6,240.00	
Guidant Australia Pty Ltd	Acuity Steerable Lead	Bipolar, passive fixation	6,240.00	
Guidant Australia Pty Ltd	Easytrak 2, Model 4514, 4515, 4516, 4517, 4518, 4519, 4520	Bipolar, passive fixation	6,240.00	
Guidant Australia Pty Ltd	Easytrak 2 Is-1 Lead - Models 4542, 4543 & 4544	Bipolar, passive fixation	6,240.00	
Guidant Australia Pty Ltd	Easytrak 3 Lead - Models 4521, 4522, 4523, 4524, 4525, 4526 and 4527	Bipolar, passive fixation	6,240.00	
Guidant Australia Pty Ltd	Easytrak 3 IS-1 Lead	Bipolar, passive fixation	6,240.00	
Medtronic Australasia Pty Ltd	Attain OTW Model 4194 Lead	Model 4194	6,240.00	
	Attain Ability 4196 LV Lead	Over the wire dual electrode left ventricular lead	6,240.00	
Medtronic Australasia Pty Ltd	Attain Ability Plus 4296	Over the wire electrode left ventricular lead	6,240.00	
Medtronic Australasia Pty Ltd	Attain Ability Straight 4396	Over the wire dual left ventricular lead	6,240.00	
St Jude Medical Australia Pty Ltd	QuickSite 1056T	Bipolar Steroid-Eluting, Titanium Nitride Coated Electrodes Guidewire/Stylet-Placed Keft Heart Lead with Fast-Pass Coating	6,240.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Medtronic Australasia Pty Ltd	QuickSite XL 1058T	Bipolar, Steroid-Eluting, Titanium Nitride Coated Electrodes, Guidewire/Stylet-Placed Left Heart Lead with Fast-Pass Coating	6,240.00	
Medtronic Australasia Pty Ltd	Quick Flex µ 1258T	4F Bipolar Left Ventricular Pacing Lead	6,240.00	
Medtronic Australasia Pty Ltd	Quartet 1458Q	Quadripolar, Left Ventricular Pacing Lead with Optim Lead Insulation	6,240.00	
Transvenous, active, steroid, left ventricular				
Medtronic Australasia Pty Ltd	Attain StarFix LV Lead	Over the wire left Ventricular Lead	5,000.00	
Transvenous, uni-polar, passive, steroid, left ventricular				
Biotronik Australia Pty Ltd	Corox OTW UP Steroid	Unipolar, steroid eluting coronary sinus pacing lead	3,120.00	
Boston Scientific Australia Pty Ltd	Acuity Spiral	Unipolar passive fixation	3,120.00	
Medtronic Australasia Pty Ltd	Attain Over the Wire Model 4193	Titanium, polyurethane	3,120.00	
St Jude Medical Australia Pty Ltd	QuickSite Model 1056K	Unipolar, Steroid Eluting, Titanium Nitride Electrode, Guidewire/Styletplaced Left Heart Lead with Fast-Pass Coating	3,120.00	
Transvenous, bi-polar, passive, steroid, right ventricular/atrial				
Biotronik Australia Pty Ltd	Selox ST	Transvenous Bipolar Passive Steroid Ventricular Pacing Lead, fractal coated	1,248.00	
Biotronik Australia Pty Ltd	Selox JT	Sub 6F, steroid-eluting, transvenous, endocardial, bipolar passive-fixation lead that carries a J-shaped distal end	1,248.00	
Biotronik Australia Pty Ltd	Siello JT	Sub 6F, steroid-eluting, transvenous, endocardial, bipolar passive-fixationlead that carries a J-shaped distal end	1,248.00	
Biotronik Australia Pty Ltd	Siello T	Sub 6F, steroid-eluting, transvenous, endocardial, bipolar passive-fixation lead	1,248.00	
Guidant Australia Pty Ltd	Guidant Aust Selute Picotip Steroid Eluting Bipolar Lead	Model 4035, Model 4064	1,248.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Guidant Australia Pty Ltd	Fineline II Sterox IROX Lead	Bipolar passive fixation	1,248.00	
Guidant Australia Pty Ltd	Fineline II Sterox IROX Lead	Bipolar passive fixation	1,248.00	
Guidant Australia Pty Ltd	Fineline II Sterox IROX Lead	Bipolar, passive fixation	1,248.00	
Medtronic Australasia Pty Ltd	Medtronic Capsure Z Novus Model 5554 Pacing Lead	Silicone; Contents: 1 x lead with anchoring sleeve, stylet & guide, 1 x vein lifter, 2 x fixation tools, extra stylets	1,248.00	
Medtronic Australasia Pty Ltd	Medtronic Capsure SP Novus Model 5092	Bipolar, steroid, pasive fixation pacing lead	1,248.00	
Medtronic Australasia Pty Ltd	Medtronic Capsure SP Novus Model 5594 Lead 30cm	Bipolar, steroid, passive fixation pacing lead	1,248.00	
Medtronic Australasia Pty Ltd	Medtronic Capsure Z Novus Model 5054 Pacing Lead	Silicone; Contents: 1 x lead with anchoring sleeve, stylet & guide, 1 x vein lifter, 2 x fixation tools, extra stylets	1,248.00	
Medtronic Australasia Pty Ltd	CapSure Sense pacemaker lead Models 4074 & 4574	Bipolar, steroid, passive fixation pacing lead	1,248.00	
Sorin group	Petite ER Series	Steroid eluting passive fixation pacing lead. Permanent pacing lead, Petite ER series, is indicated for the pacing and sensing of the ventricle. This permanent pacing lead is used in conjunction with an IS-1 compatible implantable pulse generator (pacemaker). Permanent pacing lead, Petite ERJ series, is indicated for the pacing and sensing of the atrium. This permanent pacing lead is used in conjunction with an IS-1 compatible implantable pulse generator (pacemaker).	1,248.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Sorin group	Refino ER Series	Steroid eluting passive fixation pacing lead. Permanent pacing lead, Model Refino ER, is indicated for the pacing and sensing of the ventricle. This permanent pacing lead is used in conjunction with an IS-1 compatible implantable pulse generator (pacemaker). Permanent pacing leads, Models Refino ERJ and ERJU are indicated for the pacing and sensing of the atrium. This permanent pacing lead is used in conjunction with and IS-1 compatible implantable pulse generator (pacemaker).	1,248.00	
St Jude Medical Australia Pty Ltd	Isoflex S, Models 1646T, 1642T and 1636T	endocardial, Steroid Eluting, Silicone, Passive Fixation Pacing Leads with Fast-Pass Coating	1,248.00	
St Jude Medical Australia Pty Ltd	Isoflex P 1644T and 1648T	Endocardial, Steroid Eluting, Polyurethane, Passive-Fixation Bipolar Pacing Leads with Fast-Pass Coating	1,248.00	
St Jude Medical Australia Pty Ltd	Isoflex 1944T & 1948T	Passive-Fixation, Bipolar, Steroid Eluting, Endocardial Pacing Lead with Optim insulation	1,248.00	
Guidant Australia Pty Ltd	Guidant Aust Selute Picotip VDD Lead	VDD bipolar, passive fixation	1,544.00	
Medtronic Australasia Pty Ltd	Medtronic Capsure VDD2 Model 5038 AV Pacing Lead	Silicone; Contents: 1 x lead with anchoring sleeve, stylet & guide, 1 x vein lifter, 2 x fixation tools, extra stylets	1,544.00	
Transvenous, bi-polar, active, steroid, right ventricular/atrial				
Biotronik Australia Pty Ltd	Dextrus (marketed by Boston Scientific)	Bipolar, silicone, active fixation, steroid eluting, pacing lead	1,248.00	
Biotronik Australia Pty Ltd	Selox SR	Lead, pacemaker, implantable, endocardial	1,248.00	
Biotronik Australia Pty Ltd	Setrox S	Bipolar active fixation lead with fractal coated and steroid eluting electrode	1,248.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Biotronik Australia Pty Ltd	Siello S	Bipolar active fixation lead with fractal coated and steroid eluting electrode	1,248.00	
Biotronik Australia Pty Ltd	Safio S	Steroid eluting active fixation pacemaker lead with an electrically active extendable/ retractable screw for fixating the lead in the myocardium. The lead body is insulated in Silicone. The entire lead is conditionally safe to be used in a MRI system.	1,248.00	
Guidant Australia Pty Ltd	Fineline II EZ Sterox IROX Lead	Bipolar, active fixation	1,248.00	
Guidant Australia Pty Ltd	Fineline II EZ Sterox IROX Lead	Bipolar, active fixation	1,248.00	
Guidant Australia Pty Ltd	Flextend Lead Models 4086, 4087 & 4088	Bipolar, active fixation	1,248.00	
Medtronic Australasia Pty Ltd	CapSureFix Novus Model 4076 Pacing Lead	Active fixation pacemaker lead	1,248.00	
Medtronic Australasia Pty Ltd	CapSure Fix MRI Pacing Lead	Model 5086, MRI Conditional	1,248.00	
Medtronic Australasia Pty Ltd	Medtronic Capsurefix Model 5568 Pacing Leads	Bipolar, steroid, active fixation pacing lead	1,215.00	
Medtronic Australasia Pty Ltd	Medtronic Capsurefix Novus Model 5076 Pacing Lead	Silicone; Contents: 1 x lead with anchoring sleeve, stylet & guide, 1 x vein lifter, 2 x fixation tools, extra stylets	1,248.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
Sorin Group	Physique ER Series	Steroid eluting active fixation pacing lead. Permanent pacing lead, Model Physique ER is indicated for the pacing and sensing of the ventricle or atrium. This permanent pacing lead is used in conjunction with a compatible implantable pulse generator. Permanent pacing lead, Model Physique ERJ is indicated for the pacing and sending of the atrium. This permanent pacing lead is used in conjunction with a compatible implantable pulse generator (pacemaker) IS-1	1,248.00	
Sorin Group	PY2-ER Series	Steroid eluting active fixation pacing lead. Permanent pacing lead PY2-ER series, is indicated for pacing and sensing of the ventricle and/or atrium of the heart. This lead is used in conjunction with a compatible implantable pulse generator (Pacemaker)	1,248.00	
St Jude Medical Australia Pty Ltd	Tendril SDX Models 1688T and 1688TC	Endocardial Steroid-Eluting Active Fixation Pacing Lead	1,248.00	
St Jude Medical Australia Pty Ltd	Tendril ST 1788T/TC and 1782TC	Endocardial Bipolar Steroid-Eluting Active Fixation Pacing Leads	1,248.00	
St Jude Medical Australia Pty Ltd	Tendril ST 1888TC and 1882TC	Endocardial Bi-polar Steroid-Eluting Active Fixation Pacing Leads	1,248.00	
St Jude Medical Australia Pty Ltd	Tendril STS 1988TC and 2088TC	Endocardial Bi-polar Steroid-Eluting Additive Fixation Pacing Leads	1,248.00	
St Jude Medical Australia Pty Ltd	Tendril MRI LPA 1200M	The Tendril MRI™ lead, Model LPA1200M, is an MR Conditional, bipolar, steroid-eluting, active fixation implantable pacing lead with Optim™ insulation.	1,248.00	
St Jude Medical Australia Pty Ltd	OptiSense 1699T/1699TC	Endocardial, Bi-polar Active-fixation Pacing Leads with Optim Insulation	1,248.00	

Sponsor	Product name	Description	Min benefit ($)	Max benefit ($)
St Jude Medical Australia Pty Ltd	OptiSense Model 1999	Active-Fixation Bipolar, Steroid Eluting, endocardial, atrial pacing lead with Optim insulation	1,248.00	
Medtronic Australasia Pty Ltd	Model 3830 PACING LEADS	Active fixation pacemaker leadComposition: Insulation is polyurethane, Electrodes are Titanium Nitride coated Platinum, the screw is steroid-coated	2,600.00	