



Pulmonx Announces That One of the Leading Health Care Providers in the United States Now Covers the Zephyr Valve for Bronchoscopic Lung Volume Reduction in Patients With Severe Emphysema

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- Coverage decision aligns with the FDA's decision to approve the Zephyr Valves under the "Breakthrough Devices" status.
- Zephyr Valves are the only minimally invasive device for emphysema available in the US.
- Approved by FDA in June 2018, Zephyr Valves have been approved outside the United States for many years and more than 15,000 emphysema patients have been treated worldwide.

REDWOOD CITY, Calif., November 27, 2018 – Pulmonx, a leader in pulmonary device technology, announced today that their Zephyr® Endobronchial Valve System is included in a new national coverage policy from Aetna®. Aetna is a leading health benefits company in the United States that covers more than 22 million members. With this coverage decision, Aetna's members will have access to lung volume reduction with the Zephyr Valves, the only FDA approved minimally invasive device for the treatment of patients with emphysema. Zephyr Valves are introduced into the lungs through a bronchoscope. The treatment has been shown to improve patients' quality of life by allowing them to breathe easier, be less short of breath, and be more active.^[1]

"Patients with severe emphysema need new treatment options. The Zephyr Valve has been shown in four consecutive published clinical trials to improve the pulmonary function, exercise capacity, and quality of life of these patients^{[1],[2],[3],[4]} which led FDA to designate the Zephyr Valve a 'breakthrough device,'" states Glen French, President and Chief Executive Officer of Pulmonx. "Aetna's coverage policy is serving its members well by making this well-proven new treatment available to them."

Under its policy Aetna specifically names the Zephyr Valve System as an approved bronchoscopic option for lung volume reduction and considers it medically necessary for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

"Zephyr Valves are a major step forward in treating severe emphysema and it is very exciting to see a large health plan like Aetna offer coverage to its members. This coverage gives patients access to a new treatment that can improve their lives long term without the risk of major surgery," said MeiLan Han, MD, Professor of Medicine in the Division of Pulmonary and Critical Care at the University of Michigan. Dr. Han is co-chair of the University of Michigan COPD Quality Improvement Committee and co-authored the University of Michigan COPD Guidelines. "Patients with severe emphysema often suffer with poor breathing and mobility. As a physician who cares for patients with COPD, I am looking forward to being able to offer a minimally invasive treatment to patients that can help them breathe easier and get back to living a more active life."

The one-time procedure is 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 advantage over the current standard of care and therefore its availability is also in the best interest of patients."

More on the Zephyr Valves

Since 2007, more than 15,000 patients have been treated with The Zephyr Valve worldwide. Zephyr Valve treatment is included in emphysema treatment guidelines issued by leading health organizations worldwide, including the Global Initiative for Chronic Obstructive Lung Disease (GOLD) and the UK's National Institute for Health and Care Excellence (NICE).

More about COPD and Emphysema

More than 15 million Americans suffer from COPD, and 3.5 million of those patients have emphysema^[5]. Despite taking the best available medications, over one million emphysema patients suffer symptoms of hyperinflation, where 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.MylLungsMylife.com.

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Aetna's coverage policy: http://www.aetna.com/cpb/medical/data/100_199/0160.html

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[1] Am J Respir Crit Care Med Vol 198, Iss 9, pp 1151–1164, Nov 1, 2018

[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; Vol 194, Iss 9, pp 1073-1082 and Data on file at Pulmonx

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

[5] American Lung Association. Trends in COPD (Chronic Bronchitis and Emphysema): Morbidity and Mortality. March 2013.