

**Clinical
Commissioning
Policy:
Lung volume
reduction by surgery
or endobronchial
valve for severe
emphysema in adults**

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1 Executive Summary

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between people in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About Lung volume reduction by surgery or endobronchial valve for emphysema in adults

Lung volume reduction (LVR) is an approach which removes the most damaged areas of lung so that the healthier parts can work better. By removing the enlarged lung air spaces that occur in emphysema, less air is trapped so that breathing is more efficient and comfortable. There are two National Institute for Health and Care Excellence (NICE) guidance documents (IPG114, 2005 and IPG600, 2017), on LVR procedures. One approach involves surgery to cut out part of the diseased lung; the other is to insert a valve or valves into the airways to stop air from getting into the diseased parts of the lungs. LVR is also included as treatment in the updated NICE Guidance 115, (2019) for the diagnosis and management of chronic obstructive pulmonary disease (COPD) in over 16 year olds.

About current treatments

Emphysema is one of a group of long-term lung diseases that form COPD. In emphysema, there is damage to the air sacs in the lungs which become baggy, trap air and become over-inflated, making it difficult to breathe. People with emphysema experience cough, sputum production, tiredness and weight loss, can be very limited in day to day activities, have acute attacks which are a common cause of hospital

admission, and have reduced life expectancy. Clinicians use the terms heterogenous or homogenous emphysema to describe whether there is a target area of the lung that can be treated with LVR. Homogenous means there is no target area, heterogeneous means there is a target area. The greater the clarity of the target area the better the expected outcome of the treatment.

Current treatments for emphysema include practical advice (such as stopping smoking), exercise and breathing retraining, oxygen treatment and lung transplant. Inhaled medication can improve some symptoms but does not change the progression of the disease.

About the new treatment

There are currently two procedures for LVR which are undertaken in clinical practice. These two treatments have the most robust evidence and clinical experience to identify the patients who will gain the most benefit from treatment. Both approaches involve targeting the area of the lung with the worst emphysema. This is because air trapped in damaged areas of lung tissue takes up space in the chest and stops healthy lung tissue from inflating.

In carefully selected patients with severe emphysema, these two treatments can improve breathlessness, exercise capacity, lung function and quality of life as well as prolonging survival.

LVR through surgery (LVRS)

LVRS is done as keyhole surgery under a general anaesthetic. The surgeons make two or three small openings in the chest wall to access the lung. The worst affected part of the lung is stapled off and removed. The remaining lung then re-inflates and can work more effectively.

LVR through endobronchial valve (EBV) technique

Under a general anaesthetic or sedation, a thin flexible tube with a camera on the end (bronchoscope) is moved through the patient's nose or mouth into the lungs. Small, one-way valves (duckbill type) are passed through the tube and placed in the airways that supply the most diseased part of the lungs. The valves stop air from getting into the diseased parts of the lungs when breathing in but allow air and mucus out when breathing out. This causes the target area of lung to shrink, which has the same effect as if it had been surgically removed. Valves only work in people where a whole lobe of lung (there are three on the right and two on the left) can be blocked off. If the emphysema has broken down the barrier that separates the lobes then air can get into the target lobe from the adjacent one so the valves don't have any effect. Both treatments need the involvement of a multi-disciplinary clinical team (MDT) to ensure that only people who will benefit from one or other LVR procedure go on to have the best procedure for them.

What we have decided

NHS England has carefully reviewed the evidence to treat severe emphysema with LVR in adults. We have concluded that there is enough evidence to consider making treatments with both surgery and endobronchial duckbill valves available in centres with an experienced MDT.

We have also concluded that in line with NICE guidance IPG517 coils, umbrella-type valves and other novel technologies should remain within the research setting. The proposed pathway by assessment through an MDT would enable patients with emphysema not suitable for surgery or valves to be able to access ongoing research studies with these alternative developing therapies in line with the research recommendation in NICE IPG517, (2015).

2 Introduction

Background – Despite maximal medical therapy severe emphysema remains extremely debilitating, leading to a reduction in the quality of life, increased use of healthcare resources and eventually premature death. Currently, LVR treatments

are carried out in only a few hospitals in England so patient access is variable. Access to different techniques is also variable and can depend on individual operator preference.

Signs and symptoms – breathlessness, reduction in exercise capacity and ability to do day to day activities, weight loss, hyperinflated chest, bronchospasm, chronic cough, infective exacerbations, impairment in quality of life.

Existing treatment – smoking cessation, bronchodilating inhalers, corticosteroid inhalers, systemic steroids, pulmonary rehabilitation, supplemental oxygen therapy, domiciliary non-invasive ventilation, lung transplant.

Proposed intervention –LVR by surgery or endobronchial valve insertion after assessment by a specialist MDT.

Rationale – by excising non-functioning lung tissue or by causing collapse of poorly functioning emphysematous lung tissue, a reduction in lung volume produces a change in chest wall mechanics enabling more efficient respiration. It also stops the remaining, healthier lung from being compressed, which allows it to function better. In appropriately selected individuals these treatments reduce gas trapping in the lung and by doing this improve lung function and reduce the sensation of breathlessness, improving exercise capacity and quality of life, as well as prolonging survival by delaying the development of respiratory failure and the need for frequent hospitalisation in what is otherwise a persistent and progressive condition.

3 Definitions

Emphysema is one of the group of lung conditions that compose COPD. It affects the air sacs at the end of the airways in the lungs. They break down and the lungs become baggy and full of holes which trap air. People with severe emphysema typically have significant breathlessness and have a poor quality of life with a limited life-expectancy.

LVRS is a surgical operation which removes the worst affected areas of the lung so that the healthier parts can work better. By removing the enlarged air spaces, less air is trapped so that breathing is more efficient and comfortable.

EBV is a procedure where small, one-way valves are placed in the airways that supply the most emphysematous part of the lungs. The valves stop air from getting into the target lobe of the lung when breathing in but allow air and mucus out when breathing out. The target lobe shrinks so lung volume is reduced which enables more efficient and comfortable breathing.

4 Aims and Objectives

This policy considered: LVR for symptomatic severe pulmonary emphysema by either surgery or endobronchial valve placement.

The objectives were to:

- Establish a policy for the appropriate use of these procedures in correctly selected patients discussed by a multidisciplinary team.
- Ensure equitable access to these selection processes and treatments across England.

5 Epidemiology and Needs Assessment

Emphysema is one of the presentations of COPD. It is caused by the inhalation of noxious materials, most commonly tobacco smoke, which causes elastic tissue in the lung parenchyma to be broken down. COPD is strongly linked to socioeconomic disadvantage because of smoking rates being higher in people in routine and manual occupations. It is also linked to early life disadvantage which impairs lung growth and to occupations where individuals inhale dust, fumes and chemicals such as industrial jobs and domestic cleaning.

COPD is one of the leading causes of morbidity and mortality in the world. There are around 1.1 million people with a diagnosis of COPD in England [QOF data 2019] as well as a substantial number of individuals with the condition who have not yet been diagnosed (Nacul et al, 2010). Respiratory disease is identified as a clinical priority in the NHS Long Term Plan. Over 50% of people currently diagnosed with COPD are under 65 years of age. 24 million working days are lost each year from COPD with £3.8 billion lost through reduced productivity.

Of the medical therapies used in management, only smoking cessation has been shown to modify the natural history of the condition. Oxygen therapy is associated with survival benefit. Emphysema is often associated with other conditions that need assessment and effective interventions in a holistic care approach; about 40% also have heart disease, and significant numbers have depression and/or anxiety disorder.

While COPD is very common, it is estimated that only a very small proportion of people with COPD may meet the criteria to be assessed for lung volume reduction. The NICE COPD Guideline (2019) recommendation includes LVR as an intervention that should be offered to suitable patients after appropriate assessment. Accurate data on the number of individuals in England who would be potentially eligible for LVR are lacking. Whittaker et al (2020), using CPRD data from primary care estimated that 0.2% of people with COPD would meet clinical criteria to be assessed for a possible LVR procedure (2,200 in England). Of these, based on data from Akuthoza et al (2012) only 30% of those who were clinically eligible actually had an appropriate pattern of emphysema on their CT scan and this suggests an estimated 660 individuals in England would be suitable for an LVR procedure increasing to around 1200 over 5 years (Hopkinson et al, (2019) and McNulty et al, (2014).

6 Evidence Base

NHS England has concluded that there is sufficient evidence to support a policy for the routine commissioning of this treatment for the indication.

Evidence Review: LVR using video assisted thoracoscopy surgery (VATS) for severe emphysema

Summary of results

- The results suggest that VATS is an effective intervention for improving Quality of Life (QoL), exercise capacity and lung function in patients with severe emphysema in the short-term. Uncertainty remains about the risk of death and serious complications associated with the surgery.
- It is unclear whether there is a difference in effectiveness and safety between VATS and open surgery as the majority of results were statistically non-significant and most studies included both approaches. Only one study compared VATS and open surgery. However, results would suggest if there are any differences between the approaches, they are likely to be relatively small. Hospital stay was shorter for VATS and costs appear lower, although the costs reported are from over ten years ago and from a US setting.
- Overall, the results should be treated with caution as the included trials were relatively small. In addition, a couple of the trials were unbalanced in respect to known prognostic factors at baseline which may have introduced bias. Finally, the trials comparing VATS to medical management had short follow-up times of up to 12 months before cross-over, so the long-term effectiveness of VATS is not known although its utilisation in the previous reported open surgery studies with longer follow up should be noted.

Evidence Review: LVR by Endobronchial Valves for severe emphysema

Summary of results:

- Results on a range of measures suggests that duckbill type valves provide significant meaningful benefit to patients in terms of lung function, exercise capacity and QoL, despite issues such as heterogeneity and lack of blinding

in most studies. Evidence relating to some of these outcome measures indicates there is a greater benefit in patients with heterogeneous emphysema, patients without Collateral Ventilation (CV) to the target lobe and those where lobar occlusion is complete, although patients with homogenous emphysema with heterogeneous perfusion may benefit too. However, risk benefits need to be carefully appraised when making individual patient decisions and the fact that cost-effectiveness is not clear.

- Umbrella type valves appear to have a negative effect or no effect on these outcome measures. However, this may be due to the treatment strategy tested rather than the type of valve, as the strategy in the two RCTs was partial occlusion of bronchi bilaterally without accounting for CV status, whereas in the duckbill valve trials it was complete occlusion of the most damaged areas of lung in those without collateral ventilation.

Evidence Review: LVR using open surgery for severe emphysema

Summary of results:

- The results are based on one large RCT with long follow-up and two smaller studies with shorter follow-up, all of good quality.
- The evidence suggests that open LVRS is likely to be an effective intervention for improving QoL, exercise capacity and lung function in selected patients with severe emphysema in the short-term with some sustained benefits shown in QoL and exercise capacity in the longer term. Despite the early mortality and complication risks observed with open LVRS, overall long-term survival appears to be improved. Patients with upper lobe emphysema and low exercise capacity were shown to benefit most from open LVRS.
- The cost-effectiveness of open LVRS, even for the sub-group of patients with greatest benefit, is higher than usual commissioning thresholds. Furthermore, the long-term cost-effectiveness estimates are subject to large uncertainty.

7 Criteria for Commissioning

The evidence reviews show that LVR by either surgical technique or endobronchial valves show evidence of effectiveness. Patients need to undergo an assessment by an LVR MDT to determine the most appropriate intervention. This is an essential part of the service and no patients undergoing LVR should do so without discussion at an LVR MDT. They ensure the selection criteria are met; assess which technique is most suited to the individual patient (based on anatomy and physiology) and assess the individual risk and whether LVR is appropriate at that time. The appropriate member then discusses the conclusions of the MDT with the patient to enable informed consent. An LVR MDT should consist of a surgeon, COPD physician, interventional bronchoscopist, radiologist, and specialist nurse as a minimum, with appropriate administrative support.

Patients with a limited life expectancy or multiple co-morbidities who do not meet eligibility criteria should not be referred for consideration at the LVR MDT given the early complication rate. Referrals should come from secondary care clinicians currently involved in the care of the patient.

Referral to LVR MDT

In line with NICE guidance (2019), to be eligible for MDT assessment and consideration for treatment the following approach should be followed. Offer a respiratory review to assess whether a lung volume reduction procedure is a possibility for people with COPD when they complete pulmonary rehabilitation and at other subsequent reviews, if at the respiratory review all referral criteria apply:

Referral Criteria

- Evidence of symptomatic hyperinflation due to emphysema with impaired quality of life. Medical Research Council (MRC) Dyspnoea Scale 3 or more
- Non-smoker at least 4 months
- Completion of a Pulmonary Rehabilitation programme within last 12 months or ongoing participation in a post-PR exercise programme

- Six minute walk distance >140m or Incremental Shuttle Walk Test (ISWT) >80m
- Forced Expiratory Volume in one second (FEV₁) <50% predicted
- Carbon Monoxide Diffusion Capacity (DLco) or Carbon Monoxide Transfer Coefficient Kco > 20% predicted
- Residual Volume (RV): Total Lung Capacity (TLC) > 55%
- RV> 150%
- PaCO₂<7KPa (partial pressure of carbon dioxide)
- Body Mass Index (BMI)> 18,

Patients unsuitable for referral to the LVR MDT include those with:

- Severe co-morbidities such as renal, hepatic or cardiac failure, or other chronic respiratory disease such as pulmonary fibrosis
- Severe progressive disease including disseminated malignancy
- Severe pulmonary hypertension

MDT Assessment

The MDT will require additional information on the following criteria to inform their decision making regarding the appropriateness of LVR and the preferred method:

- The use of quantitative lung perfusion scans and high-resolution computer tomography (HRCT) to determine the distribution of emphysema in either upper or lower lobes as target areas for volume reduction.
- The greater the clarity of target areas the better the likely outcome from treatment.
- An assessment of exercise ability, either shuttle walk test (SWT) or 6 minute walking distance (6MWD) to determine the required fitness for LVR or the need for further pulmonary rehabilitation.
- The calculation of predicted procedural risk using published indices of body mass index, airflow obstruction, dyspnoea, exercise capacity index (BODE) and Glenfield risk scoring (Greening et al, 2017).

Those thought suitable for LVR with appropriate physiology and target areas should proceed to bronchoscopy assessment to determine the presence of collateral ventilation between lobes which would exclude EBV. In cases with clearly defined fissures (CT software can be used as an adjunct to estimate the likelihood of collateral ventilation)

Either the St George's Respiratory questionnaire or the COPD Assessment Test (CAT) score should be measured as a baseline Quality of Life assessment.

Exclusion criteria

The main reasons for the MDT to determine that LVR is clinically inappropriate are:

- Lack of suitable target areas.
- Excessive risk. Risk of morbidity and mortality after LVRS is related to the severity of the emphysema as measured by absolute FEV₁ and predicted Diffusion Lung Capacity (DLco) and the patient's nutritional status as measured by BMI. (Greening et al, 2017)
- Presence of significant lung comorbidity – fibrosis

Eligibility Criteria for LVR Intervention:

LVRS (method to be determined after MDT assessment)

- Upper lobe heterogeneous emphysema
- RV:TLC >60, TLco or Kco >20, BMI >18
- Collateral ventilation and low exercise capacity
- Predominantly apical disease with collateral ventilation and low exercise capacity.
- Lower lobe heterogeneous emphysema with collateral ventilation

Patients with collateral ventilation should be fully informed of the individualized risk of LVRS and treatment undertaken in those consenting.

Patients with previous thoracic surgery may be considered and should be fully informed of the individualized risk of LVRS and treatment undertaken in those consenting.

EBV:

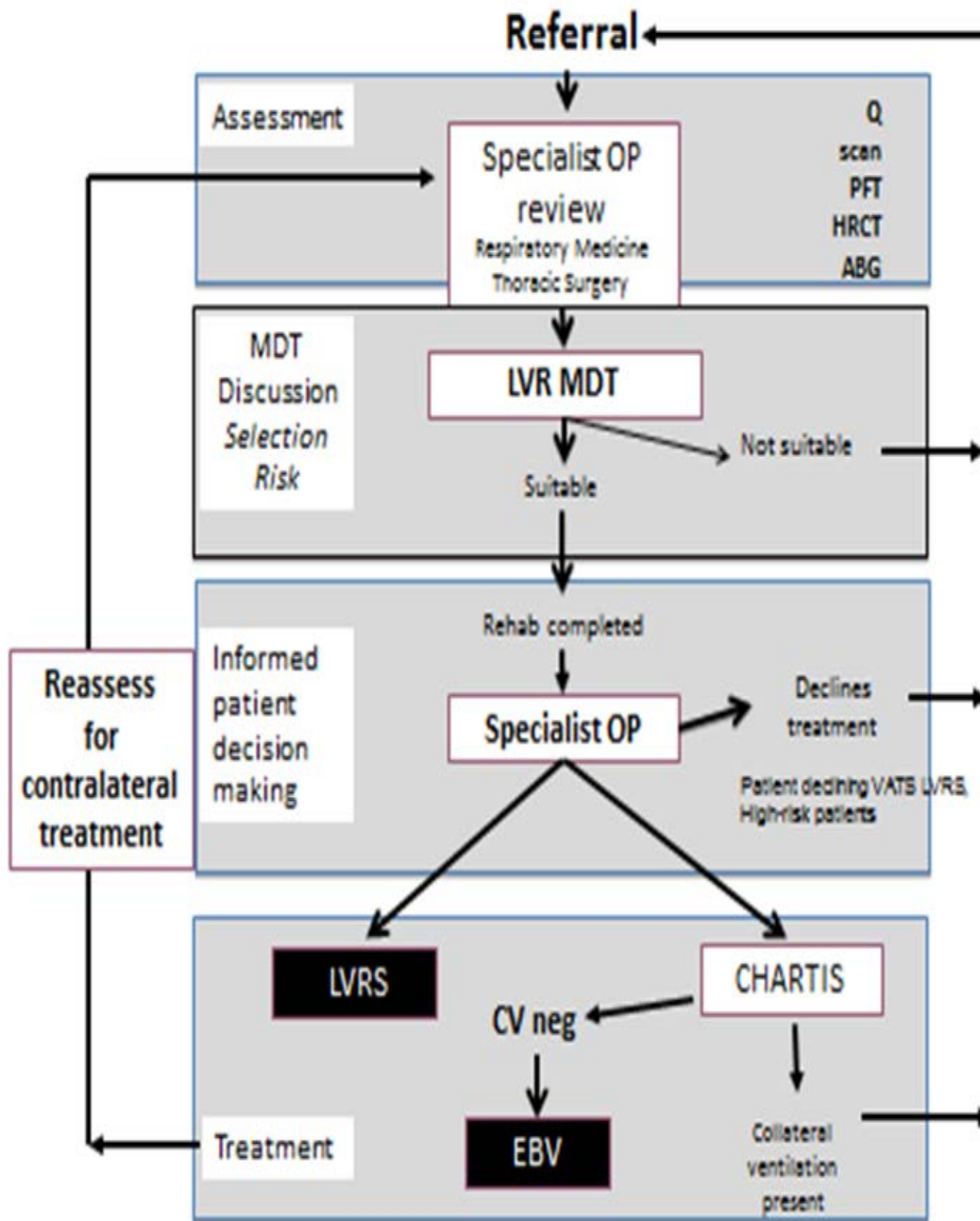
- Upper or lower lobe heterogenous emphysema without collateral ventilation.
- RV >180%, TLco >20, BMI >18.
- Previous thoracic surgery

LVRS or EBV:

- Upper or lower lobe heterogenous emphysema without collateral ventilation.
- RV > 180% and/or RV:TLC >60, TLco >20, BMI >18

Patient choice is of key importance and careful explanation of the potential treatment risks and benefits of both procedures must be given.

8 Patient Pathway



9 Governance Arrangements

NICE guidance should be followed.

EBV should not be carried out as a day case procedure due to post procedural risks.

All future LVR procedures must be entered into the UK Lung Volume Registry (UKLVR).

LVRS procedures are already entered into the Society for Cardiothoracic Surgery's Audit. Outcomes for complications and 30 day mortality are published.

A dashboard of quality measures is to be developed and linked to the Thoracic Surgery Adults Service Specification 170016/S.

Commissioned LVR services should be delivered by thoracic services, respiratory services and interventional bronchoscopy services working together through a joint MDT.

Provider organisations must register all patients using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined.

10 Mechanism of Funding

LVRS and EBV are both within tariff so will be identified and paid for through standard coding methodology.

NICE IPG517 states that coils and other novel technologies should currently remain within the research setting and NHS England will not fund these specific interventions.

11 Audit Requirements

National data collection process for commissioned services with outcome data and benchmarking and production of an annual national report.

Each commissioned service will produce an annual report regarding patients assessed and those treated but also those considered. This should be available to commissioners.

All interventions should be entered into the relevant national register.

LVR procedures must be entered into the UK Lung Volume Registry (UKLVR).

LVRS procedures must also be entered into the Society for Cardiothoracic Surgery Audit.

12 Documents That Have Informed This Policy

National Institute for Health and Care Excellence (NICE) Lung volume reduction surgery for advanced emphysema [IPG114]. *NICE*. February 2005.

<https://www.nice.org.uk/Guidance/IPG114>

National Institute for Health and Care Excellence (NICE) Insertion of endobronchial nitinol coils to improve lung function in emphysema [IPG517] *NICE*. March 2015.

<https://www.nice.org.uk/guidance/ipg517>

National Institute for Health and Care Excellence (NICE) Endobronchial valve insertion to reduce lung volume in emphysema Interventional procedures guidance [IPG600]. *NICE*. December 2017. <https://www.nice.org.uk/guidance/ipg600>

National Institute for Health and Care Excellence (NICE) Chronic obstructive pulmonary disease in over 16s: diagnosis and management NICE guideline [NG115]. *NICE*. December 2018 Last updated: 26 July 2019

<https://www.nice.org.uk/guidance/ng115>

NHS. The NHS long term plan. 2019. <https://www.longtermplan.nhs.uk/>

NHS England. (2020). Gender Identity Services for adults; surgical interventions.

NHS England. (2018) Lung volume reduction using video assisted thoracoscopic surgery for severe emphysema

NHS England. (2018) Lung Volume Reduction by Endobronchial Valves for Severe Emphysema

NHS England. (2017) Thoracic Surgery Adults Service Specification (170016/S)

<https://www.england.nhs.uk/publication/thoracic-surgery-adults/>

13 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

14 References

Akuthota P, Litmanovich D, Zutler M, Boiselle PM, Bankier AA, Roberts DH, Celli BR, DeCamp MM, Berger RL. An Evidence-Based Estimate on the Size of the Potential Patient Pool for Lung Volume Reduction Surgery. *Ann Thorac Surg* 2012 (94) 205-11. doi: 10.1016/j.athoracsur.2012.03.047

Greening NJ, Vaughan P, Oey I, Steiner MC, Morgan MD, Rathinam S, Waller DA. Individualised risk in patients undergoing lung volume reduction surgery: the Glenfield BFG score. *Eur Respir J*. 2017 Jun 1;49(6):1601766. doi: 10.1183/13993003.01766-2016

Hopkinson NS, Molyneux A, Pink J, Harrisingh MC on behalf of the Guideline Committee. Chronic obstructive pulmonary disease: diagnosis and management: summary of updated NICE guidance. *BMJ* 2019 (366) I4486 (NICE NG115) <https://www.bmj.com/content/366/bmj.I4486>

McNulty W, Jordan S, Hopkinson NS. Attitudes and access to lung volume reduction surgery for COPD – a survey by the British Thoracic Society. *BMJ Open Respiratory Research* 2014;1:e000023. <https://bmjopenrespres.bmj.com/content/1/1/e000023>

Nacul L, Soljak M, Samarasundera E, Hopkinson NS, Lacerda E, Indulkar T, Flowers J, Walford H, Majeed A. COPD in England: a comparison of expected, model-based prevalence and observed prevalence from general practice data. *J Pub Health* 2010 (33) 108-116 <https://doi.org/10.1093/pubmed/fdq031>

Whittaker H, O Connell, J Campbell, A Elbehairy, NS Hopkinson*, JK Quint* (joint senior) Eligibility for Lung Volume Reduction Surgery in Chronic Obstructive Pulmonary Disease patients identified in a UK primary care setting. *Chest* 2020 (157) 276-285 <https://pubmed.ncbi.nlm.nih.gov/31381881/>

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