Engagement Report

Topic details

Title of policy or policy statement:	Transcatheter Edge to Edge Repair (percutaneous mitral valve leaflet repair) for moderately severe or severe secondary mitral regurgitation due to left ventricular dysfunction and/or dilatation (adults).
Programme of Care:	Internal Medicine
Clinical Reference Group:	Cardiac services
URN:	2254

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. The clinical commissioning policy proposition went out to stakeholder testing between 31st July and 14th August 2023. There were 14 responses.

2. Background

Secondary mitral regurgitation (SMR) is defined as mitral regurgitation (MR) that is a consequence of left ventricular (LV) dysfunction or segmental abnormality and LV dilatation but with normal mitral valve leaflets and cords. Moderate or severe SMR is present in approximately one-third of patients with heart failure and reduced left LV ejection fraction. It contributes to progression of the heart failure condition and confers a worse prognosis.

In this policy proposition, Transcatheter Edge to Edge Repair (TEER), a minimally invasive procedure involving a clip being secured onto the edges of the mitral valve leaflet, is proposed for patients who are not suitable for surgery and have symptoms of heart failure despite guideline recommended medical therapy.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks between 31st July 2023 and 14th August 2023. The comments have then been shared with the Policy

Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you support the Equality and Health Inequalities Impact Assessment?
- Does the Patient Impact Assessment present a true reflection of the patient and carers lived experience of this condition?
- Do you agree with the inclusion criteria?
- Do you agree with the following exclusion: Inability for patient to undergo Transoesophageal Echocardiology that is required for guidance of procedure?
- Do you agree with the following exclusion: Comorbidity, frailty (as defined by Rockwood score >6), or life expectancy from non-cardiovascular causes makes intervention inappropriate. Specifically, patients with a life expectancy <1 year.
- Do you agree with the following exclusion? Echocardiographic evidence of intracardiac mass, thrombus or active endocarditis.
- Do you agree with the following exclusion? Contraindication to general anaesthesia
- Do you agree with the following exclusion? Severe right ventricular dysfunction
- Do you agree with the following exclusion? Severe fixed pulmonary hypertension
- Do you agree with the following exclusion? Implant of CRT or CRT-D within the last 30 days
- Do you agree with the starting and monitoring criteria?
- Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.
- Please declare any conflict of interests relating to this document or service area.

A 13Q assessment has been completed following stakeholder testing.
The Programme of Care decided that public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

There were 14 respondents to the stakeholder testing: 5 clinicians and 9 organisations. All respondents supported the proposition.

How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group (PWG) and the Internal Medicine PoC. The following themes were raised during engagement with registered stakeholders:

Keys themes in feedback	NHS England Response
Relevant Evidence	
The following paper was identified, which is a 5 year follow up of patients in the COAPT trial. The 2 year follow up results were included in the evidence review. Reference: Gregg W. Stone et	The paper was reviewed by the PWG public health lead as per published policy development process and the evidence made no material change to the conclusions of the evidence review.

al. Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation. NEJM.org March5 2023. DOI: 10.1056/NEJMoa2300213	
Inclusion/exclusion criteria	
Inclusion: The British Society of Echocardiography graded mitral regurgitation into 3 categories: mild, moderate and severe with no "moderately severe"	The PWG considered the phrase moderately severe remains appropriate, as the estimation of secondary MR severity is not straightforward and the term leaves some latitude.
Inclusion: The COAPT trial (the only RCT showing benefit) was limited to patients in whom significant LV dilation had not already occurred. LV size should be considered in the inclusion criteria. Suggestion to use an indexed volume to determine LV dilatation	The LV size inclusion/exclusion criteria have been informed by the COAPT trial and therefore align with the evidence. LV size is included in the inclusion criteria already but has now been added into the colour diagram in Appendix 1 that enables clinicians/MDTs to assess anatomical suitability for the intervention.
Inclusion: patients with severe atrial functional mitral regurgitation should also be included - MR predominantly due to annular dilatation resulting from chronic AF. This is a subdivision of function MR	The population covered by this policy proposition are patients where the aetiology of MR is ventricular dysfunction. Patients where the MR is due to AF were not included in the evidence review and there is no evidence for the intervention in this group. However, patients with AF co-existing with MR secondary to ventricular dysfunction are not excluded from this proposition.
Exclusion: Intracardiac echo could be used as an alternative to TOE in patients unable to have TOE. Furthermore, clinicians should to enquire about Dysphagia (difficulty in swallowing) during initial assessment for TOE.	TOE is used for standard practice, rather than intracardiac echo, which may not be available in all centres. If there were any significant changes to standard practice, the proposition can be reviewed. This should therefore remain an exclusion. Suitability for TOE and assessment of this is captured by guidelines.
Exclusion: Life expectancy of <1 year is commonly used, including in TAVI. Firstly, this is very difficult to determine.	Footnote added: life expectancy from non-cardiovascular causes and appropriateness for intervention should be assessed on an individual patient basis by MDT, taking into account quality of life and relevant frailty assessment. In frail and/or elderly patients, access to elderly care input and comprehensive geriatric assessment should be available to support decision making and patient selection

Exclusion: chronic stable thrombus should not be an exclusion.	Presence of thrombus was an exclusion criterion for the studies in the evidence review and therefore there is no evidence for the intervention in these patients. Exceptional scenarios, for example chronic stable thrombus, may be considered on a case-by-case basis depending on expert analysis of relevant imaging and patient related factors.
Exclusion: Tests of reversibility of pulmonary hypertension are largely confined to heart transplant centres.	All provider centres should be able to assess this
Impact Assessment	
The Patient Impact Form is a comprehensive reflection of the experiences our patient community face, however a further focus on the impact on carers could be made.	PIA form has been updated accordingly.
Current Patient Pathway	
The patient population overlaps with patients who would benefit from transplant/LVAD. The stepwise algorithm is somewhat misleading, as it relies on clinicians potentially with no prior experience in transplant/LVAD to identify/ refer patients for transplant/LVAD.	Add wording into starting criteria: MDTs should consider all suitable treatment options available and appropriate for each patient before proceeding with TEER, involving heart failure team assessment. In cases of advanced ventricular impairment, MDTs should consider patient referral for discussion at a transplant centre within their regional network. Updated pathway: to reflect that the appropriate specialist LVAD/HTx team should assess patients with advanced ventricular failure.
Query regarding the minimum number of procedures providers should be undertaking.	Only centres providing primary TEER will be eligible for providing TEER for SMR, therefore these providers already have expertise in using the devices and procedure safely. There is no minimum currently, however ongoing work is being done involving providers.
Suggestion to replace the term “clip” with the term “implant” in the plain language summary.	PWG consider that the current description of the procedure accurately characterises the procedure.
Follow up: question if annual echo surveillance is necessary or whether it would be more appropriate with a change in symptoms?	Frequency of follow up is likely to be locally determined by expertise of MDT, taking into account patient specific factors, however the policy outlines recommendations for capturing the key outcomes and complications of interest.

Changes/addition to policy	
SLDA suggested as a complication that should be recorded under audit/monitoring.	SLDA (single leaflet device attachment) has been added into the outcomes that require recording into NICOR.
Suggestion that heart failure be added into the first paragraph of the document, in line with the plain language summary	Wording amended as follows: [this policy] focusses on patients with heart failure, an impaired LVEF, and secondary mitral regurgitation.

5. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

- In summary: [this policy] focusses on patients with heart failure, an impaired LVEF, and secondary mitral regurgitation.
- In audit requirements: SLDA (single leaflet device attachment) has been added into the outcomes that require recording into NICOR.
- In starting criteria: “MDTs should consider all suitable treatment options available and appropriate for each patient before proceeding with TEER. Decision making in high-risk patients is complex and shared decision-making principles which are patient centred should be applied. “
- In starting criteria: “In cases of advanced ventricular impairment, MDTs should consider patient referral for discussion at a transplant centre within their regional network before making a decision around TEER suitability.”
- In monitoring criteria: patients may require specialist inpatient periprocedure heart failure team input, for example pre-procedure optimisation.
- In appendix 1 anatomical guidelines: RV size and LV size has been added to the list of parameters to consider.
- In patient pathway: Updated pathway to reflect that the appropriate specialist LVAD/HTx team should assess patients with advanced ventricular failure.

6. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.