



National Institute for Health and Care Excellence (NICE) Issues New Guidelines for COPD, Recommending Severe Patients Be Evaluated for Bronchoscopic Lung Volume Reduction

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- NICE makes a “strong” recommendation that patients with severe COPD be referred for evaluation for bronchoscopic lung volume reduction, including the Zephyr® Endobronchial Valve System.
- NICE has broadened the criteria for evaluation and a new group of people for whom lung volume reduction surgery was unsuitable may now be evaluated for treatment with Zephyr Valves, a less invasive treatment option.

REDWOOD CITY, California, December 10, 2018 – Pulmonx, a leader in interventional pulmonary device technology announced today that the National Institute for Health and Care Excellence (NICE) in the UK has expanded its guidance on the diagnosis and management of COPD to include which patients should be referred for evaluation for bronchoscopic lung volume reduction with Zephyr® Endobronchial Valves. The Zephyr Valves offer a minimally-invasive treatment option that has been shown to improve quality of life of emphysema patients by allowing them to breathe easier, be less short of breath, and be more active.^[1]

Key highlights in the NICE Report include:

- “Strong” recommendation to assess patients with severe COPD for suitability for lung volume reduction procedures, including use of Zephyr Endobronchial Valves based on an in-depth analysis of patient outcomes data including improved lung function, quality of life, exercise capacity and survival.
- “The criteria for referring patients for lung volume reduction assessment has been broadened, because treatment options now include endobronchial valves, a less invasive option which may benefit patients who were not candidates for more invasive surgical treatments. The broadening of criteria will lead to more referrals and improved access to treatment for patients.”
- Emphysema patients who have completed pulmonary rehabilitation, stopped smoking, have lung function of less than 50% of predicted, can walk at least 140 meters in 6 minutes (a standard exercise test), and suffer from breathlessness should be referred for evaluation for lung volume reduction procedures.

“NICE is respected globally for their in-depth evidence reviews and systematic approach to clinical guideline development. We appreciate NICE’s thorough review of clinical data from multiple published Zephyr Valve randomized clinical trials ^{[1],[2],[3],[4],[5],[6]} and believe this guidance will be a valuable resource for providers and payers seeking to improve patient care” said Glen French, President and Chief Executive Officer of Pulmonx.

The guideline committee further concluded that the endobronchial valve is likely to be cost effective compared with medical management.

“Patients with COPD suffer from breathlessness and that results in poor mobility and a lower quality of life. These patients need new, less invasive options and I am very pleased to see NICE recognize this need and recommend lung volume reduction with the Zephyr Valves,” said Professor Pallav Shah of the Royal Brompton Hospital, London. “We hope to see other physicians refer more COPD patients to pulmonary specialists be evaluated for this less-invasive option.”

More on the Zephyr Valves

Bronchoscopic lung volume reduction with the Zephyr Valve is a one-time procedure performed through a bronchoscope; it requires no cutting or incisions. During the procedure, an average of four tiny valves are placed in the airways to block off the diseased parts of the lungs. This allows trapped air to escape until the lobe is reduced in size. Reducing hyperinflation and preventing air from getting trapped in the diseased parts of the lung allows the healthier parts of the lungs to expand and take in more air. This results in patients being able to breathe easier and have less shortness of breath.^[1] Patients treated report immediate relief and the ability to go back to doing everyday tasks with ease.

The Zephyr Valve was approved by the FDA in June 2018, through an expedited review because it “represents a breakthrough technology as the device offers bronchoscopic lung volume reduction without surgery and its associated risks. This device offers significant clinically meaningful advantages over the current standard of care and therefore, its availability is also in the best interest of patients.” Since 2007, more than 15,000 patients have been treated with the Zephyr Valve worldwide. Zephyr Valve treatment is included in emphysema treatment guidelines such as the Global Initiative for Chronic Obstructive Lung Disease (GOLD) Global Strategy for Prevention, Diagnosis and Management of COPD, and is already recommended for routine use in the UK’s National Institute for Health and Care Excellence (NICE) Interventional Procedures Guidance on Endobronchial Valves (<https://www.nice.org.uk/guidance/ipg600>).

More about COPD and Emphysema

Chronic obstructive pulmonary disease (COPD) is a progressive, life-threatening lung disease that includes emphysema and chronic bronchitis. More than 65 million people suffer with COPD globally and it is estimated that 3.2 million deaths were caused by the disease in 2015 (5% of all deaths

globally).^[7] Despite taking the best available medications, many COPD and emphysema patients suffer symptoms of hyperinflation, where air becomes trapped in the lungs and prevents fresh air from entering the lungs and thereby causing severe shortness of breath. Breathing becomes inefficient and patients must work very hard just to breathe – making normal activities, like walking, eating or even bathing, difficult. There are few treatment options for most patients with emphysema and there is no cure. Until now, the only other options for these patients were highly invasive treatments such as lung volume reduction surgery or lung transplantation.

About Pulmonx

Based in Redwood City, California, and Neuchâtel, Switzerland, Pulmonx is the world leader in interventional pulmonology treatments for obstructive lung disease. For more information, visit www.MyLungsMyLife.com

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NICE Guidelines: <https://www.nice.org.uk/guidance/ng115/chapter/Recommendations#lung-surgery-and-lung-volume-reduction-procedures>

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[1] Criner G. et al. Am J Respir Crit Care Med. 2018; 198 (9):1151–1164.

[2] Kemp S et al. Am J Resp Crit Care Med. 2017; 196 (12): 1535-1543.

[3] Valipour et al. Am J Respir Crit Care Med. 2016; 194(9): 1073-1082, and Data on file at Pulmonx.

[4] Klooster K. et al. N Engl J Med. 2015; 373: 2325-2336, + Supplementary Appendix

[5] Davey et al. Lancet 2015; 386(9998), 1066-1073.

[6] Sciurba et al. N Engl J Med 2010; 363(13), 1233-1244.

[7] Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980–2015: a systematic analysis for the Global Burden of Disease Study 2015. The Lancet 2016; 388: 1459-1544