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

URN: 1622
TITLE: Lung volume reduction by surgery or endobronchial valve for severe emphysema

CRG: Specialised Respiratory
NPOC: Internal Medicine
Date: 20 June 2018

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?	Yes broadly but the policy criteria need to be much clearer. Inclusion and exclusion need to be specific, clarified. Patients with a limited life expectancy do need to be excluded from treatment given the early complication rate. However, this needs to be defined more broadly; reference to palliative care, gold standards framework and disseminated cancer should be removed.			
Is the intervention described in the policy the same or similar as the intervention for which evidence is presented in the evidence review?	Yes, the strength of the evidence regarding the interventions is very variable with open surgery having the strongest evidence base. Video assisted thoracoscopic surgery (VATS) may be approximately comparable to surgery. The evidence supporting endobronchial valves (duckbill and umbrella) is based on systematic reviews that include some RCTs, although characterised by heterogeneity and lack of blinding in most studies. There is very limited evidence comparing the approaches with each other.			
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?	Comparators are with medical treatment. There is some cost-effectiveness evidence available comparing these interventions with medical therapy and it appears unlikely that open surgery is cost-effective at usual thresholds. VATS may be a slightly less costly intervention but there is no specific evidence that VATs is cost-effective at usual thresholds. There is significant uncertainty with regard to valves due to methodological weaknesses in the cost effectiveness studies, although at best valves appear to be at the high end of usual thresholds.			
Are the clinical benefits demonstrated in the evidence review consistent with the eligible population	Yes, there appear to be some quality of life, and lung function benefits associated with the recommended interventions (i.e. not umbrella valves). There appears to be a mortality benefit from open surgery that emerges over a few years, despite the early increased risk of death as a result of the procedure. Mortality			

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?	benefits were not demonstrated for the other interventions. There is a significant risk of early mortality / complications from the interventions.
Rationale Is the rationale clearly linked to the evidence?	Yes.
<u>Advice</u> 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 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.	The evidence of effectiveness is of variable quality. There is uncertainty regarding the exact relative place in the pathway re these interventions. The magnitude of clinical benefit is limited. The interventions may not be cost effective at usual thresholds. The number of potentially eligible patients is significant. The Commissioning Plan would require careful consideration given the potential volume of the service that would be required. The draft policy sections 8 and 9 need to be revised. The criteria need to be revised: • Clear exclusion criteria (see note above re-limited life expectancy). • Clear criteria for eligibility for lung volume reduction interventions of any kind. • Clear criteria for each of the interventions and where there is overlap regarding patients who could benefit equally from the interventions, the clinical criteria placing patients in this group should be clear. • The section titled ‘Standard inclusion criteria to inform referral to the MDT’ should be converted to eligibility criteria. • The section titled ‘The main reasons for the MDT not to offer LVR are’ should be converted to exclusion criteria. • The section titled ‘Indications for intervention’ should be converted into eligibility criteria.

<table>
<tr><td></td><td colspan="3">The MDT is clearly a very important aspect of the service and patients who are thought likely to meet the criteria for a lung volume intervention need to be referred to an appropriate MDT. It is the role of the MDT to assess patients against the criteria, and for patients identified as eligible, the MDT should then discuss with the patient whether they want to proceed.
The policy should therefor make reference to the MDT in this context.
The policy may include the recommended membership of the MDT and
The policy needs to be clear if CT software should be used to estimate collateral ventilation in order to demonstrate whether the patient meets the clinical criteria for lung volume reduction. Section 9 includes a useful flow chat. However, the details of follow up requirements should be removed as these represent elements of what may be included in a service specification for these services. The governance and audit sections need to be expanded so there is clarity about the clinical measures. This may need to include more details on the clinical measures included in the Lung Volume Registry and include comments on the availability of the registry data to commissioners. CPAG summary reports to be amalgamated and revised. The revised policy and CPAG summary need to be assessed by the clinical effectiveness team and then sent to the Chair for Chairs action if appropriate. The Chair may refer the policy and associated papers back to Clinical Panel if needed. </td></tr>
<tr><td rowspan="3">Overall conclusion</td><td rowspan="2">This is a proposition for routine commissioning and</td><td>Should proceed for routine commissioning</td><td>X</td></tr>
<tr><td>Should reversed and proceed as not for routine commissioning</td><td></td></tr>
<tr><td></td><td>Should proceed for</td><td></td></tr>
</table>

	This is a proposition for not routine commissioning and	not routine commissioning	
		Should be reconsidered by the PWG	

Overall conclusions of the panel
Report approved by:
David Black
Deputy Medical Director Specialised Services
17 July 2018

Post Clinical Panel Actions

The number of potentially eligible patients was reviewed as part of the Impact Assessment and within England it is estimated the actual caseload would be significantly lower.

The Commissioning Plan has considered the revised volumes within the service that would be required.

In Section 8 the criteria for inclusion and exclusion have been revised and cover each of the interventions, The MDT arrangements and the requirement for patient involvement in the final decision have been added.

The policy references that CT software should be used to estimate collateral ventilation.

Section 9 the flowchart has had the details of follow up requirements removed.

The governance and audit sections were expanded to include more details on the clinical measures included in the Lung Volume Registry and other registries.
The data on the Lung Registry is in the public domain so available to commissioners.

CPAG summary reports were amalgamated and revised.

The revised policy and CPAG summary were assessed by the Clinical Effectiveness Team.