GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Policy Position PP162

Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension (all ages)

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Version 1.0

Document information	
Document purpose	Policy Position
Document name	Balloon pulmonary angioplasty (BPA) for chronic thromboembolic pulmonary (all ages)
Author	Welsh Health Specialised Services Committee
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Commissioning Team	Cardiac
Target audience	Chief Executives, Medical Directors, Directors of Nursing, Directors of Finance, Directors of Planning, Respiratory Consultants, Cardiologists,
Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
Document No	PP162
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Contents

Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission Balloon pulmonary angioplasty (BPA) for people with chronic thromboembolic pulmonary hypertension 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 NHS England and has concluded that Balloon pulmonary angioplasty (BPA) for people with chronic thromboembolic pulmonary hypertension should 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 Balloon pulmonary angioplasty (BPA) for chronic thromboembolic pulmonary hypertension 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

Chronic thromboembolic pulmonary hypertension (CTEPH) is a form of lung disease where blood pressure in the lungs is raised due to blood clots in the blood vessels in the lung. This causes right heart strain and may cause premature death. Normally, if blood clots travel to the lungs (pulmonary emboli), they are broken down either by the body or by treatments e.g. anti-coagulation therapy. However, in CTEPH the blood clots damage the main artery (pulmonary arteries) and block the blood flow through the lungs. This causes breathlessness, fatigue, dizziness, chest pain, body swelling, coughing up of blood and an inability to exercise which all impact on patient's poor quality of life. Often patients cannot work and need to take oxygen all the time just to remain comfortable when resting. Usually the disease, if not treated, leads to heart failure and death.

1.2 Aims and Objectives

This Policy Position aims to define the commissioning position of WHSSC on the use of Balloon pulmonary angioplasty for people with chronic thromboembolic pulmonary hypertension.

The objectives of this policy are to:

- ensure commissioning for the use of balloon pulmonary angioplasty is evidence based
- ensure equitable access to balloon pulmonary angioplasty
- define criteria for people with chronic thromboembolic pulmonary hypertension to access treatment
- improve outcomes for people with chronic thromboembolic pulmonary hypertension.

1.3 Current Treatment

The treatment of choice for CTEPH is surgery to remove the clots; this is called pulmonary endarterectomy (PEA). This is a very complex, high risk operation requiring a lowering of body temperature and stopping blood circulation for a controlled period of time and is delivered at only one specialised centre in the UK. The average operative time is 8 hours. PEA has a mortality of 5%. The majority of patients improve after surgery and some are cured but 20-40% of patients are not suitable for surgery due to

inaccessible disease or prohibitive risk. These patients are currently treated medically and they have a worse life expectancy and poorer quality of life than those successfully treated by surgery. Available medical treatments include blood thinners, water tablets, long term oxygen therapy, drugs that control heart palpitations and pulmonary vasodilators. The latter can have severe side effects and are very expensive. Medical therapy other than Riociguat has not demonstrated long-term survival benefits in this condition when studied in clinical trials.

1.4 Proposed Treatment

Balloon pulmonary angioplasty (BPA) aims to treat chronic thromboembolic pulmonary hypertension (CTEPH) with the patient awake using a 'keyhole' surgical technique. BPA treats narrowing in the scarred lung arteries with a balloon that is inflated to stretch open the lumen, improving lung blood flow. To reduce the risk of complications, the procedure is performed in stages and several sessions (4-6 per patient) are usually required to achieve therapeutic benefit.

1.5 What NHS Wales has decided

WHSSC has carefully reviewed the relevant guidance issued by National Institute of Health and Care Excellence (NICE) and NHS England. We have concluded that there is enough evidence to fund the use of balloon pulmonary angioplasty (BPA) for chronic thromboembolic pulmonary hypertension within the criteria set out in section 2.1 and 2.2.

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of BPA for chronic thromboembolic pulmonary hypertension in-line with the criteria identified in the policy.

2.1 Clinical Indications

BPA will be commissioned for patients with symptomatic CTEPH who have disease not suitable for PEA and angiographic lesions amenable to BPA: It is anticipated that most patients will be adults but children may also be considered for this procedure.

The broad clinical indications for considering balloon pulmonary angioplasty for Chronic Thromboembolic Pulmonary Hypertension are:

- distribution of thromboembolic disease too distal to be considered a suitable candidate for PEA
- lesions suitable for BPA are considered to be webs and slits; lesions with severe narrowing or complete obstruction by webs could also be treatable as long as distal run-off is confirmed on imaging
- symptomatic, haemodynamic and/or prognostic benefit for the patient expected. The service should have the expertise to determine whether or not a patient might benefit from PEA or whether BPA is a more appropriate intervention.

2.2 Inclusion Criteria

WHSSC will commission BPA for CTEPH in accordance with the following criteria:

- patient has a mean pulmonary arterial pressure greater than 25 mmHg at right heart catheterisation, **and**
- patient is symptomatic in WHO functional class III or IV, **and**
- the pulmonary vascular obstructions (i.e. the disease distribution) are distal, not suitable for pulmonary endarterectomy, **and**
- the presence of narrowed or blocked vessels (occluded sub-segmental pulmonary arteries) identified using conventional pulmonary angiography, **and**
- there is a balloon pulmonary angioplasty MDT meeting decision that there are sufficient, accessible, vascular lesions for BPA treatment to improve patient symptoms and haemodynamics. The MDT meeting will be attended by:
    - Consultant Interventional cardiologist or consultant interventional radiologist performing BPA

  - Consultant Radiologist with interest into pulmonary vascular diseases
  - Consultant Respiratory Physician
  - BPA coordinator nurse and minute taker, **and**
- the patient has already been discussed by the PEA MDT meeting and assessed as not suitable for PEA.

2.3 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.

2.4 Patient Pathway (Annex i)

Patients with suspected CTEPH will be diagnosed and managed by a specialist PH centre. Patients will be referred from one of these centres (six in England) to the designated provider of PEA, where the patient's suitability for PEA will be assessed. If disease distribution is unsuitable for PEA, the patient will be referred to the BPA provider team.

2.5 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: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

2.6 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 and for children, teenagers and young adults.

2.7 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**
  - Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension, Interventional procedures guidance, IPG554. April 2016

- **NHS England policies**
  - Clinical Commissioning Policy: Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension (all ages). NHS England Reference: 170031P. April 2018

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

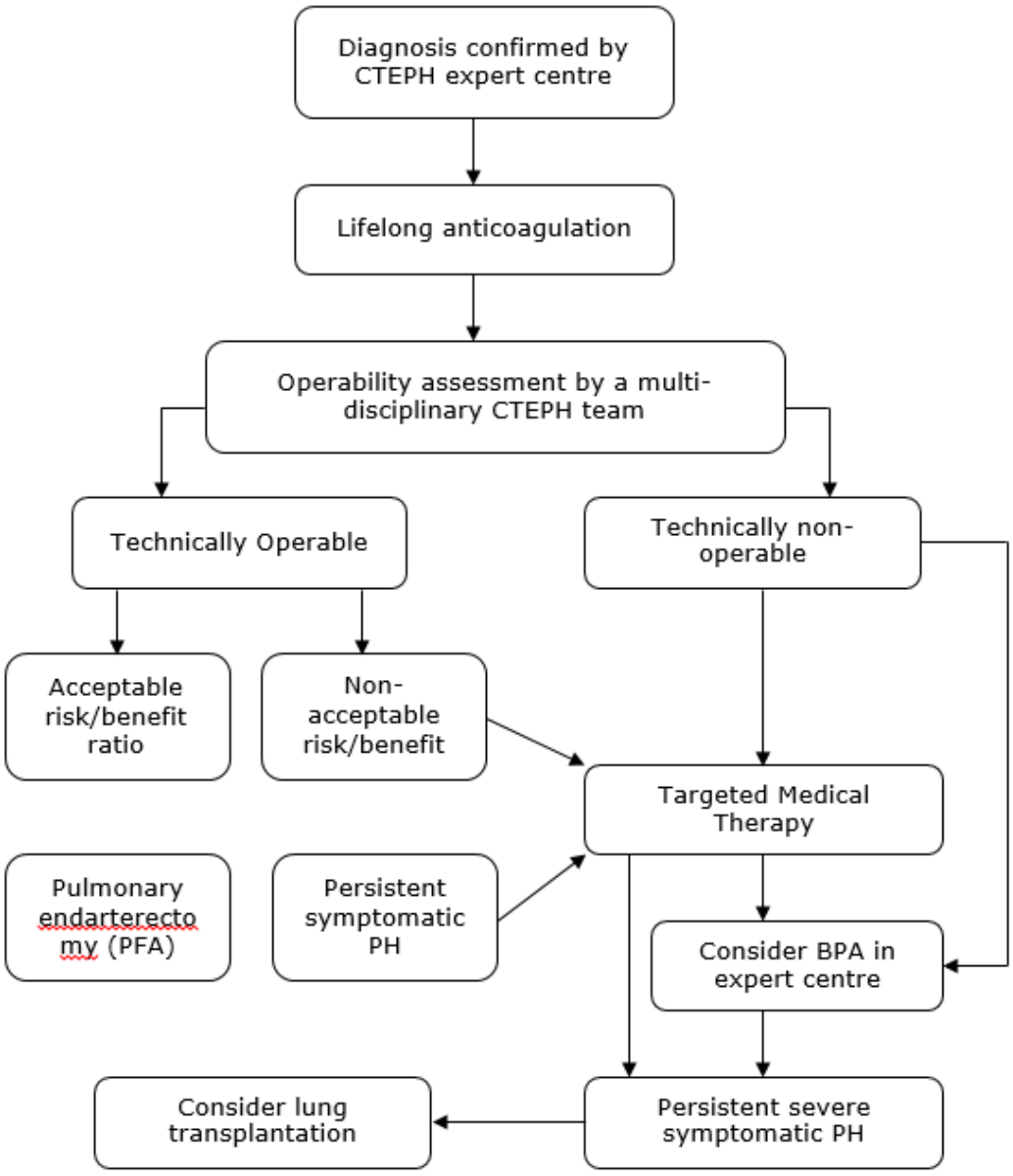
6. Equality Impact and Assessment

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



Annex ii Checklist

Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension (all ages)

The following checklist should be completed for every patient to whom the policy applies:

- Where the patient meet the criteria **and** the procedure is included in the contract **and** the referral is received by an agreed centre, the form should be completed and retained by the receiving centre for audit purposes.
- The patient meets the criteria **and** is received at an agreed centre, but the procedure is not included in the contract. The checklist must be completed and submitted to WHSSC for prior approval to treatment.
- The patient meets the criteria but wishes to be referred to a non-contracted provider. An Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration.
- 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.

Annex iii Codes

Code Category	Code	Description
OPCS-4	L13.5	Percutaneous transluminal balloon angioplasty of pulmonary artery NEC
	Y53	Approach to organ under image control or Y78 Arteriotomy approach to organ under image control
	Note: A code from category Y53.- Approach to organ under image control or Y78 Arteriotomy approach to organ under image control may also be assigned to these procedures if image control has been used. Codes in categories Y53.- or Y78.- are used as secondary codes. If the method of image control is unspecified, Y53.9 Unspecified approach to organ under image control or Y78.9 Unspecified approach to organ under image control is assigned.	
ICD-10	I27.2	Other secondary pulmonary hypertension