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Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Commissioning Policy: CP58

Commissioning Policy

Trans-catheter Aortic Valve Implantation (TAVI) for Severe Symptomatic Aortic Stenosis (SSAS)

March 2019

Version 1.0

Document information	
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Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
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Contents

Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission Trans-Catheter Aortic Valve Implantation (TAVI) as an alternative to Surgical Aortic Valve Replacement (SAVR) for people with Severe Symptomatic Aortic Stenosis (SSAS) in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed this clinical condition and the options for its treatment. It has considered the place of TAVI in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Disclaimer

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

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.

1. Introduction

This policy has been developed as the Commissioning Policy for the planning and delivery of Trans-catheter Aortic Valve Implantation (TAVI) for Severe Symptomatic Aortic Stenosis (SSAS) for people resident in Wales. This service will only be commissioned by the Welsh Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

TAVI is a technically complex procedure that should only be undertaken in specialised centres and delivered conjointly by cardiac surgeons and cardiologists with specialist training and experience in complex endovascular interventions. Centres doing this procedure must have vascular surgical support for the emergency treatment of complications and subsequent patient care.

It is recognised that intervention for aortic stenosis is evolving and therefore this policy will be reviewed at regular periods (to be determined), particularly in light of emerging evidence for patients deemed to be at intermediate risk.

1.1 Plain Language Summary

Patients whose aortic valve (one of several valves in the heart) is not functioning effectively, usually because of narrowing (or stenosis) require a valve replacement which is conventionally done through open heart surgery. For some patients the risk of surgery is high. TAVI is an alternative and less invasive way of placing a new aortic valve into the heart by using a catheter (a thin tube) and the body's blood system to access the heart.

TAVI is funded for patients who are judged by the specialist heart team in the agreed cardiac centres, to be at high risk for open heart surgery, primarily as a result of other conditions (co-morbidities) or anatomical constraints.

TAVI is also funded for patients who are judged not to be safely suitable at all for open heart surgery.

1.2 Aims and Objectives

This policy aims to define the commissioning position of WHSSC on the use of Trans-catheter Aortic Valve Implantation (TAVI) for people with Severe Symptomatic Aortic Stenosis (SSAS).

The objectives of this policy are to:

- ensure commissioning for the use of TAVI is evidence based
- ensure equitable access to TAVI
- define criteria for people with SSAS. to access treatment
- improve outcomes for people with SSAS

1.3 Epidemiology

The natural history of aortic valve stenosis has changed in past decades possible due to more patients surviving long enough to develop symptomatic aortic stenosis. Patients presenting with severe asymptomatic aortic stenosis present late in life, typically in their late 70's. The onset of symptoms heralds a rapid decline in functional status when treated with medical therapy alone.

Epidemiological studies have determined that more than one in eight people aged 75 and older have moderate or severe aortic stenosis with a prevalence of 3%.

1.4 Current Treatment

Current treatment options for severe symptomatic aortic stenosis are Surgical Aortic Valve Replacement (SAVR) and Transcatheter Aortic Valve Implantation (TAVI) for patients considered high risk for surgery.

SAVR is the gold standard for treatment of severe AS but TAVI offers a new treatment option for patients considered high risk for surgery.

1.5 Proposed Treatment

TAVI is a means of implanting a new aortic valve into the heart. It is an alternative to conventional SAVR for patients with severe symptomatic aortic stenosis at high risk of surgical complications. In this procedure, the valve is delivered via transfemoral, transapical or transaortic access without the need for open-heart surgery.

1.6 What NHS Wales has decided

WHSSC has carefully reviewed the evidence of Trans-catheter Aortic Valve Implantation (TAVI) for Severe Symptomatic Aortic Stenosis (SSAS). We have concluded that there is enough evidence to fund the use of TAVI, within the criteria set out in section 2.1.

1.7 Relationship with other documents

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

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

- **National Institute of Health and Care Excellence (NICE) guidance**
  - Transcatheter aortic valve implantation for aortic stenosis. NICE interventional procedure guidance IPG586, July 2017 www.nice.org.uk/guidance/ipg586

- **Relevant NHS England policies**
  - Clinical Commissioning Policy: Transcatheter Aortic Valve Implantation. Reference NHSCB/A09/P/a, April 2013 www.england.nhs.uk/wp-content/uploads/2013/04/a09-p-a.pdf

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of Trans-catheter Aortic Valve Implantation (TAVI) for Welsh patients with Severe Symptomatic Aortic Stenosis (SSAS), in-line with the criteria identified in the policy.

TAVI is a treatment approach for patients with severe symptomatic aortic stenosis and aims to provide a less invasive alternative to open cardiac surgery for treating aortic stenosis, avoiding the need for sternotomy and cardiopulmonary bypass.

It is suitable for patients who are high risk and those that are deemed inoperable (i.e. have been turned down for surgery).

2.1 Inclusion Criteria

Patients who are considered to be high risk or inoperable should be referred to the relevant TAVI Multidisciplinary Team (MDT) for consideration of the most appropriate aortic intervention.

TAVI should be considered if the patient:

- has a confirmed diagnosis of severe symptomatic aortic stenosis and has been discussed at the TAVI MDT and
- is considered high risk for SAVR (owing to age, frailty and co morbidities) or
- is deemed inoperable but the TAVI MDT concludes that significant symptomatic and/or survival benefit will be offered by TAVI e.g. porcelain aorta.

2.2 Exclusion Criteria

Patients with symptomatic aortic stenosis who are at low and intermediate surgical risk should be referred directly to the cardiac surgical service for consideration of Surgical Aortic Valve repair/replacement, unless they have an anatomical factor that renders them inoperable. If the cardiac surgeon subsequently considers, after their own clinical assessment that the risk status of the patient is uncertain, they are encouraged to discuss the patient at the TAVI MDT.

TAVI should not be undertaken in:

- patients with limited years life expectancy possibly linked to other co-morbidities such as malignancy or advanced lung disease
- in patients with such a burden of co-morbidities that no symptomatic benefit is likely

- patients who have a preference for TAVI but would be more appropriately managed with open heart surgery

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)

All referrals should be considered by the TAVI MDT. The selection of patients for TAVI should be consistent with the criteria set out in this policy. Only patients considered by the TAVI MDT and who meet the criteria for TAVI in this policy will be funded by WHSSC.

2.6 Designated Centre

South Wales

TAVI is provided for South Wales from two centres:

- Morriston Hospital, Swansea Bay, University Health Board
- University Hospital of Wales, Cardiff and Vale UHB

Patients in South Wales with severe symptomatic aortic stenosis who are considered to be suitable for TAVI should be referred to the TAVI MDT at either Moriston Hospital or University Hospital of Wales.

North Wales

Patients from North Wales who may be appropriate for TAVI should be referred to the TAVI MDT at Liverpool Heart and Chest Hospital.

Mid Wales

Patients from Mid Wales who may be appropriate for TAVI should be referred to TAVI teams at either University Hospital Birmingham or University Hospitals North Midlands.

2.7 MDT

TAVI must only be undertaken following documented discussion of the patient within the TAVI MDT.

The core MDT should consist of:

- at least one interventional cardiologist with a special interest in TAVI
- at least one cardiac surgeon with a specialist interest in TAVI and SAVR
- a general cardiologist
- a radiologist / imaging cardiologist (specialising in echo/CT)

The decision for undertaking TAVI must be agreed by the core team outlined above.

Other clinical specialists should be members of the broader TAVI Team and available when required to assess/and/or review specific patients and should include:

- Care of the Elderly Physician
- Vascular surgeon
- Vascular Radiologist
- Cardiac anaesthetist

The MDT should be supported by an MDT coordinator/administrator who will be responsible for documenting the decisions made, suggested treatment strategies, MDT outcomes and collection and submission of data onto the UK TAVI registry.

The outcomes and decisions from the MDT meetings will be documented in the clinical notes with a letter to the patient, the referring cardiologist and general practitioner.

The MDT should determine the risk level associated with open surgery and with TAVI for each patient and balance the two in coming to its final recommendations. If the MDT concludes that TAVI should be offered, a recommendation about the type of device and mode of vascular access most suitable for them should also be agreed.

Centres doing this procedure should have both cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.

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.

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. Evidence

WHSSC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

In creating this updated policy WHSS commissioned Cedar Evaluation Centre to produce an evidence review on the clinical and cost effectiveness of TAVI in adults with heart failure secondary to aortic stenosis for which surgery is considered suitable but high risk.

The clinical indications (and list of exclusions) for the treatment of Aortic Stenosis with TAVI are based upon a recent systematic review of the evidence and clinical consensus provided by the All Wales TAVI working group. The evidence review focused on adults with heart failure secondary to aortic stenosis for which SAVR is considered suitable (but high risk). However a number of ongoing RCT's comparing TAVI with surgical AVR in patients who are at intermediate or low risk were also identified. In this cohort of patients a review of the emerging evidence may be helpful in the future to determine if the current policy should be amended.

Inoperable group

Evidence from one RCT (PARTNER 1B) suggests that TAVI has a survival advantage over medical therapy in patients who cannot undergo surgery, but TAVI carries a higher risk of vascular complications. Despite remaining uncertainty over cost effectiveness and the safety issues associated with the use of TAVI in patients ineligible for surgery, the evidence of clinical benefit supports the use of TAVI for inoperable patients.

High risk group

Evidence is available from the PARTNER 1A and CoreValve RCTs. There is some evidence to suggest that TAVI may result in better survival than SAVR in patients at high risk for surgery. SAVR carries a greater risk of major bleeding at 30 days, new onset atrial fibrillation and acute kidney injury. TAVI carries a greater risk of major vascular complications. The evidence review supports the use of TAVI for patients deemed to be at high surgical risk, although it is worth noting the uncertainty surrounding the generalisability of the trial participants' risk scores to clinical practice in Wales.

Cost effectiveness

Based on all available evidence from a UK healthcare provider perspective TAVI is likely to be a cost-effective use of resource in high-risk (but operable) and inoperable patients with aortic stenosis. The data used in the studies, along with sensitivity analyses conducted, suggest that despite higher initial costs of the TAVI procedure there is significant patient benefits that lead to later cost savings. The TAVI intervention significantly reduces

the time a patient needs to spend in hospital and TAVI is associated with lower subsequent hospital admissions after the procedure. In the published economic studies the choice of device is a crucial factor in estimating the costs. This TAVI is likely to be a cost effective procedure, however uncertainty surrounding long term outcomes in this patient group and their impact on costs remains.

Safety

Recently updated NICE Interventional Procedures Guidance (IPG) on the safety and efficacy of TAVI for aortic stenosis supports its use provided that standard arrangements are in place for clinical governance, consent and audit. Further details can be found on the NICE website (NICE IPG586, 2017).www.nice.org.uk/guidance/ipg586, published, 26 July 2017.

It is recognised that intervention for aortic stenosis is evolving and therefore this policy will be reviewed at regular periods (to be determined), particularly in light of emerging evidence for patients deemed to be at intermediate or low risk for open surgery.

Details of the full Rapid Evidence Review; Transcatheter aortic valve implantation for high risk surgical patients is available on request to WHSSC.

3.1 References

- National Institute for Health and Care Excellence (2017) Transcatheter aortic valve implantation for aortic stenosis. NICE interventional procedure guidance [IPG586]

- National Institute for Health and Care Excellence (2014) Acute heart failure: diagnosis and management. NICE guideline [CG187]

- NHS Commissioning Board (2013) Clinical Commissioning Policy: Transcatheter Aortic Valve Implantation. Reference [NHSCB/A09/P/a]

- Health Improvement Scotland (2017) Transcatheter aortic valve implantation for severe symptomatic aortic stenosis in adults at high surgical risk.

- European Society of Cardiologists

- European Association for Cardio-Thoracic Surgery Guidelines

3.2 Date of Review

This document is scheduled for review before 2022 where we will check if any new evidence is available. If no new evidence or intervention is available the review date will be progressed.

If an update is carried out the policy will remain extant until the revised policy is published.

4. 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.

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)

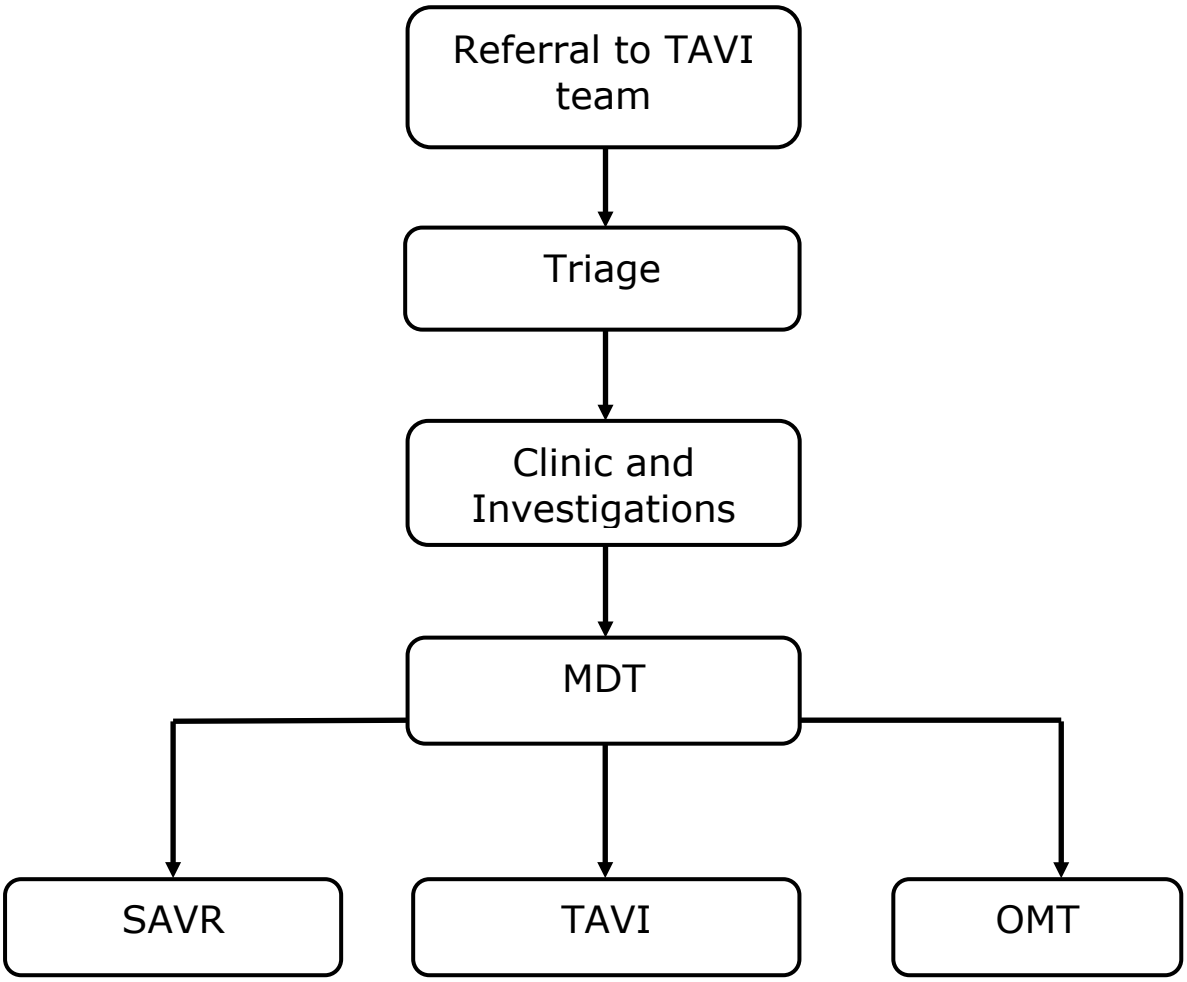
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All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

Annex i Patient Pathway



Cardiologists or other specialists who wish to refer a patient with Aortic Stenosis for a valvular intervention [either surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI)] should ensure that the following investigations have already been performed and that the results are available to the receiving centre:

Bloods including FBC, U+E's and liver function
ECG
Transthoracic echo
Coronary angiogram
Gated CT

Clinic
As agreed at each centre

MDT
Core TAVI team and additional team members as required.

Annex ii Codes

Code Category	Code	Description
OPCS-4	K26	Plastic repair of aortic valve
	Y49.4	Transapical approach to heart
	Y79	Approach to organ through artery
	Y53	Approach to organ under image control
	U20.2	Transoesophageal echocardiography
ICD-10	135.0	Aortic (valve) stenosis

Annex iii Abbreviations and Glossary

Abbreviations

IPFR Individual Patient Funding Request

WHSSC Welsh Health Specialised Services

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.