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Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Policy Position PP151

Complex Devices: Implantable Cardioverter Defibrillators and Cardiac Resynchronisation Therapy for arrhythmias and heart failure

January 2019

Version 1.0

Document information	
Document purpose	Policy Position
Document name	**Complex Devices**: Implantable Cardioverter Defibrillators and Cardiac Resynchronisation Therapy for arrhythmias and heart failure
Author	Welsh Health Specialised Services Committee
Publication date	January 2019
Commissioning Team	Cardiac
Target audience	Chief Executives, Medical Directors, Directors of Finance, Interventional Cardiologists, Cardiologists, Cardiac Surgeons
Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
Document No	PP151
Review Date	March 2025

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission Complex Devices, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) for arrhythmias and heart failure in accordance with the criteria outlined in this document.

In creating this policy WHSSC has reviewed the relevant guidance issued by National Institute of Health and Care Excellence (NICE) and has concluded that Complex Devices, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) for arrhythmias and heart failure could be made available.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy position statement.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy position statement.

1. Introduction

This Policy Position has been developed for the planning and delivery of Complex Devices, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) for arrhythmias and heart failure for people resident in Wales. This proposed service will only be commissioned by the Welsh Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain language summary

Arrhythmia is a condition where the heart contracts irregularly, or at a faster or slower pace than normal. It is caused by an abnormality in the myocardial tissue (heart muscle) or in the electrical conduction system of the heart. Many patients presenting with arrhythmias, with or without symptoms, are treated with anti-arrhythmic drug therapy.

Heart failure is caused by any structural or functional disorder that impairs the heart's ability to function efficiently as a pump to support circulation. It causes breathlessness, fatigue and fluid retention. Treatment of heart failure aims to improve life expectancy and quality of life. Management of chronic heart failure in adults in primary and secondary care is initially treated with medication. However, as the condition becomes more severe, heart function and symptoms may no longer be controlled by medication alone, and can be improved by the implantation of a heart rhythm device which can sense and stimulate the atria and right and left ventricles (the chambers in the heart) independently. These devices are known as cardiac resynchronisation therapy pacing (CRT-P) devices or cardiac resynchronisation therapy defibrillator (CRT-D) devices.

1.2 Aims and Objectives

This Policy Position aims to define the commissioning position of WHSSC on the use of Complex Devices, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) for arrhythmias and heart failure.

The objectives of this policy are to:

- ensure commissioning for the use of Complex Devices, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) for arrhythmias and heart failure is evidence based
- ensure equitable access to Complex Devices, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) for arrhythmias and heart failure
- define criteria for people with arrhythmias and heart failure to access treatment
- improve outcomes for people with arrhythmias and heart failure.

1.3 Background

Implantable Cardioverter Defibrillators (ICD's) are treatment to prevent sudden cardiac death in patients at risk of life threatening arrhythmia. Arrhythmia is a condition where the heart contracts irregularly, or at a faster or slower pace than normal. Arrhythmias that arise from ventricles (ventricular arrhythmias) can occur unexpectedly and can cause sudden death.

ICD implant may be either as primary prevention (for individuals at high risk of a first life threatening arrhythmic event) or as secondary prevention (patients at risk of further life threatening arrhythmic events).

NICE Technology Appraisal Guidance on Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure[1], (TA314) defines ICD as:

> *"Implantable cardioverter defibrillators are small, battery powered devices that are implanted under the skin just below the collarbone, with leads inserted in the heart. The devices operate by sensing the electrical activity of the heart, and delivering electrical impulses or shocks to restore normal rhythm if necessary".*

Cardiac Resynchronisation Therapy (CRT) is treatment for heart failure. CRT may be either bi-ventricular pacing only (CRT-P) or bi-ventricular pacing with an ICD (CRT-D) in case of severe arrhythmia. The CRT is to improve the heart's pumping efficiency by re-synchronising the pumping action of the chambers.

NICE Technology Appraisal Guidance on Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure[1], (TA314) defines CRT as:

> *"Cardiac resynchronisation therapy with pacing (CRT-P), also known as bi-ventricular pacing, involves implanting a pulse generator in the upper chest. Three leads connect this to the right atrium and both ventricles, and the device resynchronises the contraction of the ventricles, thereby improving the heart's pumping efficiency.*
>
> *Cardiac resynchronisation therapy with a defibrillator device (CRT-D) combines ICD and CRT-P devices. A CRT-D device defibrillates the heart internally in the event of an acute*

[1] Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure | Guidance and guidelines | NICE

arrhythmic event and improves ventricular efficiency and blood flow."

1.4 What NHS Wales has decided

WHSSC has carefully reviewed the relevant guidance issued by National Institute of Health and Care Excellence (NICE). We have concluded that there is enough evidence to fund the use of Complex Devices, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) for arrhythmias and heart failure, within the criteria set out in section 2.1.

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee propose to approve funding of Complex Devices, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) for arrhythmias and heart failure in-line with the criteria identified in the policy.

2.1 Inclusion Criteria

The broad clinical indications for considering complex device treatment are patients with:

- cardiomyopathy or an inherited cardiac condition who are at risk of sudden cardiac death from ventricular arrhythmia
- heart failure and left ventricular dysfunction
- heart failure and left ventricular dysfunction

2.1.1 Arrhythmia

Secondary Prevention ICD for treating people with serious ventricular arrhythmia who without a treatable cause have:

- survived a cardiac arrest caused by either ventricular tachycardia (VT) or ventricular fibrillation

or

- spontaneous sustained VT causing syncope or significant haemodynamic compromise

or

- sustained VT without syncope or cardiac arrest, and also have an associated reduction in left ventricular ejection fraction (LVEF) of 35% or less but their symptoms are no worse than class III of the New York Heart Association (NYHA) functional classification of heart failure.

Primary Prevention ICD for treating people who:

- have a familial cardiac condition with a high risk of sudden death, such as long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia

or

- have undergone surgical repair of congenital heart disease and have poor left ventricular function with unexplained syncope.

2.1.2 Heart Failure

WHSSC will commission Implantable Cardioverter Defibrillators (ICDs), Cardiac Resynchronisation Therapy (CRT) with defibrillator (CRT-D) or CRT with pacing (CRT-P) as treatment options for:

- People with heart failure who have left ventricular dysfunction with a left ventricular ejection fraction (LVEF) of 35% or less as specified in table 1.

Table 1: NYHA Classification

	NYHA class			
QRS interval	**I**	**II**	**III**	**IV**
<120 milliseconds	**ICD if there is a high risk of sudden cardiac death**			**ICD and CRT not clinically indicated**
120–149 milliseconds without LBBB	ICD	ICD	ICD	CRT-P
120–149 milliseconds with LBBB	ICD	CRT-D	CRT-P or CRT-D	CRT-P
≥150 milliseconds with or without LBBB	CRT-D	CRT-D	CRT-P or CRT-D	CRT-P
LBBB, left bundle branch block; NYHA, New York Heart Association				

2.2 Designated Providers

North Wales

The complex devices service providers for North Wales are:

- Betsi Cadwaladr University Health Board (Wrexham Maelor Hospital and at Bangor Hospital)
- Liverpool Heart and Chest Hospital NHS Foundation Hospital.

New and follow-up patients are referred to the local service at either Wrexham or Bangor. Patients requiring complex device implantation following cardiac surgery or for device related intervention that requires tertiary centre expertise (e.g. lead removal), are referred to Liverpool Heart and Chest Hospital.

South Wales

The complex devices service providers for South Wales are:

- Abertawe Bro Morgannwg University Health Board (Morriston Hospital Swansea and the Princess of Wales Hospital, Bridgend)
- Cardiff and Vale University Health Board (University Hospital of Wales)
- Cwm Taf University Health Board (Royal Glamorgan Hospital)

Patients requiring complex device implantation following cardiac surgery or for device related intervention that requires tertiary centre expertise (e.g. lead removal), are referred to Cardiff and Vale University Health Board (University Hospital of Wales) or Abertawe Bro Morgannwg University Health Board (Morriston Hospital).

Mid Wales

In addition to the South Wales providers, the complex devices service providers including lead extraction for Mid Wales are:

- North Staffordshire NHS Foundation Trust
- University Hospitals Birmingham NHS Foundation Trust.

Wye Valley NHS Trust provide a CRT-P service only to Mid Wales

2.3 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.4 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Patient Pathway (Annex i)

Please see annex i.

2.6 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: http://www.whssc.wales.nhs.uk/individual-patient-funding-requests

2.7 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

2.8 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinician considering treatment should:

- discuss all the alternative treatment with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

3. Documents which have informed this policy

The following documents have been used to inform this policy:

- **National Institute of Health and Care Excellence (NICE) guidance**
  - Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure. Technology Appraisal Guidance, TA314. June 2014.

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

4. Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

5. Putting Things Right: Raising a Concern

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

6. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Annex i Patient Pathway

Elective Referral Pathway