Engagement Report for Clinical Commissioning Policy Statements

Unique Reference Number	1622
Policy Title	Lung Volume Reduction by surgery or endobronchial valve for severe emphysema in adults
Accountable Commissioner	Kathy Blacker
Clinical Reference Group	A01 Specialised Respiratory B03 Specialised Cancer Surgery
Which stakeholders were contacted to be involved in policy development?	Specialised Cancer Surgery CRG British Lung Foundation (PWG and CRG member) Pulmonix (the manufacturer of endobronchial valves)
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	Royal College of Physicians (CRG member) British Thoracic Society (CRG member) Society of Cardiothoracic Surgery in GB and Ireland
Which stakeholders have actually been involved?	Royal College of Physicians (CRG member) British Thoracic Society (CRG member) British Lung Foundation Pulmonix (company information assisted with Impact Assessment development) Specialised Cancer Surgery CRG Society of Cardiothoracic Surgery in GB and Ireland
Explain reason if there is any difference from previous	

question	
Identify any particular stakeholder organisations that may be key to the policy development that you have approached that have yet to be engaged. Indicate why?	None
How have stakeholders been involved? What engagement methods have been used?	Policy working group meeting and subsequent contact for policy development. Stakeholder engagement process. 14 day email engagement exercise with registered stakeholders
What has happened or changed as a result of their input?	Some wording to policy proposition has been amended.
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 NHS England's consultation portal website. Stakeholders who sent in comments have had an email response.
What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?	4 weeks.

Organisation Responding	Feedback Received	PWG response
NHS Trust	**<u>Quality of life measurement should not be restricted to the SGRQ.</u>** SGRQ is a predominantly research and regulatory quality of life (QoL) measure, with over 50 items, it is time consuming and burdensome to patients. The COPD Assessment Test (CAT) score is a shorter clinical QoL measure developed by the authors of SGRQ, it has been widely validated against the SGRQ including sensitivity to change e.g. following exacerbation and pulmonary rehabilitation. In addition it has a recognised minimally clinically important difference (MCID). Therefore the CAT score is essentially interchangeable with SGRQ as a QoL measure in COPD and has been adopted as the key metric in national and international guidelines. **<u>We are concerned that homogenous disease is not in the inclusion criteria for EBV.</u>** IMPACT trial showed a benefit. **<u>Proposed pathway – Not all referrals need specialist centre clinic appointment before MDT discussion, only those who may be potentially eligible</u>** Geographically centralised centres are likely to necessitate long distances for patients to travel for assessment and treatment. The proposed pathway suggests that all referrals are assessed by the clinician in the specialist centre before MDT. We would advise that discussion of physiology, HRCT, quant CT, 6MWT be discussed at the MDT to assess potential eligibility first and then potentially eligible patients be offered an appointment at the specialist centres. This would not overload outpatient capacity at specialist centres (for example by making patients travel unnecessarily to the commissioned centre if they are already deemed to be ineligible on the basis of imaging/CT). **<u>Funding</u>** The current tariffs for LVR cover the cost of the procedure but not administrative support of MDT	PWG agree and have added CAT score to the policy proposition. PWG feel and have explained in the policy proposition that clinicians use the term homogenous to describe when there is no clear target area. There must be target areas to carry out the procedure. PWG feel that services may have different arrangements to assess

	working, this should be including in NHSE commissioning Conflicts of interest: I chair the Bristol Lung Volume Reduction MDT on behalf of North Bristol NHS Trust & UHBristol NHS Trusts.	patients prior to MDT consideration and that this may be done remotely in some areas. The impact assessment will take this into account.
Individual NHS Trust	No further comments on the proposed changes to the document.	Thank you.
NHS Hospital	Intro: “stapled” off is probably a more accurate plain language word than “shaved” for LVRS Clinical indication: breathlessness at rest is a feature of very severe end stage COPD and as a requirement will lead to late referral. The typical LVR patient is breathless on exertion and has to stop for breath after a short distance (ie MRC 4dyspnoea score of 4). LVR is for “severe” rather than “very severe” COPD. Existing treatment should include smoking cessation The guidance should match the draft NICE COPD guidance to consider possible suitability for LVR in patients who are still significantly limited by breathlessness at the end of a course of pulmonary rehabilitation. PAGE 27 here https://www.nice.org.uk/guidance/gid-ng10026/documents/short-version-of-draft-guideline Section 6: there are 1.3 million people in the UK with a diagnosis of COPD (see QOF	PWG wish to keep the term shaved as it describes the outcome rather than the process and feel that stapled may give patients the wrong impression. The term ‘at rest’ has been removed.

	data https://www.gpcontract.co.uk/browse/UK/Chronic%20obstructive%20pulmonary%20disease/17 (most recent 1.2 million number excludes Scotland). The estimate of prevalence is Clark 2014 not Clarke. Also as the prevalence has increased the number now is about 17,000 Surgical approaches for lung volume reduction in emphysema. **Clark** SJ, Zoumot Z, Bamsey O, Polkey MI, Dusmet M, Lim E, Jordan S, **Hopkinson NS**. Clin Med (Lond). 2014 Apr;14(2):122-7. doi: 10.7861/clinmedicine.14-2-122. Evidence review for LVRS should state evidence from NETT trial of substantial sustained survival benefit with LVRS vs controls. The National Emphysema Treatment Trial (NETT) Part II: Lessons learned about lung volume reduction surgery. **Criner** GJ, Cordova F, Sternberg AL, Martinez FJ. Am J Respir Crit Care Med. 2011 Oct 15;184(8):881-93. doi: 10.1164/rccm.201103-0455CI Section 8 LVR suitability – people with lung fibrosis are not suitable for LVR procedures. Also marked hypoxia (PO_2<7) is a contraindication whereas hypercapnia is not (nor is being on NIV) The SGRQ is time consuming for clinical practice – I would suggest the CAT score instead as this is widely embedded in clinical use and consistent with draft NICE guidance update MDT assessment – exclusions should include frailty and multimorbidity and an explicit reference to ability to survive a pneumothorax which will occur in around 20% of valve treated patients, usually within the first three days. The treatment pathway for valves should include that they are not a day case procedure – patients need to be observed for 3 nights after the procedure because of the risk of post-procedure pneumothorax which can be fatal. Section 9 referral pathway A major issue is late referral and this only addresses once the person has been referred. In order to be consistent with draft NICE guidance it should include a pathway from pulmonary rehabilitation for consideration in potential candidates (MRC score 4 or 5, FEV1 <50% no major contraindications) for considering referral for a respiratory review (CT, lung volumes, gas transfer) to see if they meet criteria to enter LVR MDT process). In the current pathway rehab occur after	Smoking cessation has been added to this section. There is a tension between QOF stated prevalence and other estimates of prevalence such as BLF. PWG feel that the current evidence does not demonstrate effectiveness in patients with hypercapnia >7. PWG feel that the ability to survive a pneumothorax will be covered by the existing inclusion/

	MDT which might happen but should not be the usual. Conflicts of interest: NSH has been involved in clinical trials of LVR involving surgery and valves. Conflicts of interest: none to declare.	exclusion criteria. Pulmonary rehabilitation now included.
British Thoracic Society	We welcome the clear criteria for referral to a LVR MDT, but recommend the addition of completion of pulmonary rehabilitation within the last 12 months (both in regards to assessing symptom burden following otherwise optimal treatment and operative risk). Minor comments for consideration: 1. Section 6: the British Lung Foundation Respiratory Health of the Nation project estimated the number of patients currently diagnosed with COPD was substantially higher (~1.2 million rather than 835,000). 2. Patients with severe airflow obstruction, but FEV_1 above 40%, would be accepted for discussion in some centres provided all other criteria are met, most importantly regarding symptom burden (despite optimal Rx including rehab), degree of hyperinflation and, for safety, TLCO>20% and FEV1>20%. Conflicts of interest: none to declare.	Added, thanks you. There is a tension between QOF stated prevalence and other estimates of prevalence such as BLF. PWG feel that the current evidence does not demonstrate effectiveness LVR in patients with FEV_1 above 40% or lower than 20% although

		recognises that there are patients who might not fit each criterion perfectly.
Manufacturer	changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation. Please note the Evidence Review on LVR by Endobronchial Valves does not include the most recent RCT (LIBERATE) on Zephyr Endobronchial Valves (Criner et al AJRCCM 2018, Published as Articles In Press May 2018). Relative to the Proposed Criteria for Commissioning, the minimum set of Patient Selection criteria used in our training guidance, derived from the totality of the evidence accrued thus far from clinical and product experience, includes: • Severe emphysema (evidenced by CT scan and medical history) – without specificity to heterogeneity • BMI<35 kg/m^2 • FEV_1 % predicted ≤45% and ≥15% • TLC≥100% predicted post bronchodilator • RV≥175% predicted post bronchodilator • 6MWD >100 m and < 500 m • Non smoker for > 4 months • Little to no collateral ventilation between treatment and ipsilateral lobe We recommend that the Referral and Inclusion Criteria should be consistent with this experience. Of note and to ensure consistency, the Draft NICE guidance for COPD management	The PWG Public Health Consultant will review the paper but PWG clinicians feel that there is nothing in the paper requiring changes to the policy. PWG feel that the current evidence does not demonstrate effectiveness LVR in patients with FEV_1 above 40% or lower

	(https://www.nice.org.uk/guidance/indevelopment/gid-ng10026) should be included as an input to this document and provides guidance reasonably consistent with the list above. Importantly, inclusion criteria for EBV should not be restricted to solely heterogeneous disease. As noted in the Commissioning document (*Section 7, summary of the Evidence review: Evidence relating to some of these outcome measures indicates there is a greater benefit in patients with heterogeneous emphysema…although patients with homogenous emphysema with heterogeneous perfusion may benefit too*. The Cochrane report quoted in the evidence review indicates on page 31 a significant mean difference [in FEV1] of 16.36% [in homogeneous patients].) TLCO >20 should not be a definitive inclusion criteria and previous thoracic surgery should not be an inclusion criteria for EBV. Patients with severe pulmonary hypertension may be referred and considered on a case by case basis, based on a MDT evaluation. Conflicts of interest: Pulmonx is the manufacturer of the Zephyr Valve	than 20% although recognises that there are patients who might not fit each criterion perfectly. The NICE COPD Guidance is not yet published so we cannot yet refer to this in the policy proposition, but the PWG do not anticipate any significant changes that would require amendments to the policy. PWG feel and have explained in the policy proposition that clinicians use the term homogenous to describe when there is

		no clear target area. There must be target areas to carry out the procedure. PWG do not agree that TLCO >20 should not be a definitive inclusion criteria and previous thoracic surgery should not be an inclusion criteria for EBV, or that patients with severe pulmonary hypertension should be treated as there is currently no evidence of effectiveness.

Royal College of Physicians	RCP endorses the response of the British Thoracic Society	Thank you.
Society for Cardiothoracic Surgery in GB and Ireland	We would support the principle that surgical or bronchoscopic LVR interventions should only be offered in units that have robust LVR multidisciplinary teams and can offer the full range of appropriate investigations and treatments for this complex group of patients, with selection based on accepted evidence. There is however a need for more evidence as to the value of other endoscopic interventions and it is hoped that trial data will better define their efficacy in due course.	Thank you for your comments.