NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

FINAL SCOPE

ENDURALIFE-powered CRT-D devices for the treatment of heart failure

1 Technology

1.1 Description of the technology

The ENDURALIFE battery technology is designed to provide extended longevity in Boston Scientific cardiac resynchronisation therapy-defibrillator (CRT-D) devices compared to similar previous and current CRT-D devices. ENDURALIFE battery technology uses a lithium manganese dioxide (Li/MnO_2) battery chemistry, which is reported to be less susceptible to the variations in voltage and resistance associated with early battery depletion. CRT-D devices with ENDURALIFE battery technology are also designed to use less current than standard devices and are packaged in devices that are smaller and thinner than previous CRT-D devices. The ENDURALIFE battery technology is designed to be used only in Boston Scientific CRT-D and ICD devices.

1.2 Regulatory status

The ENDURALIFE-powered CRT-D devices received a CE mark in February 2008 for treatment of heart failure. ENDURALIFE battery technology was first incorporated into the COGNIS CRT-D platform in February 2008. The ENDURALIFE battery technology brand was launched in early 2015 but the technology itself has been in place in all Boston Scientific CRT-D devices since 2008, under 3 separate CE marks.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- Extended longevity devices could help improve patient experience by increasing the time between replacements (and hence reducing the number of avoidable replacement surgeries) a patient may be faced with in their lifetime.
- A reduction in replacement rates could be particularly beneficial for heart failure patients who are already very unwell and may have difficulty lying down for extended periods of time.
- A reduction in the number of replacement surgeries can reduce the risk of complications which is higher in replacement procedures than in de novo (initial) implant procedures. The increased risk of complications and infections can have a measurable impact on morbidity and mortality

The benefits to the healthcare system claimed by the sponsor are:

- A reduced chance of needing earlier replacement of the CRT-D device. The reduction of avoidable replacement procedures will lead to savings for the healthcare system - reduction in hospital admissions, bed days, and procurement costs. Preliminary estimates suggest it could represent £33 million over 6 years.
- More efficient use of resources as reduced replacement rates will allow more new patients to be implanted within the same resource constraints thus supporting the implementation of NICE's technology appraisal guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure and bridging the gap with recommended levels of CRT-D implants in the UK.
- A reduction in costs associated with replacement such as post-operative complications and infections.

1.4 Relevant diseases and conditions

The ENDURALIFE-powered CRT-D devices are intended for use in patients with heart failure, specifically those who are at risk of sudden cardiac death.

Heart failure is caused by any structural or functional cardiac disorder that impairs the heart's ability to function efficiently as a pump to support the circulation. It usually develops because the heart muscle is either too weak or too stiff. This condition can predispose to the development of life-threatening heart rhythm disturbances (arrhythmias) that originate from the main heart pumping chambers (ventricles) and put the patient at risk of sudden cardiac death. Heart failure affects about 900,000 people in the UK. The condition develops in people of all ages, but is most common in the elderly – more than half of all people with heart failure are over the age of 75. Heart failure can result from a number of other serious cardiac conditions, including coronary heart disease, valvular heart disease and high blood pressure (hypertension). The Hospital Episode Statistics (HES) database indicates that there were approximately 4,282 de novo CRT-Ds fitted in England in the 12 months to September 2015.

Heart failure has a poor prognosis and an estimated 30–40% of patients will die within a year of diagnosis. Although prognosis is poor, there is evidence of a trend towards improvement with contemporary treatment. The 6 month mortality rate decreased from 26% in 1995 to 14% in 2005.

The implantation of CRT-D devices may be associated with procedural complications including local infection (Sohail et al. 2010). CRT-D device replacement procedures requiring lead replacement or upgrade are associated with a 4% risk of major complications requiring an intervention, procedure or hospitalisation for management and a minor complication rate of 7.4% (Poole et al, 2010).

1.5 Current management

The NICE guideline on chronic heart failure in adults covers the overall management. The NICE technology appraisal on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure recommends CRT-D as an adjunctive treatment option for people with

heart failure on optimal medical therapy who have left ventricular dysfunction with a left ventricular ejection fraction (LVEF) of 35% or less as specified in table 1 (adapted from The NICE technology appraisal on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure https://www.nice.org.uk/guidance/ta314/chapter/1-Guidance) .

Table 1 Treatment options with CRT-D for people with heart failure who have left ventricular dysfunction with an LVEF of 35% or less (according to NYHA class, QRS duration and presence of LBBB)

	NYHA class			
QRS interval	I	II	III	IV
<120 milliseconds				
120–149 milliseconds without LBBB				
120–149 milliseconds with LBBB		✓	✓	
≥150 milliseconds with or without LBBB	✓	✓	✓	

NYHA - The New York Heart Association Functional Classification provides a simple way of classifying the extent of heart failure.
QRS - The QRS complex is a name for the combination of three of the graphical deflections seen on a typical electrocardiogram.
LBBB - Left bundle branch block is a cardiac conduction abnormality seen on the electrocardiogram (ECG).

Implantation of an ENDURALIFE-powered CRT-D device uses standard techniques. Three pacing leads are inserted into the heart transvenously usually via the cephalic or subclavian veins. The leads are positioned to pace the right atrium, the right ventricle and the left ventricle. The leads are attached to the ENDURALIFE-powered CRT-D implantable pulse generator that is then placed in a subcutaneous pocket that is fashioned in the anterior chest wall below the clavicle.

Clinical experts have stated that people with an implanted CRT-D are typically followed up by physiologists in a technical device clinic and either a routine cardiology clinic or specialist heart failure clinic. At each attendance, the patient's clinical status is noted and device interrogation incorporates: the testing of the pacing function; the defibrillation leads including sensing and pacing thresholds; lead impedance; the percentage of time spent pacing; and

the occurrence of arrhythmias. The rate of battery depletion and therefore the anticipated remaining life span of the device are also noted.

Remote device monitoring systems, which may reduce the need for device clinical attendances, are available for all CRT-D devices, including those with ENDURALIFE battery technology.

2 Reasons for developing guidance on ENDURALIFE-powered CRT-D devices for heart failure

The Committee considered that the ENDURALIFE-powered CRT-D devices could plausibly offer significant benefits for patients with heart failure and for the healthcare system, as compared with other CRT-D devices.

The Committee considered that the class of ENDURALIFE-powered CRT-D devices should be evaluated, rather than any individual device.

The committee noted that this is an area of rapid technological change but were informed by experts that the ENDURALIFE battery technology represents a significant step-change in CRT-D device development.

3 Statement of the decision problem

	Final scope issued by NICE
Population	Patients undergoing CRT-D device implantation for heart failure in line with NICE Technology Appraisal 314
Intervention	CRT-D devices with ENDURALIFE battery technology
Comparator(s)	• CRT-D devices not incorporating ENDURALIFE battery technology (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: • Device survival • Battery survival (or time to battery depletion) • CRT-D component failure • Number of invasive procedures including replacement surgeries • Incidence of complications due to replacement procedures for battery depletion and/or CRT-D component failure (as per definitions in the REPLACE registry) • Inpatient admissions; bed days (related to interventions) • Death • Patient satisfaction • Quality of life • Device-related adverse events
Cost analysis	Comparator(s): • CRT-D devices not incorporating ENDURALIFE battery technology. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Scenario and sensitivity analyses will be undertaken to address uncertainties in the model parameters including: - Warranty periods - Differences in performance between older and newer devices - Differences in battery performance between older and newer devices
Subgroups to be considered	None
Special considerations, including those related to equality	Heart failure can affect people of all ages, but it is more common in older people – more than half of all people with heart failure are over the age of 75. Older people are protected groups under the Equality Act 2010.
Special	

considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
	If yes please provide further details here:	

4 Related NICE guidance

Published

- Acute heart failure: diagnosis and management NICE guideline CG187 (2014). Available from: www.nice.org.uk/guidance/cg187
- Chronic heart failure in adults: management NICE guideline CG108 (2010). Available from: www.nice.org.uk/guidance/cg108
- Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure NICE technology appraisal guidance 314 (2014). Available from: www.nice.org.uk/guidance/ta314
- Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults NICE interventional procedure guidance 482 (2014). Available from: www.nice.org.uk/guidance/ipg482
- Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure NICE interventional procedure guidance 463 (2013). Available from: www.nice.org.uk/guidance/ipg463
- Chronic heart failure in adults (2011) NICE quality standard 9
- Acute heart failure: diagnosis and management in adults (2015) NICE quality standard 103
- The AutoPulse non-invasive cardiac support pump for cardiopulmonary resuscitation (2015) NICE medtech innovation briefing 18.
- Services for people with chronic heart failure (2011) NICE commissioning guide 39

- Structural heart defects (2015) NICE pathway
- Acute heart failure (2015) NICE pathway
- Chronic heart failure (2015) NICE pathway
- Heart rhythm conditions (2014) NICE pathway

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Chronic heart failure NICE quality standard. Publication expected February 2016
- Heart failure – sacubitril valsartan. NICE technology appraisal. Publication expected May 2016.
- CareLink service for remote monitoring of people with cardiac devices. NICE Medtech Innovation Briefing. Publication expected May 2016.
- LATITUDE NXT for monitoring cardiac devices at home. NICE Medtech Innovation Briefing. Publication expected May 2016.
- Chronic heart failure NICE guideline. Publication expected March 2018
- Heart failure (acute) – serlaxin. NICE technology appraisal. Publication to be confirmed.
- Heart failure (acute decompensated) – nesiritide. NICE technology appraisal. Publication date to be confirmed.
- Implantable vagus nerve stimulator in heart failure. NICE technology appraisal. Publication to be confirmed.

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- British Cardiovascular Intervention Society

- British Cardiovascular society
- British Geriatric Society
- Heart Rhythm UK
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Physicians of Edinburgh
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh
- Royal College of Surgeons of England
- Society for Cardiothoracic Surgery in Great Britain and Ireland
- The British Society for Heart Failure

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- British Cardiovascular Intervention Society
- British Cardiovascular society
- British Geriatric Society
- Heart Rhythm UK
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Physicians of Edinburgh
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh
- Royal College of Surgeons of England
- Society for Cardiothoracic Surgery in Great Britain and Ireland
- The British Society for Heart Failure

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Arrhythmia Alliance
- Atrial Fibrillation Association
- British Cardiac Patients Association
- British Heart Foundation
- Cardiac Risk in the Young (CRY)
- Cardiovascular Care Partnership UK (formerly Heartcare Partnership)
- Pumping Marvellous Foundation
- Royal College of Surgeons Patient Liaison Group
- The Ashley Jolly SADS UK Trust (SADS UK)
- The Somerville Foundation (formerly Grown Up Congenital Heart Patients Association)
- UK Health Forum (formerly National Heart Forum (UK))