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Arbenigol Cymru (PGIAC)
Welsh Health Specialised
Services Committee (WHSSC)

Specialised Services Policy Position PP104

Personalised External Aortic Root Support (PEARS) for surgical management of enlarged aortic root (adults)

March 2019

Version 1.0

Document information	
Document purpose	Policy Position
Document name	Personalised External Aortic Root Support (PEARS) for surgical management of enlarged aortic root (adults)
Author	Welsh Health Specialised Services Committee
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Target audience	Chief Executives, Medical Directors, Directors of Finance, Cardiothoracic Surgeons, Paediatric Cardiologists, Cardiologists
Description	NHS Wales will not routinely commission this specialised service in accordance with the criteria described in this policy
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Contents

1.	Policy Statement.....	4
1.1	Plain language summary.....	4
1.2	About the treatment.....	5
2.	Aims and Objectives.....	6
3.	Documents which have informed this policy	6
4.	Date of Review	6
5.	Putting Things Right: Raising a Concern.....	7
6.	Equality Impact and Assessment.....	8
Annex i	Codes.....	9
Annex ii	Abbreviations and Glossary	10

1. Policy Statement

Welsh Health Specialised Services Committee (WHSSC) have developed a Policy Position to not routinely commission Personalised External Aortic Root Support (PEARS) for surgical management of enlarged aortic root (adults) for patients resident in Wales.

In creating this policy WHSSC has reviewed the relevant guidance issued by NHS England. It has considered the place for this treatment in current clinical practice and whether the research has shown a benefit to patients. WHSSC has concluded that there is not enough evidence to make the treatment available at this time.

1.1 Plain language summary

About enlarged aortic root

The aorta is the main blood vessel that carries blood from the heart. The 'aortic root' is the section of the aorta attached to the heart. The aim of personalised external aortic root support (PEARS) is to stop the aorta getting larger and then splitting (rupture).

Most patients with enlarged aortic roots are adults and children with 'Marfan syndrome'.

Marfan syndrome is a genetic illness of the connective tissues – these are tissues that maintain the structure of the body and support internal organs and other tissues.

Other less common causes of enlarged aortic roots are:

- Bicuspid aortic valve disease where the aortic valve (the valve between the heart and the main blood vessel coming out of the heart) has only two leaflets instead of the usual three. The valve may work normally for years without the patient being aware of the problem – often until they reach their 50's or 60's.
- Adults that have had complex heart surgery as a baby.
- Adults that have had the Ross operation – a heart operation where the aortic valve is replaced with the person's own pulmonary valve (the valve between the heart and the main vessel which moves blood from the heart to the lungs). The pulmonary valve is replaced at the same time with a donor pulmonary valve.

1.2 About the treatment

PEARS is specially designed for each patient. It is a 3D printed 'sleeve' of medical grade knitted mesh. It supports the aorta, including the aortic root and the part of the aorta closest to the heart ('ascending aorta').

- It is made using computer-aided design from a special CT scan of the patient.
- This scan is used to make an individualised copy of each patient's own ascending aorta and aortic root.
- A sleeve of soft, flexible fabric can then be made around the copy.
- This is then fitted onto the patient's aorta during surgery.

PEARS is suitable for enlarged aortic roots measuring 40-55mm in diameter, and growing by >5mm per year, as measured by echocardiography.

NICE has reviewed the procedure and published Interventional Procedure Guidance 394, External aortic root support in Marfan syndrome in May 2011¹.

¹ [Overview | External aortic root support in Marfan syndrome | Guidance | NICE](#)

2. Aims and Objectives

This policy aims to define the commissioning position of WHSSC on Personalised External Aortic Root Support (PEARS) for surgical management of enlarged aortic root (adults) for the residents of Wales.

The objective is to ensure evidence based decisions are made on commissioning Personalised External Aortic Root Support (PEARS) for surgical management of enlarged aortic root (adults) for the residents of Wales.

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**
 - [External aortic root support in Marfan syndrome](#), Interventional procedures guidance (IPG391) May 2011.
- **NHS England policies**
 - NHS England Commissioning Policy - [Personalised External Aortic Root Support \(PEARS\) for surgical management of enlarged aortic root \(adults\)](#)

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 Codes

Code Category	Code	Description
OPCS-4	K33.8	Other specified operations on aortic root
	Y02.8	Other specified placement of prosthesis in organ NOC
	L25.8	Other specified other open operations on aorta
	Y02.8	Other specified placement of prosthesis into organ NOC
	Z34.1	Ascending aorta

Annex ii Abbreviations and Glossary

Abbreviations

IPFR	Individual Patient Funding Request
WHSSC	Welsh Health Specialised Services
PEARS	Personalised External Aortic Root Support

Glossary

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.