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| 1223Final 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:

**P**atients – specification of the characteristics of the patients in whom the intervention is to be considered for use;

**I**ntervention – specification of the proposed intervention

**C**omparator – specification of the therapy most likely to be replaced by the proposed intervention

**O**utcomes – 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)



### 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

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| Category 3 – Therapeutic Procedures |
| MBS 38368PERMANENT 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

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| Category 3 – Therapeutic Procedures |
| MBS 38371PERMANENT 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

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| Category 3 – Therapeutic Procedures |
| MBS 38654PERMANENT 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, 38654T8.70 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

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| Category 3 – Therapeutic Procedures |
| MBS 38365PERMANENT 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

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| Category 3 – Therapeutic Procedures |
| MBS 38350SINGLE 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

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| Category 3 – Therapeutic Procedures |
| MBS 38356DUAL 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

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| --- | --- | --- | --- | --- | --- | --- |
| **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 ≤ 35%) and QRS duration ≥ 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 ≤ 30% and QRS duration ≥ 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 proposedPERMANENT 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% = $235.45Item 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 proposedPERMANENT 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 proposedPERMANENT 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% = $883.65Item 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 38384AUTOMATIC 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 38387AUTOMATIC 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% = $244.70NOTE: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

|  |  |
| --- | --- |
|  | **Comparative effectiveness versus comparator** |
| Superior | Non-inferior | Inferior |
| **Comparative safety versus comparator** | Superior | CEA/CUA | CEA/CUA | Net clinical benefit | CEA/CUA |
| Neutral benefit | CEA/CUA\* |
| Net harms | None^ |
| Non-inferior | **CEA/CUA** | CEA/CUA\* | None^ |
| Inferior | Net clinical benefit | CEA/CUA | None^ | None^ |
| Neutral benefit | CEA/CUA\* |
| Net harms | None^ |

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? | - | - | - | - | - | - |
| 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 mortalitySudden cardiac deathHospitalisation for heart failurePatient-related quality of lifeAll adverse events(See above for complete lists of outcomes of interest) | Length of hospitalisationInitial and follow-up testsUse of pharmaceuticals before/after device implantation, including any definition of ‘optical medical therapy’Use and type of anaesthesia or sedationOther 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 & lS-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 lS-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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |