NHS England

Engagement Report for Clinical Commissioning Policy Statements

Unique Reference Number	1714
Policy Title	Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation
Accountable Commissioner	Carrie Gardner
Clinical Reference Group	Cardiac Services CRG
Which stakeholders were contacted to be involved in policy development?	Registered Stakeholders of the Cardiac Services CRG and members of that CRG
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	British Cardiovascular Society/British Cardiac Intervention Society These organisations are not currently registered as stakeholders of the Cardiac Services CRG however the current BCS president and Honorary Secretary had the opportunity to review the policy proposition as CRG members.
Which stakeholders have actually been involved?	One Individual, 1 NHS Trust and 1 manufacturer
Explain reason if there is any difference from previous question	Not all stakeholders responded to the testing request
Identify any particular	N/A

stakeholder organisations that may be key to the policy development that you have approached that have yet to be engaged. Indicate why?	
How have stakeholders been involved? What engagement methods have been used?	The policy proposition and the evidence review were sent out to stakeholders via email. Stakeholders were asked to complete a response form within two weeks. A reminder email was sent out after one week.
What has happened or changed as a result of their input?	Three submissions were received during stakeholder testing and the comments were reviewed by the PWG. The PWG notes the comment by Edwards Lifesciences Ltd and agree that the policy proposition should be as generic as possible and references to MitraClip should be changed except where it is in reference to evidence about that specific technology. Other comments were not felt to require any changes to the current policy proposition for the reasons given below: The question regarding the prior approval system is incorrect as this is the terminology used in the NHS Standard Service Conditions and is covered in detail by SC29.21. Furthermore, the number of centres are not about the policy proposition per se and further information can be found in the Integrated Impact Assessment, which will go out to public consultation. The PWG had noted the publication of new evidence in the COAPT study but felt that as that was for a clinical distinct and different cohort of patients the clinical community should consider if a new policy proposition was required and progress this if so.
How are stakeholders being kept informed of progress with policy development as a result of their input?	Stakeholders will be kept informed of the policy's progress through the NHS England consultation portal website. Regular updates are given at CRG meetings and other relevant fora.

What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?	One individual responded that a period of public consultation of up to 12 weeks would be appropriate for this policy proposition as they are launching their own technology for percutaneous mitral valve leaflet repair in a few weeks and wanted to ensure that it is considered under this commissioning proposal. A period of 30 days would be in line with other policy propositions following the cardiac Commissioning through Evaluation programme and the PWG did not feel that there was a compelling reason to have a longer period in this case. Moreover, the evidence for the new technology has not been presented and can be considered once available. The PWG also noted that an extended consultation period would make it impossible for this policy proposition to be discussed at the May prioritisation meeting. As these meetings happen twice a year this would mean a delay of six months before it could be considered which the PWG felt would have a greater impact on patients than a shorter consultation period.

Organisation Responding	Feedback Received	PWG response
1. **Individual**	The respondent supported a period of up to 6 weeks of public consultation. They provided the below comments: Use of NHS England prior approval system is mentioned – there is no such system. There is Blueteq but use of this system requires the relevant questions to be developed for providers to complete, set up can take time and it is very hard to check if completed before payment is made.	Prior approval scheme has been used as it is the correct terminology included in the NHS Standard Contract General Conditions and is covered in detail under Service condition:29.21 Blueteq is the current prior approval scheme used by NHS England The prior approval form (Blueteq) is developed as part of the policy proposal documents and will need to be completed prior to the procedure being undertaken. This is in line with other devices. All Regions will need to

	"Treatment will be commissioned from a limited number of specialised mitral valve centres" how will centre selection be done and is there a process for this? How many per a region would a limited number be? Is there a minimum number of procedures a centre would need to undertake. Will the addition of these devices to the HCTED list for each relevant provider be done centrally? No conflicts of interest were declared.	have a process in place to monitor all returns whether for drugs or devices. If this policy is approved for routine commissioning as part of the prioritisation process a procurement intervention will be required to determine the commissioned centres. More information on the number of centres is in the Integrated Impact Assessment. Yes
2. Hospital	The respondent provided the below comments: XXXX Trust is fully supportive of the commissioning of Mitraclip for the treatment of degenerative mitral regurgitation (DMR). However, there is now considerable randomised control trial evidence to	The PWG has noted the publication of new evidence with regards to the population with

	support the use of the device in the treatment of functional mitral regurgitation (FMR). The COAPT Study (N Engl J Med 2018; 379:2307-2318) concluded that among patients with heart failure and moderate-to-severe or severe FMR who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy, transcatheter mitral-valve repair resulted in a lower rate of hospitalization for heart failure and lower all-cause mortality within 24 months of follow-up than medical therapy alone. The rate of freedom from device-related complications exceeded a prespecified safety threshold. It also seems from the data so far provided from the Commissioning through Evaluation program that Mitraclip therapy for FMR is as successful as for DMR (60% of patients treated had FMR and it seems that the data is presented for the group as a whole). Based on this data it would not seem appropriate to exclude patients with function MR from this therapy. No conflicts of interest were declared.	functional mitral regurgitation (FMR). This policy proposition has focussed specifically on the DMR population as this is where there was a body of evidence of benefit to patients. If this evidence is felt to be significant a new policy proposition could be submitted for consideration.
3. Manufacturer	The respondent supported a 12-week period of public consultation. They provided the below comments: XXX welcomes the commissioning of percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation. It is an area of unmet need particularly for high surgical risk, inoperable patients. However, the	The PWG note this comment. When the policy proposition was drafted there was only

	commissioning document is titled for a general percutaneous procedure but is specific to one technology (ie. MitraClip). XXX will be launching its own technology for percutaneous mitral valve leaflet repair in a few weeks and want to ensure that it is considered under this commissioning proposal. There are a number of technologies due to be released this year that will use the percutaneous approach to treat both degenerative and functional mitral regurgitation through annular repair, leaflet repair and chordal repair. I am sure that NHS England would prefer to minimise the number of commissioning documents for the same indication so we would like consideration for this. We would like to see a proposal that will accommodate alternative technologies for this condition. Bearing in mind the proposal covers a single technology we would like a planned timeline for the commissioning review. The below conflict of interest was declared: I represent a supplier to the NHS in this area.	one available technology however the PWG agrees that the policy proposition should be as generic as possible given the potential for market changes. The policy proposition should be changed except where there is a direct reference to evidence which only relates to this particular technology