



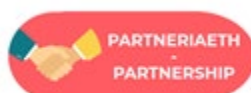
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Welsh Health Specialised
Services Committee (WHSSC)

Specialised Services Policy Position PP206

Percutaneous Mitral Valve leaflet repair for primary degenerative mitral regurgitation in adults

*June 2021
Version 2.0*



Document information

Document purpose	Policy Position
Document name	Percutaneous Mitral Valve Leaflet repair for primary degenerative mitral regurgitation in adults
Author	Welsh Health Specialised Services Committee
Publication date	June 2021
Commissioning Team	Cardiac
Target audience	Chief Executives, Medical Directors, Directors of Finance, Cardiac Surgeons, Cardiologists, Interventional Cardiologists
Description	NHS Wales routinely commission this specialised service in accordance with the criteria described in this policy
Document No	PP206
Review Date	2024

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) commission percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation in adults in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed the relevant guidance issued by NHS England and has concluded that percutaneous mitral valve Leaflet repair for primary degenerative mitral regurgitation 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 percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation for adults resident in Wales. The Policy Position has been adapted from the [NHS England Clinical Commissioning Policy: Percutaneous mitral valve leaflet repair for primary degenerative mitral valve regurgitation in adults](#). This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain language summary

The heart contains four valves which ensure the proper flow of blood through the heart. The mitral valve is on the left side of the heart and ensures the forward flow of blood into the left ventricle). The left ventricle is the main pumping chamber of the heart. The valve has two leaflets (or flaps of tissue) that open and close to ensure blood travels in one direction into the left ventricle. Sometimes the valve does not close properly resulting in blood leaking back (regurgitating) into the left upper chamber (left atrium). If the volume of blood leaking backwards is large, the heart works harder to effectively pump blood through the body. Symptoms caused by the heart having to work harder are shortness of breath and fatigue and over time this will lead to fluid retention due to heart failure. This impacts on life expectancy as well quality of life and makes daily activities harder.

The cause of mitral regurgitation is divided into degenerative (or 'primary mitral regurgitation' where the valve itself is structurally abnormal) and functional (or 'secondary mitral regurgitation' where the valve is structurally normal, but another condition affects the structure and/or function of the heart so that the valve cannot close properly). This policy focusses on adults with primary degenerative mitral regurgitation (DMR).

The current standard of care in adults is mitral valve repair or replacement surgery. However, some adults will not be able to undergo surgery because of the risk caused by other health conditions. These patients end up being treated with medication to try and control symptoms, but medical therapy cannot alter the underlying valve disease process.

1.2 Aims and Objectives

This Policy Position aims to define the commissioning position of WHSSC on the use of percutaneous mitral valve leaflet repair for adults with primary degenerative mitral regurgitation.

The objectives of this policy are to:

- ensure commissioning for the use of Percutaneous Mitral Valve Leaflet Repair is evidence based

- ensure equitable access to Percutaneous Mitral Valve Leaflet Repair
- define criteria for adults with primary degenerative mitral regurgitation to access treatment
- improve outcomes for adults with primary degenerative mitral regurgitation.

1.3 Epidemiology

A population-based study by [Nkomo et al in 2006](#) on over 28,000 adults reported prevalence of valvular heart disease (VHD) in the USA increasing to 13.3% in those over 75 years of age. This study reported only moderate to severe VHD. The most common valve condition was mitral regurgitation with a prevalence in the over 75 years of age group of approximately 8%. The dominant aetiology of MR in the VHD Euro Heart Survey on Valvular Heart Disease in 2001 was degenerative and it represents 65% of the MR population. Degenerative MR comprises a spectrum of pathologies, and mitral valve prolapse which is the main pathology treated with percutaneous mitral valve leaflet repair is seen in 50% of cases of degenerative MR. However, only half of the patients with severe symptomatic mitral regurgitation in the VHD Euro Heart Survey were offered surgery.

A population-based study in the UK using echocardiographic screening in primary care ([OxVALVE](#)) showed a higher prevalence of moderate or severe left sided valve disease increasing to 18.7% in the over 75 years old. This study projected that the number of patients with heart valve disease will double by 2046, due to an increasingly elderly population.

- The most common cause of mitral regurgitation in the elderly population is degeneration. The gradual rise in life expectancy has been accompanied by a progressively increasing frequency of degenerative valve disease.
- The preferred procedure in medically fit adults regardless of age is surgical mitral valve repair. However, only 50% of patients with severe, symptomatic mitral valve regurgitation may be eligible for this.
- The indication is hence proposed for the very high risk or surgically inoperable population.
- In contrast to percutaneous mitral valve edge-to-edge leaflet repair, medically treated patients are much more likely to suffer twice to three times as high annualised rates of death and readmissions for heart failure in the medium term (Everest II HR study, 2012; Swanns et al, 2014; Velasquez et al, 2015).
- The characteristics of this inoperable group reflect, in general, the over 80 years of age population. Conventionally, very high or “prohibitive” surgical risk is defined by an estimated surgical 30-day

mortality of $\geq 8\%$ using the STS replacement calculator or $\geq 6\%$. Such scores have limited accuracy in identifying very high-risk patients (see criteria for commissioning, section 2.1).

Population estimates of need

NHS England modelling of procedure numbers

In a population of 53 million (England), 7.8% are aged over 75 years of age, giving a target population of 4 million. Of this group, approximately 8% have moderate-severe degenerative mitral regurgitation which equals a population of 320,000. Of the group with degenerative mitral regurgitation 50% or 160,000 will have significant mitral prolapse. Of these, 25%, i.e. 40,000 adults will have anatomy suitable for invasive mitral valve intervention such as percutaneous mitral valve edge-to-edge leaflet repair. This patient population will encompass a broad group of clinical scenarios including absence of symptoms, both acute and elective presentations and comorbidities. Whilst patients who are inoperable or of high surgical risk should be considered for percutaneous mitral valve edge-to-edge leaflet repair, there will be some patients for whom any intervention will not provide an overall benefit to the patient. It is probable that only 10% of this population, i.e. 4000 patients might be considered for percutaneous mitral valve edge-to-edge leaflet repair. It is estimated that approximately 10% of patients eligible for edge-to-edge leaflet repair would be referred. It may therefore be expected that approximately 400 patients might presently be considered for percutaneous mitral valve edge-to-edge leaflet repair in England on an annual basis. This may be expected to increase annually with improved referral networks and clinical awareness¹.

NHS Wales

With a Welsh population of approximately 3 million people, this would equate to an initial figure of 22.6 procedures but this figure may be higher given the older age of the Welsh population compared to England (11.7% of the Welsh population is over 85 years or older compared to 5.5 in England) as well as the higher levels of co-morbidity in Wales².

1.4 Current Treatment

Degenerative Mitral Regurgitation (MR) is treated by surgery to repair or replace the mitral valve. Mitral valve repair is the preferred surgical intervention where possible, with lower rates of early mortality, stroke after surgery, long-term survival, freedom from re-operation and shorter length

¹ [NHS England Clinical Commissioning Policy: Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation in adults 170128P \(2019\)](#)

² [Office for National Statistics: Census data \(2011\)](#)

of stay³. Rates of mitral valve repair in Wales are below the UK average⁴. (51% in Wales between 2017 and 2020 vs 77% in UK in 2018)

Symptoms caused by MR can be conservatively managed using drugs for treating heart failure but this is not curative. However, people with MR are usually older (typically over 70 years) and frail, with multiple comorbidities. These adults have an increased risk of complications, prolonged intensive care unit stays and mortality which may make a surgical option high risk or inappropriate. Percutaneous mitral valve leaflet repair (PMVR) offers an alternative approach to treating adults with DMR who may be inoperable or at higher surgical risk but would benefit from intervention.

If mitral valve regurgitation is left untreated it leads to heart failure. Acute heart failure is the commonest emergency admission in >65 year olds causing 5% of all emergency admissions and 70% of heart failure associated healthcare costs. It carries an inpatient mortality of 11%⁵. Valvular heart disease is the second commonest cause of acute heart failure admission after coronary artery disease (27.4% of all patients)⁶. Inpatient mortality due to heart failure varies between acute hospitals (lowest 6%, highest 26%) and therefore the NCEPOD "Failure to Function" ⁷review called for urgent attention to reduce this figure by all hospitals that admit acute heart failure patients. Whilst significant progress has been made in delivering timely contemporary treatment for aortic stenosis with conventional surgery or trans-catheter aortic valve implantation (TAVI), there is no treatment currently available in Wales for patients with mitral regurgitation for whom open heart surgery is high risk or contraindicated following risk assessment.

1.5 Proposed Treatment

Mitral valve repair can now be undertaken without the need for open heart surgery. PMVR is a less invasive treatment option for MR if the mitral valve meets established anatomical eligibility criteria. The procedure is performed in a cardiac catheter laboratory using general anaesthesia and transoesophageal echocardiography guidance, with the optional use of fluoroscopy. The procedure involves inserting a flexible tube or catheter into a large vein in the groin which leads to the right side of the heart. This tube is passed to the left upper chamber of the heart (left atrium) via a technique called trans septal puncture and the valve leaflet repair device is advanced through this tube.

³ [Baumgartner H et al \(2017\) ESC/EACTS Guidelines for the management of valvular heart disease](#)

⁴ [NHS GIRFT Cardiothoracic Surgery GIRFT Programme National Speciality Report \(2018\)](#)

⁵ [NICE. Quality Standard 103. Acute Heart Failure. Published December 2015.](#)

⁶ [NICE. Quality Standard 103. Acute Heart Failure. Published December 2015.](#)

⁷ [NCEPOD Acute Heart Failure: Failure to Function \(2018\)](#)

The device is then lowered through the mitral valve into the left ventricle. The device consists of a clip mechanism that brings the leaking portions of the two leaflets of the valve together so that the blood leaking back from the lower chamber (left ventricle) into the upper chamber (left atrium) of the heart is reduced. Following PMVR, patients are woken up at the end of the procedure, do not require prolonged mechanical ventilation or use of a heart-lung bypass machine or default admission to a cardiac intensive care unit for post procedure care. A minority of patients may require admission to a cardiac intensive care unit following the procedure. The procedure usually takes 90 - 120 minutes and patients are usually discharged to a home setting two to three days after the procedure.

The device replicates an accepted surgical repair technique called an “edge-to-edge leaflet repair” to improve the valve function and in selected patients this procedure can reduce the symptoms due to severe mitral regurgitation and can improve quality of life and improve prognosis.

1.6 What NHS Wales has decided

WHSSC has carefully reviewed the relevant guidance issued by NHS England for percutaneous mitral valve repair for people with primary degenerative mitral regurgitation. We have concluded that there is enough evidence to fund the intervention within the criteria set out in section 2.1.

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding for Percutaneous Mitral Valve Leaflet repair for adults with primary degenerative mitral regurgitation in-line with the criteria identified in this policy.

Percutaneous mitral valve edge-to-edge leaflet repair will be commissioned for adults with symptomatic, severe (defined as grade 3+ and 4+) primary degenerative mitral regurgitation. Adults must be assessed by the Heart Team as inoperable or of very high risk for conventional mitral valve surgery and in whom reduction of mitral regurgitation would be expected to provide sustained symptom and quality of life benefits.

Patients should be assessed as having a high likelihood of procedural and medium-term successful outcomes with respect to effective and durable reduction in mitral regurgitation. Individual improvement in symptoms, quality-of-life, and functional status as well as survival must be considered.

Patients will be classified as having a very high or inoperable surgical risk using the Society of Thoracic Surgeons calculator or EuroSCORE II surgical risk scores, assessment of frailty, significant organ dysfunction and comorbidities.

Additional factors that may preclude surgery include severe mitral annular calcification, the presence of a "hostile chest", e.g. prior mediastinal radiation or chest malformation, aortic calcification (porcelain aorta) patent left internal mammary artery bypass graft crossing the midline or prior tracheostomy.

2.1 Inclusion Criteria

WHSSC will commission PMVR for people who meet the following criteria:

- Adults with symptomatic (NYHA 2-4a), severe mitral regurgitation (grade $\geq 3+$) due to primary abnormality of the mitral valve apparatus (degenerative MR).
- Adults determined as inoperable or very high risk for mitral valve surgery by a mitral valve specialist surgeon as part of the Heart Team assessment.
- Adults deemed anatomically suitable for percutaneous mitral valve edge-to-edge leaflet repair.
- Healthy life expectancy of at least >12 months with quality of life benefits to be gained from reduction in mitral regurgitation.

2.2 Heart Team assessment

Joint decision-making by the multidisciplinary Heart Team should govern patient selection. The core members of the Heart Team should include:

- a cardiac surgeon with mitral valve expertise,
- expert imaging cardiologist with structural intervention transoesophageal echocardiography skills,
- trans-catheter heart valve/structural heart interventional cardiologist
- a cardiologist with expertise in heart failure
- cardiac anaesthetist
- allied health professionals such as specialist heart valve nurses.
- access to elderly care input and comprehensive geriatric assessment should be available to support decision making and patient selection by the Heart Team.

2.3 Exclusion Criteria

- Adults who cannot tolerate procedural anti-coagulation.
- Active endocarditis.
- Rheumatic mitral valve disease.
- Evidence of inferior vena cava or femoral venous thrombus.
- Echocardiographic evidence of intracardiac mass, thrombus.
- NYHA functional class IVb or ACC/AHA stage D chronic heart failure.
- Severe adverse cardiac factors: severe LV impairment <20% or LVEDD >60mm, severe TR and moderate-severe RV impairment, severe pulmonary hypertension.
- Hypertrophic cardiomyopathy, restrictive cardiomyopathy, constrictive pericarditis or other structural heart disease causing heart failure.
- Life expectancy < 12 months due to non-cardiac condition.
- Severe frailty – Rockwood CSHA-CFS >6.
- Oxygen dependent lung disease.
- Severe chronic kidney or liver disease.
- Significant bleeding diathesis.
- Malnourished with low serum albumin and unintentional weight loss.
- Significant anaemia (in the absence of a clearly reversible cause).
- Dementia (if Heart Team with geriatric assessment suggests unlikely benefit).

2.4 Anatomical criteria

The following criteria should be considered as unsuitable for treatment with percutaneous mitral valve leaflet repair:

- Perforation (s) of the mitral valve leaflets
- Haemodynamically significant mitral stenosis
- Significant calcification in the leaflet grasping area.

2.5 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.

2.6 Patient Pathway (Annex i)

Adults with symptomatic, severe primary DMR should be referred via secondary cardiology services. A clear referral pathway between these services and the specialist valve intervention team should be established. A referral network that ensures equitable and efficient access to assessment and therapy for patients across all secondary care facilities should exist. The patient pathway should ensure patients are assessed by the Heart Team which must include a mitral valve specialist surgeon to determine inoperability or very high surgical risk.

2.7 Designated Centre (s)

- **South Wales and South Powys**

University Hospital of Wales
Heath Park Way
Cardiff
CF14 4XW

- **North Wales and Powys**

Manchester University NHS Foundation Trust
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
M23 9LT

2.8 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](#)

2.9 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner. (These standards can include clinical outcomes, PROMS, Quality of Life etc.).

Clinical Outcomes

A clinical audit will be required on an annual basis from providers which will include the following:

The following information must be collected:

- Post treatment related mortality up to 30 days
- Disease/procedure related complications such as stroke
- 12-month survival
- Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs)
- Any centre performing the procedure has to provide outcome data (in the form of the agreed BCIS/SCTS dataset), to a centrally held database for event tracking hosted by [NICOR \(National Institute for Cardiovascular Outcomes Research\)](#)

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.

2.10 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**
 - Percutaneous mitral valve leaflet repair for mitral regurgitation, IPG649, May 2021, www.nice.org.uk/guidance/ipg649
- **NHS England policies**
 - Clinical Commissioning Policy: Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation in adults, 170128P, July 2019, https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2019/07/Clinical-Commissioning-Policy_Percutaneous-mitral-valve-leaflet-repair-for-primary-degenerative-mitral-regurgi.pdf

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

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for [NHS Putting Things Right](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

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](#)

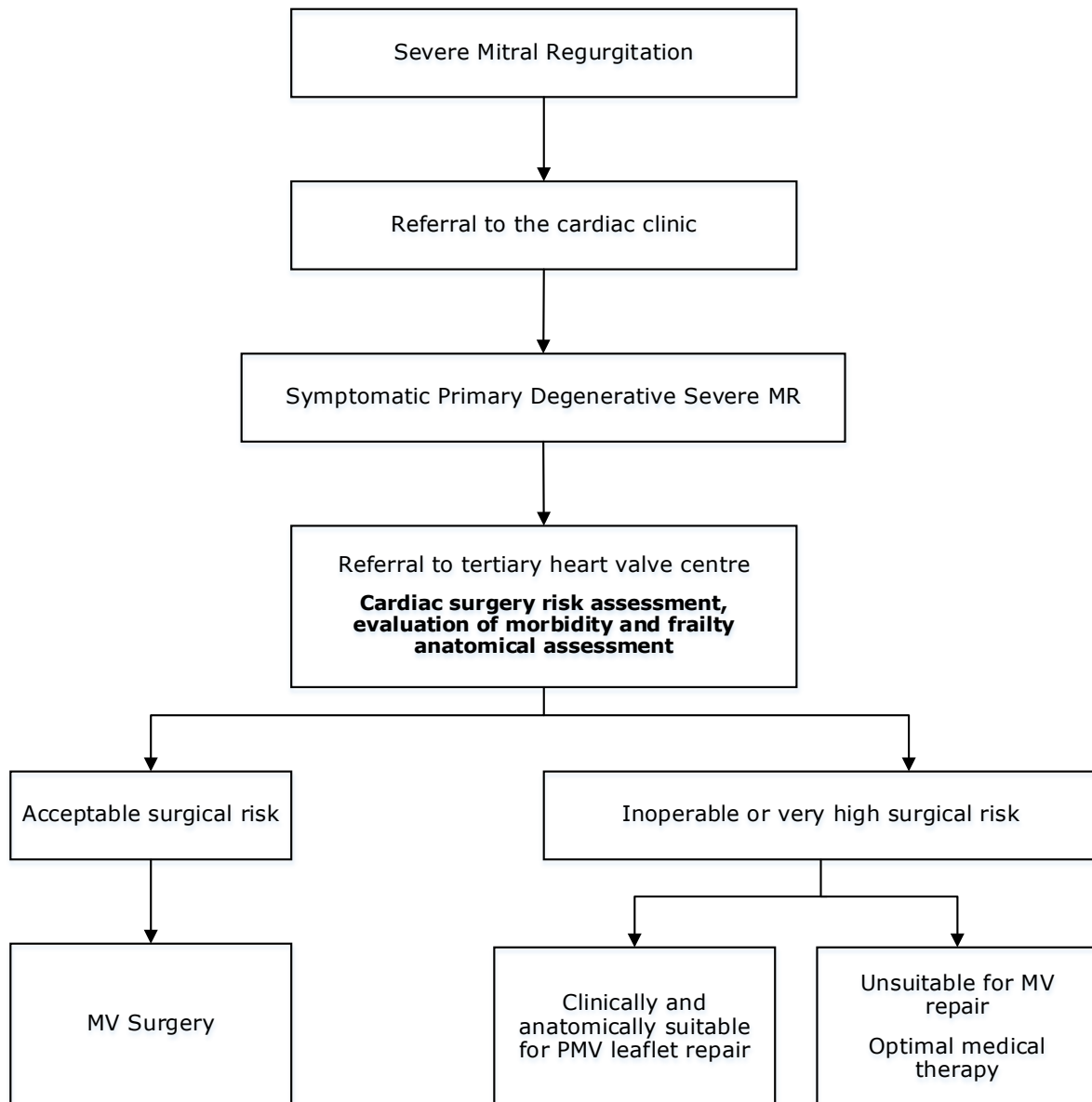
6. Equality Impact and Assessment

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 Codes

Code Category	Code	Description
OPCS-4	K25.5	Mitral Valve repair NEC
	Y76.8	Other specified minimal access to other body cavity
	Y07.2	Clipping of organ NOC
	Y53.4	Approach to organ under fluoroscopic control (if fluoroscopic imaging is used)
	U20.2	Transoesophageal echocardiography
ICD-10	134.0	Mitral Valve insufficiency
	102.0	Rheumatic chorea with heart involvement
	105.1	Rheumatic mitral insufficiency
	105.2	Mitral Stenosis with insufficiency
	108.0	Disorders of both mitral and aortic valves
	108.1	Disorders of both mitral and tricuspid valves
	108.3	Combined disorders of mitral, aortic and tricuspid valves
	023.3	Congenital mitral insufficiency

Annex iii Abbreviations and Glossary

Abbreviations

IPFR	Individual Patient Funding Request
WHSSC	Welsh Health Specialised Services
SMC	Scottish Medicines Consortium

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.

Atrium

The heart is divided into four chambers that are connected by heart valves. The upper two chambers are called atria. The atria are separated into the left atrium and the right atrium by an interatrial septum.

Computerised Tomography (CT)

Imaging scan which uses computer-processed combinations of many X-ray measurements taken from different angles to produce cross-sectional images from within a specific area.

Echocardiogram

A scan of the heart which uses a probe that sends out sound waves which are reflected back by the muscle and tissues in the heart to give information about the structures of the heart.

Mitral valve

The valve that ensures blood flows from the upper left chamber of the heart (left atrium) to the lower left chamber of the heart (left ventricle).

Mitral valve regurgitation

The leakage of blood backward through the mitral valve into the left atrium.

MitraClip

This is an example of a specific percutaneous mitral valve edge-to-edge leaflet repair technique. The device is used to treat mitral valve regurgitation for individuals who are unable to undergo open heart surgery.

Percutaneous

Through the skin.

Quality of Life (QoL)

The individual's perception of their well-being with respect to daily life.

Transoesophageal echocardiography (TOE)

A transoesophageal echocardiogram is an alternative way to perform an echocardiogram. A specialised probe containing an ultrasound transducer at its tip is passed into the patient's oesophagus.

Trans-septal puncture

A technique to access the left atrium from the right atrium by crossing the inter-atrial septum which separates the upper two chambers of the heart.

Ventricle

The heart is divided into four chambers that are connected by heart valves. The lower two chambers are called ventricles. The ventricles are separated into the left and the right ventricle by an intraventricular septum.