SPECIALISED COMMISSIONING - CLINICAL EVIDENCE EVALUATION CRITERIA FOR A PROPOSITION FOR A CLINICAL COMMISSIONING POLICY FOR ROUTINE COMMISSIONING

URN: 1693
TITLE: Mechanically assist circulatory devices for advanced heart failure.

CRG: Cardiac Services
NPOC: Internal Medicine
Lead: Ursula Peaple
Date: 18/10/17

This policy is being considered for:	For routine commissioning	X	Not for routine commissioning	
Is the population described in the policy the same as that in the evidence review including subgroups?	Partially. Panel noted some heterogeneity between studies with difference in inclusion criteria, severity and eligibility / ineligibility for heart transplant that the studies include patients who were dependent upon inotropes and some that were not. There were differences In severity and differences in eligibility for heart transplant.			
Is the intervention described in the policy the same or similar as the intervention for which evidence is presented in the evidence review?	Yes.			
Is the comparator in the policy the same as that in the evidence review? Are the comparators in the evidence review the most plausible comparators for patients in the English NHS and are they suitable for informing policy development?	Panel noted that there are no controlled studies which reported the outcomes for continuous flow left ventricular assist devices (CFVAD) compared to optimal medical therapy (OMM) in patients ineligible for transplant and dependent on inotropes who were implanted with a device as destination therapy. This is the group of patients who may be eligible for treatment through this policy proposition. Comparators are with optimal medical management, mostly using outcomes from registry data. The panel considered that the comparison with best supportive care would be appropriate given the life limiting nature of heart failure. The nature of the evidence means that the degree of benefit cannot be accurately estimated given the lack of controlled groups in the studies. Studies without a control group are known to frequently overestimate treatment benefits. The studies are somewhat heterogeneous and vary in their quality. Quality of life is important in this group of patients. All studies which reported quality of life outcomes reported significant improvements although some of these were highly selective in recruiting subjects for analysis (i.e. those who died or were too unwell to complete a quality of life assessment were excluded from			

	the analysis). The subjects included in the analysis vary from study to study and in some cases patients who have died have been excluded from the analysis.
Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy? Are the clinical harms demonstrated in the evidence review reflected in the eligible and /or ineligible population and/or subgroups presented in the policy?	We note the benefit in terms of extension of life and benefits reported in the 6 minute walking test. The Panel noted the significant risks and harms associated with the intervention. These include bleeding, stroke, and infection.
Rationale Is the rationale clearly linked to the evidence?	Yes with regard to the evidence of clinical effectiveness. . Panel considered the evidence of cost effectiveness and noted the high QALY estimates from studies with the most optimistic reported as being £91,000 per Quality Adjusted Life Year (QALY). The true figure could be significantly higher. The upper threshold for cost effectiveness used, for example by NICE when making recommendations to the NHS on health care interventions, is very much lower. Given the uncertainty regarding the magnitude of net clinical benefit and the likelihood that the introduction of this technology as destination therapy into the NHS would displace treatments and services for patients of greater value, the the Panel are recommending a not for routine commissioning policy.
Advice The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover: • Uncertainty in the evidence base • Challenges in the clinical interpretation	We note the poor quality of life and short life expectancy for patients with advanced refractory heart failure. We note that these devices are likely to extend life and provide some improvement in function. However, there were also significant harms associated with their use and the very high cost in relation to the benefit achieved means that this intervention would be well outside the usual parameters for routine commissioning. It should therefore proceed as a not for routine commissioning policy. The current draft policy document needs to be amended

<table>
<tr><td>and applicability of policy in clinical practice
• Challenges in ensuring policy is applied appropriately
• Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review.</td><td colspan="3">to remove the section on eligibility criteria as these will not apply. It needs to contain the evidence, including the cost effectiveness evidence and a statement needs to be added indicating the reasons for a not for routine commissioning position.

The Clinical panel may reconsider a policy in this area when evidence regarding longer term outcomes are available that demonstrated continued survival and quality of life benefits. Adverse effects over time will need to be taken into account. Evidence will need to support an estimated cost-effectiveness / value that offers value to patients and the NHS</td></tr>
<tr><td rowspan="4">Overall conclusion</td><td rowspan="2">This is a proposition for routine commissioning and</td><td>Should proceed for routine commissioning</td><td></td></tr>
<tr><td>Should reversed and proceed as not for routine commissioning</td><td>X</td></tr>
<tr><td rowspan="2">This is a proposition for not routine commissioning and</td><td>Should proceed for not routine commissioning</td><td></td></tr>
<tr><td>Should be reconsidered by the PWG</td><td></td></tr>
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<u>Overall conclusions of the panel</u>
Report approved by: David Black