MSAC Application 1814

Bronchoscopic Lung Volume Reduction with Endobronchial Valves for the Treatment of Emphysema

PICO Set

Population

Describe the population in which the proposed health technology is intended to be used:

Emphysema overview & demographics

Chronic Obstructive Pulmonary Disease (COPD) is a severe and progressive disease with an important impact on quality of life and survival, causing major disability, morbidity and mortality. It is one of the top three causes of death worldwide, and represents an important global health challenge that is both preventable and treatable (Global Initiative for COPD, 2025).

Over 2.5% of Australia's total population lives with COPD, including 7.7% of Australians over 30 years of age. COPD is one of Australia's leading causes of death, representing 3.6% of total disease burden and 4.0% of all deaths in 2023 (AIHW, 2024). The prevalence of COPD, which includes emphysema, has remained relatively stable over the last decade (Australian Commission on Safety and Quality in Healthcare, 2025). However, the diagnosis rate is projected to increase due to incidental diagnoses stemming from the National Lung Cancer Screening Program.

COPD is comprised of many phenotypes that include chronic bronchitis (mucus-predominant), emphysema with hyperinflation, frequent exacerbators, and large-airway instability. Interventional options map to these phenotypes. Emphysema is characterised by irreversible enlargement of the alveolar spaces due to the destruction of alveolar walls. This leads to loss of elastic recoil, airway collapse during exhalation, and air trapping, resulting in hyperinflation and impaired gas exchange. COPD patients with a predominant emphysema phenotype present with the most severe breathlessness due to pronounced air trapping.

For context on disease impact and severity used in selection for advanced therapies, the Lung Foundation of Australia and Thoracic Society of Australia and New Zealand (TSANZ) have created the COPD management plan known as COPD-X (Yang et al., 2024). Internationally, a similar guideline exists known as the Global Initiative for Chronic Obstructive Lung Disease (GOLD) (Global Initiative for COPD, 2025). These guidelines each provide specific criteria for the severity of disease determined by forced expiratory volume in one second (FEV_1) compared to the predicted values, going from mild to severe. In the COPD-X, FEV1 cut-offs are

- Mild: FEV1 = 60-80% predicted
- Moderate: FEV1 = 40-59% predicted
- Severe: FEV1 < 40% predicted

In the GOLD guidelines, FEV1 cut-offs are:

- Mild: FEV1 ≥ 80% predicted
- Moderate: 50% ≤ FEV1 < 80% predicted
- Severe: 30% ≤ FEV1 < 50% predicted
- Very severe: FEV1 < 30% predicted

Another tool used for categorising the severity of patients with COPD is the multidimensional BODE index (Body mass index (BMI), Obstruction (FEV1), Dyspnoea (mMRC), Exercise capacity (6MWD)) (Celli et al., 2004).

This PICO set focuses on a subset of adults with severe or very severe emphysema (15% < FEV1 < 45%) as per current inclusion criteria for relevant endobronchial valves) with static or dynamic hyperinflation who remain symptomatic despite optimized guideline-based therapy. In this subgroup, reducing hyperinflation can improve elastic recoil and respiratory mechanics; therefore, bronchoscopic lung volume reduction (BLVR) with endobronchial valves (EBV) is a valuable is a valuable treatment option that has been shown to significant improve symptoms, exercise tolerance, and reduce exacerbations (Global Initiative for COPD, 2025).

Risk factors & symptoms

The 2025 Gold report underlines the complex interaction between the genetic susceptibility and the environmental risk, and how these factors are influenced and interact over an individuals lifetime. That is, lifelong exposures and the biological memory (the previous interaction between genetics and the environmental risk (Global Initiative for COPD, 2025)).

Upwards of 80-90% of patients with COPD identified as cigarette smokers (WHO, 2024). 87% of people with COPD were estimated to be living with one or more other chronic conditions – the most common comorbidities were mental and behavioural conditions (49%), arthritis (45%), asthma (42%) and back problems (42%) (AIHW, 2024). A rare hereditary condition, alpha 1 antitrypsin deficiency, can also lead to emphysema and liver abnormalities, but this only accounts for 1% to 2% of COPD cases (Sandhaus et al., 2016). Age is also a risk factor since the decline in lung function with age can induce COPD (Global Initiative for COPD, 2025).

"Patients with COPD typically complain of breathlessness, wheezing, chest tightness, fatigue, activity limitation, cough with or without sputum production, and may experience acute events characterized by increased respiratory symptoms called exacerbations that influence their health status and prognosis and require specific preventive and therapeutic measures" (Global Initiative for COPD, 2025).

Typical prognosis

There is no curative treatment for emphysema that can reverse the underlying disease process. As the disease progresses, symptoms such as dyspnoea and fatigue typically become more pronounced, significantly impairing daily activities and reducing the quality of life. In the most advanced stages, emphysema leads to severe hypoxemia (low oxygen), hypercapnia (elevated carbon dioxide), and pulmonary hypertension. Additionally, the coexistence of other illnesses significantly worsens the prognosis for patients with COPD, with progressive reductions in quality of life contributing to psychological comorbidities often left undiagnosed, such as anxiety, depression, and social isolation (Global Initiative for COPD, 2025).

Smoking is the most important risk factor for COPD, and smoking cessation has been shown to reduce mortality (Yang et al., 2024). However, addressing risk factors and

managing symptoms has also been shown to effectively slow disease progression, and treatment with lung volume reduction (surgical and endobronchial) can enhance lung function, exercise capacity, and quality of life (Yang et al, 2024).

Introduction of the NLCSP

The introduction of the National Lung Cancer Screening Program (NLCSP) in July 2025 is expected to increase the incidental detection of emphysema, as. patients screened for lung cancer are also at high risk for other conditions such as coronary artery calcifications and emphysema, which are easily revealed on low-dose CT scans (Bonney 2025). Many individuals with emphysema are currently unrecognised until late-stage symptomatic presentation, so recognition through NLCSP provides an opportunity to appropriately manage and treat the population identified with clinically significant disease. This has implications for earlier intervention with smoking cessation, pulmonary rehabilitation, and optimisation of inhaled therapy, but also raises the prospect of more patients being considered for advanced interventions such as BLVR. As a result, the NLCSP will indirectly increase demand for emphysema-related diagnostic workup and management services, creating both opportunities and pressures across the respiratory care pathway.

Sub-populations and diagnosis

Emphysema can be classified into 4 distinct types based on the pattern and location of lung damage observed:

- **Centriacinar emphysema** is the most common form, primarily affecting the central portions of the acinus, particularly in the upper lobes of the lungs. This type is strongly associated with smoking and is characterized by the destruction of the central bronchioles, while the peripheral alveolar structures remain relatively spared.
- **Panacinar emphysema** involves the uniform destruction of the entire acinus, including both the respiratory bronchioles and alveolar sacs. This variant is commonly observed in individuals with alpha-1 antitrypsin deficiency and typically affects the lower lobes of the lungs.
- **Paraseptal emphysema** involves damage to the distal alveolar spaces near the periphery of the lungs, often leading to the formation of bullae, which can occasionally result in spontaneous pneumothorax.
- **Irregular emphysema** is less prevalent and typically localized to areas of the lung that have previously healed from infections or inflammatory processes. Although it does not usually contribute significantly to airflow obstruction, it can still be identified in imaging studies.

The diagnosis of chronic obstructive pulmonary disease (COPD) is established through pulmonary function testing (PFT), with spirometry serving as the gold standard. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, the diagnostic criterion for COPD is a post-bronchodilator Forced Expiratory Volume in one second to Forced Vital Capacity (FEV1/FVC) ratio of less than 0.70, indicating persistent airflow limitation (Güder et al., 2012).

Relevant sub-population

The target subgroup for the proposed intervention consists of patients with pronounced (severe to very severe) hyperinflation and minimal or no collateral ventilation, between the target lobe and the ipsilateral lobes, as these anatomical and physiological characteristics make it possible to isolate a lung lobe and induce atelectasis using a one-way valves. In these patients, gas trapping and hyperinflation are the principal driver of dyspnoea and reduced exercise tolerance, and reduction in gas trapping and hyperinflation leads to significant improvements in respiratory mechanics, gas exchange, and overall quality of life.

Per the COPD-X guidelines, the subgroup most appropriate for referral to lung volume reduction comprises adults with confirmed COPD by spirometry (post-bronchodilator FEV_1/FVC ratio < 0.7), severe physiologic impairment and activity limitation (e.g., breathless on minimal exertion, daily activities severely curtailed) with reduced FEV_1, who remain highly symptomatic despite fully optimised standard medical management, that is, stepped pharmacotherapy with verified inhaler technique and adherence, structured pulmonary rehabilitation, smoking-cessation support and recommended vaccinations (influenza, SARS-CoV-2, pneumococcal) (Yang et al., 2024).

Excluded sub-populations

While there is strong evidence for its clinical value in the subset of patients described above, there are circumstances where BLVR with the insertion of one-way valves is contraindicated or unlikely to provide value. These include:

- Patients for whom bronchoscopic procedures are contraindicated
- Severe large bullae (encompassing greater than 30% of either lung).
- Patients with evidence of an active pulmonary infection

Specify any characteristics of patients with, or suspected of having, the medical condition, who are proposed to be eligible for the proposed health technology, describing how a patient would be investigated, managed and referred within the Australian healthcare system in the lead up to being considered eligible for the technology:

Eligible patients would typically be patients who have a suitable target lobe, and no other contraindications.

In the Australian healthcare setting, eligibility for bronchoscopic lung volume reduction is typically confirmed via a staged investigation–optimisation–referral pathway, grounded in COPD-X recommendations. To better manage COPD and its comorbidities, the specialist must use a patient centred approach rather than a single-disease approach while managing a comprehensive medication review (Yang et al., 2024). Taken together, the eligible patient profile follows a clear sequence of clinical checkpoints.

Clinical evaluation typically begins with a review by a general practitioner (GP) of the patient's history for conditions and symptoms associated with emphysema, such as persistent cough, dyspnoea and exercise intolerance. If COPD is suspected, the GP will usually perform an initial spirometry test to assess lung function and to confirm

physiological COPD with a spirometry result of $FEV_1/FVC < 0.7$ (Yang et al., 2024). Patients are usually referred to a respiratory physician, interventional pulmonologist, or multidisciplinary team (MDT) for further evaluation and management upon diagnosis, particularly in advanced stage COPD or complex cases. These physicians would assess the severity of the disease, symptom burden, and eligibility for advanced therapies such as BLVR.

Disease severity is assessed and stratified to help guide treatment escalation as per FEV_1 bands outlined in the GOLD and COPD-X guidelines described above. Symptoms may not always correlate to measured severity, so additional questionnaires such as the COPD assessment test (CAT) and Modified Medical Research Council (mMRC) dyspnoea scale are commonly used for the formal assessment and tracking of symptoms over time (Global Initiative for COPD, 2025; Yang et al., 2024). Chest x-ray is not diagnostic of COPD, but can be a useful diagnostic step in the breathless patient with suspected emphysema. It is typically one of the first investigations in evaluating suspected COPD and to exclude other potential causes of the patient's symptoms. Arterial blood gas measurements are usually not necessary for mild to moderate COPD cases. However, they are recommended when oxygen saturation falls below 92% or when evaluating for hypercapnia in cases of severe airflow obstruction.

In those with suspected or proven COPD a high resolution CT chest is also recommended to assess the extent of lung damage and confirm the presence of emphysema. This CT provides a more definitive assessment than a chest x-ray and is considered the gold standard diagnostic imaging to confirm emphysema and evaluate the extent of parenchymal damage (Martini & Frauenfelder, 2020). The CT scan helps determine the distribution of disease and whether the patient has intact interlobar fissures for eligibility for BLVR treatment.

In the majority of patients with emphysema, treatment will begin with lifestyle interventions such as smoking cessation, promoting physical activity and nutrition and measures to prevent infection, and is often paired with pharmacotherapy and supportive therapy in more advanced cases. Pharmacotherapy includes bronchodilators (beta-2 agonists and muscarinic antagonists), either alone or in combination or with anti-inflammatory medications such as corticosteroids. Supportive therapy for more advanced emphysema includes oxygen therapy, non-invasive ventilatory support, pulmonary rehabilitation, and palliative care. These interventions aim to improve quality of life, enhance functional capacity, and manage symptoms in advanced stages of the disease. Throughout medical therapy, common comorbidities (e.g., cardiovascular disease, osteoporosis, anxiety/depression, diabetes, sleep apnoea), are screened for and managed, as these conditions frequently influence eligibility, risk, and timing for more advanced interventions.

Advanced and / or unresponsive cases of COPD may then be escalated to and considered for BLVR with one-way valves. Research shows c.19% of patients meet acceptable criteria (Welling et al., 2020) to be eligible for BLVR. After being assessed for eligibility by the multidisciplinary pulmonary team, patients will undergo comprehensive pre-procedural evaluation, including comprehensive pulmonary function testing (to assess residual

volume, total lung capacity, diffusing capacity, and FEV_1), 6-minute walk testing, and arterial blood gases. A ventilation-perfusion (V/Q) scan and quantitative CT chest analysis may also be ordered to further assess regional emphysema burden and identify target lobes.

Quantitative CT and physiological measurement tools are also used to evaluate fissure integrity and collateral ventilation that support appropriate patient and lobe selection.

Provide a rationale for the specifics of the eligible population:

The proposed patient population is consistent with pivotal RCTs for the Zephyr valve (LIBERATE, IMPACT, TRANSFORM, STELVIO, BELIEVER) and Spiration valve (EMPROVE, REACH). The proposed MBS item does not specify exclusion criteria, but it is expected that these would be realised in practice through the multidisciplinary pulmonary team who determine eligibility for the procedure.

BLVR treatment with one-way valves is only effective in patients with little to no collateral ventilation, with different valve manufacturers (Pulmonx (Zephyr) and Olympus (Spiration)) are the only ARTG/TGA-approved producers) having their own methodologies and selection toolkit. These selection criteria maximise responder rates and minimise unnecessary interventions in non-responders. These eligibility criteria are purposeful: they operationalize COPD-X guidance that lung volume reduction should be reserved for a very specific subgroup and delivered in expert centres, after establishing a firm COPD diagnosis and exhausting best practice conservative care (Yang et al., 2024)

Are there any prerequisite tests?

Yes – as described above several tests would be required in the management leading up to BLVR.

Are the prerequisite tests MBS funded?

Yes – see table 1 below for details of relevant pre-requisite MBS items. However, if the Chartis system is used to confirm physiological presence or absence of collateral ventilation status, this is not currently specifically reimbursed.

Table 1: MBS items for prerequisite tests

MBS item	Procedure
11505	Measurement of spirometry, that: a) involves a permanently recorded tracing, performed before and after inhalation of a bronchodilator; and b) is performed to confirm diagnosis of: i) asthma; or ii) chronic obstructive pulmonary disease (COPD); or iii) another cause of airflow limitation; each occasion at which 3 or more recordings are made Applicable only once in any 12 month period

11503	Complex measurement of properties of the respiratory system, including the lungs and respiratory muscles, that is performed: a) in a respiratory laboratory; and b) under the supervision of a specialist or consultant physician who is responsible for staff training, supervision, quality assurance and the issuing of written reports on tests performed; and c) using any of the following tests: i) measurement of absolute lung volumes by any method; ii) measurement of carbon monoxide diffusing capacity by any method; iii) measurement of airway or pulmonary resistance by any method; iv) inhalation provocation testing, including pre-provocation spirometry and the construction of a dose response curve, using a recognised direct or indirect bronchoprovocation agent and post-bronchodilator spirometry; v) provocation testing involving sequential measurement of lung function at baseline and after exposure to specific sensitising agents, including drugs, or occupational asthma triggers; vi) spirometry performed before and after simple exercise testing undertaken as a provocation test for the investigation of asthma, in premises equipped with resuscitation equipment and personnel trained in Advanced Life Support; vii) measurement of the strength of inspiratory and expiratory muscles at multiple lung volumes; viii) simulated altitude test involving exposure to hypoxic gas mixtures and oxygen saturation at rest and/or during exercise with or without an observation of the effect of supplemental oxygen; ix) calculation of pulmonary or cardiac shunt by measurement of arterial oxygen partial pressure and haemoglobin concentration following the breathing of an inspired oxygen concentration of 100% for a duration of 15 minutes or greater; x) if the measurement is for the purpose of determining eligibility for pulmonary arterial hypertension medications subsidised under the Pharmaceutical Benefits Scheme or eligibility for the provision of portable oxygen—functional exercise test by any method (including 6 minute walk test and shuttle walk test); each occasion at which one or more tests are performed

	Not applicable to a service performed in association with a spirometry or sleep study service to which item 11505, 11506, 11507, 11508, 11512, 12203, 12204, 12205, 12207, 12208, 12210, 12213, 12215, 12217 or 12250 applies Not applicable to a service to which item 11507 applies.
56301	Computed tomography—scan of chest, including lungs, mediastinum, chest wall and pleura, with or without scans of the upper abdomen, without intravenous contrast medium, not being a service to which item 56801 or 57001 applies and not including a study performed to exclude coronary artery calcification or image the coronary arteries (R)
56307	Computed tomography—scan of chest, including lungs, mediastinum, chest wall and pleura, with or without scans of the upper abdomen, with intravenous contrast medium and with any scans of the chest, including lungs, mediastinum, chest wall or pleura and upper abdomen before intravenous contrast injection, when undertaken, not being a service to which item 56807 or 57007 applies and not including a study performed to exclude coronary artery calcification or image the coronary arteries (R)
66566	Quantitation of: (a) blood gases (including pO_2, oxygen saturation and pCO_2); and (b) bicarbonate and pH; including any other measurement (e.g. haemoglobin, lactate, potassium or ionised calcium) or calculation performed on the same specimen - 1 or more tests on 1 specimen
61348	Lung perfusion study and lung ventilation study using aerosol, technegas or xenon gas (R)
61333	Lung ventilation study using Galligas and lung perfusion study using gallium-68 macro aggregated albumin (^{68}Ga-MAA), with PET, if the service is performed because the service to which item 61348 applies cannot be performed due to unavailability of technetium-99m (R)

Source: www.mbsonline.gov.au

Provide details to fund the prerequisite tests:

N/A (MBS funded)

Intervention

Name of the proposed health technology:

Bronchoscopic Lung Volume Reduction (BLVR) via insertion of endobronchial one-way valves.

Describe the key components and clinical steps involved in delivering the proposed health technology:

Whilst there are several different modalities that BLVR can use, endobronchial valves (EBVs) are the most well established bronchoscopic method for lung volume reduction in severe emphysema.

In specialist care, a comprehensive review to confirm or exclude alternative diagnoses and assess severity is conducted. COPD-X guidelines note that a chest CT can help detect emphysema and bronchiectasis and that additional investigations may be needed based on clinical judgement. Severity, symptoms and exacerbation risk should be assessed regularly to inform escalation (Yang et al., 2024)

Subsequently, once a pre-selected target lobe (identified on high-resolution/quantitative CT and multidisciplinary review) is confirmed to be collateral ventilation negative, the intervention is then delivered as a minimally invasive bronchoscopic procedure in a hospital-based interventional pulmonology or thoracic surgery unit, for which the patient receives general anaesthesia.

During the procedure, valves are placed via bronchoscopy into targeted segmental or subsegmental bronchi where they allow air to exit the diseased lung region but prevent it from re-entering. The procedure uses a loading system and a delivery catheter to place valves into the segmental and subsegmental bronchi of a targeted lobe, resulting in one-way airflow which causes the treated area to collapse (atelectasis) and produces the desired reduction in lung volume. Several valves (on average 4 to 6 valves per procedure) of different sizes can be implanted in the bronchial tree to completely occlude the lobe.

Each valve is compressed or preloaded in its loading system and mounted on a dedicated delivery catheter, which is advanced through the working channel of a flexible adult bronchoscope to the target airway; deployment is performed by actuating the system's release mechanism (e.g., handle actuation or sheath retraction) to release the valve into the airway, after which the catheter is withdrawn and single-use loading components are discarded. The sequence is repeated according to the number of valves required to isolate the lobe; at the end of the procedure, the delivery catheter and any ancillary single-use components are removed and discarded per standard practice.

Once deployed in the target airway, the valve is fixed against the bronchial wall in a stent-like manner either through self-expanding force or through fixation onto a set of anchors. A membrane integrated within the frame forms a circumferential seal with the airway to maintain apposition during inhalation, exhalation, and coughing, and is designed to function despite the presence of mucus or local inflammation.

After implantation, the operator confirms valve position, stability, and unidirectional function bronchoscopically, with additional valves placed as needed. Because of monitoring needs, BLVR is delivered to admitted patients in a hospital facility, with a short inpatient stay (3 days are recommended).

, Generally, only one session of BLVR, covering a singular lobe, is conducted per patient. In some cases, additional sessions may be considered if multiple lobes need treatment.

Valves are removable if needed. When indicated, retrieval is performed bronchoscopically using grasping forceps. Individual valves can be removed en bloc with the bronchoscope.

BLVR will typically be performed by interventional pulmonologists, thoracic surgeon, or respiratory physician. The operator must undergo specialized training in advanced bronchoscopic procedures including device-specific training as provided by manufacturers. Most tertiary hospitals will already possess the core infrastructure for BLVR: an interventional bronchoscopy suite or operating theatre (with appropriate scopes and immediate access to chest drainage), CT imaging (Diagnostic Imaging Accreditation scheme (DIAS)-accredited) for pre-procedure assessment, respiratory function laboratories, and pulmonary rehabilitation.

Identify how the proposed technology achieves the intended patient outcomes:

The therapeutic intent of BLVR with EBVs is volume reduction of diseased, hyperinflated lobe to improve respiratory mechanics (reduced hyperinflation, improved diaphragm function), redistribute ventilation and perfusion toward healthier regions. This has been shown to improve dyspnoea, exercise capacity, lung function, and reduce exacerbations.

This is achieved by the EBV's one-way mechanism which blocks inflow into the diseased lobe during inspiration. During inspiration, the valve is closed to prevent inspired air from entering the diseased, distended region. Whereas during expiration, the one-way valve opens and releases the air trapped in the distended area, also allowing secretions to pass through. Once the air has been evacuated, the volume of the targeted (most diseased) lobe decreases, causing its atelectasis (lobar collapse). The result is less hyperinflation and gas trapping, improved breathing mechanics, and more efficient gas exchange. The induced atelectasis improves mechanics of the remaining, healthier lung regions, and translates into gains in FEV_1, 6 minute walk distance, exercise tolerance, BODE index and health-related quality of life in selected patients. The improvement of the BODE index as well as observational long term data and pooled analysis also suggest a potential long term survival benefit.

COPD-X explicitly states that lung volume reduction (surgical and endobronchial) can enhance lung function, exercise capacity and quality of life, provided there is careful assessment at an expert centre and appropriate patient selection (Yang et al., 2024)

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?

No – This application is being made for a product agnostic item code.

Explain whether it is essential to have this trademark component or whether there would be other components that would be suitable:

No - A brand-agnostic MBS item that facilitates the use of current and future one-way valve systems providing they have good quality RCT evidence and TGA/ARTG-listing would be optimal.

At the moment the Zephyr valve (Pulmonx) and Spiration valve (Olympus) are the only TGA-listed and ARTG-listed one-way endobronchial valve (EBV) systems used for BLVR. There are some differences, but the mechanism of action is similar (bronchoscopic

placement of one-way valves to reduce hyperinflation). A brief overview of the two currently available products is provided below:

	Zephyr valve (Pulmonx)	Spiration valve (Olympus)
Materials used	Nitinol retainer with a silicone/polymer one-way "duckbill" valve within a stent-like frame.	Self-expanding nitinol umbrella frame with a polymer canopy membrane and central hub.
Valve shape/design	Cylindrical, internal valve housed in a stent-like retainer that opens on exhalation and closes on inspiration.	Umbrella-shaped, spoked nitinol frame that forms a canopy seal when deployed in the airway. The air passes between the airway and the valve at expiration.
Mechanism of action	One-way duckbill valve blocks inspiratory inflow and allows expiratory egress of trapped gas and secretions to induce target-lobe atelectasis.	shaped valve opens against the bronchial wall and blocks inspiratory inflow, at expiration the umbrella folds and trapped gas and secretions egress to induce lobar collapst.
Anchoring/sealing	Radial force of the nitinol retainer apposes the device to the bronchial wall; integrated silicone membrane provides circumferential seal.	Self-expanding umbrella with atraumatic anchors/legs apposes to the airway wall; canopy membrane provides circumferential seal at inspiration.
Placement strategy/sizing	Multiple diameter-matched valves, on average 4 per target lobe, placed via a dedicated catheter under bronchoscopy to achieve complete lobar occlusion.	Multiple diameter-matched umbrella valves, on average 4 per target lobe, placed similarly to achieve complete lobar occlusion.
Removability/repositioning	Removable and repositionable using bronchoscopic graspers engaging device-specific retrieval features; allows adjustment or explant if needed.	Removable and repositionable with graspers or snare engaging the umbrella hub/frame; allows adjustment or explant if needed .
Eligibility criteria/methodology	Primary assessed via HRCT and quantitative CT scan analysis for fissure integrity, and absence of collateral ventilation is confirmed physiologically intra-procedurally using a bronchoscope (known as Chartis assessment) in the same	Primary assessed via HRCT and quantitative CT scan analysis for fissure integrity.

	setting where valves are ultimately placed if warranted.	

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):

Yes

Provide details and explain:

BLVR is a highly specialised, non-invasive procedure and can only be delivered in hospital facilities by interventional pulmonologists or thoracic surgeons with required experience and credentials.

To be eligible for BLVR, patients must meet several criteria- including a confirmed diagnosis of emphysema with severe hyperinflation, suitable target lobes with little to no collateral ventilation between the target and ipsilateral lobes. Additionally, confirmation of non-bullous disease is highly recommended for better outcomes.

BLVR is intended to be a once-off treatment per target lobe, with placement of an average of 4 valves depending on lung anatomy.

BLVR treatment with EBVs is intended for lifetime. In certain instances, it may be necessary to remove and /or replace one or all valves. This may be necessary, for example, in case of valve migration, recurrent infection, or pneumothorax that does not resolve with standard treatment.

If applicable, advise which health professionals will be needed to provide the proposed health technology:

Initial screening and referral to the multidisciplinary team (MDT) is completed by general practitioners and non-interventional pulmonologists who assess for emphysema diagnosis and order baseline tests alongside radiologists who interpret imaging results. GPs and pulmonologists are also responsible for post-procedure follow-up and long-term management and review of patients.

Eligibility for BLVR will subsequently be determined by an MDT including a leading interventional pulmonologist (typically alongside a thoracic surgeon, thoracic radiologist and an anaesthetist).

The BLVR procedure itself is conducted by a trained interventional pulmonologist, thoracic surgeon, or respiratory physician responsible for the bronchoscopy and valve placement , alongside an anaesthetist and bronchoscopy nurses for procedural assistance and patient monitoring. The primary proceduralist must be trained and credentialed as per specific valve manufacturer requirements.

Physiotherapists, pharmacists and respiratory physicians aid in immediate post-procedure review and management, with thoracic surgeons/Intensive Care Unit (ICU) on-call for complication management..

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:

N/A - no component of valve placement can be delegated outside trained primary proceduralists as described above. However, the patient work-up such as imaging (High Resolution CT scan - HRCT) and pulmonary function testing may be conducted by appropriately trained respiratory technicians or radiologists.

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:

Any registered medical practitioner (e.g. general practitioner or specialist) may refer to a respiratory physician for evaluation and work-up. Eligibility for BLVR will subsequently be determined by an MDT or lead respiratory physician / interventional pulmonologist with experience in advanced COPD management, typically working in secondary or tertiary care centres.

Is there specific training or qualifications required to provide or deliver the proposed service, and/or any accreditation requirements to support delivery of the health technology?

Yes

Provide details and explain:

BLVR should be performed only by a credentialled interventional pulmonologists, thoracic surgeon, or respiratory physician with advanced technical knowledge and experience in bronchoscopy. Additionally, valve manufacturers have mandatory, device-specific training requirements in order to meet credentialling standards.

Pulmonx (Zephyr valve): completion of Zephyr University (e-learning modules, didactic sessions, interactive case reviews, and hands-on workshops using lung models), alongside completion of 3 proctored Zephyr cases under the Pulmonx pathway and a 45-day outcomes review of those cases with Pulmonx medical affairs.

Olympus (Spiration valve): completion of the Spiration Valve System (SVS) professional education program (didactic sessions, hands-on/virtual training) alongside executing of a physician compliance agreement. At least one physician within a centre must complete the SVS professional education program for the centre to receive 'initial site qualification' by Olympus.

Indicate the proposed setting(s) in which the proposed health technology will be delivered:

☐ Consulting rooms
☐ Day surgery centre
☐ Emergency Department
☒ Inpatient private hospital
☒ Inpatient public hospital
☐ Laboratory
☐ Outpatient clinic
☐ Patient's home

☐ Point of care testing
☐ Residential aged care facility
☐ Other (please specify)

Bronchoscopic lung volume reduction (BLVR) with one-way endobronchial valves procedure can be safely delivered in multiple healthcare environments depending on the patient's clinical status and the institution's infrastructure.

In most cases, it is performed in an inpatient public or private hospital operating theatre or a dedicated bronchoscopy suite. Regardless of the setting, access to immediate post-procedural monitoring, chest radiography, and pneumothorax management facilities must be available.

Is the proposed health technology intended to be entirely rendered inside Australia?

Yes

Provide additional details on the proposed health technology to be rendered outside of Australia:

N/A

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e., how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian healthcare system). This includes identifying healthcare resources that are needed to be delivered at the same time as the comparator service:

The primary comparator to this intervention is optimised Standard Medical Management (SMM) for severe emphysema.

Lung Volume Reduction Surgery (LVRS) or other forms of BLVR (e.g., coils, sealants, thermal ablation) could be considered as near-market and / or secondary comparators, but they are not yet routinely available in Australia and thus will not be considered in detail as part of this application.

Lung transplantation could also be considered, but only in very rare cases.

Please provide a description of the comparator:

<u>Optimised standard medical management (SMM)</u>

Optimised SMM (the current standard of care) of emphysema is followed in accordance to current guidelines (Yang et al., 2024). This includes:

Pharmacological management:

- Inhaled long-acting bronchodilators (LAMA, LABA, or LAMA/LABA combinations)
- Inhaled corticosteroids in selected patients with frequent exacerbations
- Short-acting bronchodilators as rescue therapy

Non-pharmacological management:

- Pulmonary rehabilitation programs (exercise, education, self-management training)
- Long-term oxygen therapy for those with chronic hypoxaemia
- Non-invasive ventilation when indicated
- Smoking cessation support (behavioural and pharmacological)
- Vaccinations (influenza, pneumococcal, COVID-19)

Supportive and palliative care:

- Management of comorbidities (e.g. cardiovascular disease, osteoporosis, depression)
- Symptom relief for breathlessness (e.g. fan therapy, opioids in select)
- Symptom-directed palliative care where appropriate

In patients who remain highly symptomatic and hyperinflated despite optimal SMM, invasive options are considered. This escalation historically included LVRS, but has since been superseded by BLVR with one-way valves as the preferred treatment option). In routine pathways, SMM is delivered to all, and BLVR with one-way valves is considered only after SMM failure in appropriately selected, hyperinflated patients.

List any existing MBS item numbers that are relevant for the nominated comparators:

N/A - typically pharmacological in nature and not directly funded via the MBS

Provide a rationale for why this is a comparator:

Optimised SMM is the appropriate comparator for BLVR because it reflects the true baseline management pathway for patients with advanced emphysema in Australia. BLVR with endobronchial valves is proposed in addition to (or after) optimal SMM in patients who remain symptomatic and hyperinflated, so SMM is the appropriate primary comparator.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?

☒ None (used with the comparator)
☐ Displaced (comparator will likely be used following the proposed technology in some patients)
☐ Partial (in some cases, the proposed technology will replace the use of the comparator, but not all)
☐ Full (subjects who receive the proposed intervention will not receive the comparator)

Outline and explain the extent to which the current comparator is expected to be substituted:

BLVR with EBVs is intended to address an unmet clinical need for Australian patients with severe emphysema who remain symptomatic and hyperinflated despite fully optimized SMM. The anticipated pattern of use in Australia therefore involves BLVR with one-way valves as an adjunct to ongoing SMM in selected patients.

Outcomes

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator):

Please select your response

☒ Health benefits
☒ Health harms
☐ Resources
☐ Value of knowing

Outcome description – include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

1. Health benefits

1.1. **Survival / prognosis**

- **BODE Index for COPD survival prognosis** = a multidimensional score which combines FEV1, 6MWD, mMRC Dyspnoea Scale, and Body Mass Index to predict survival. A reduction of the BODE index of 1 point is clinically meaningful and indicates a significant reduction of mortality (Martinez et al, 2008). A BODE index of less than 5 points is associated with increased survival of more than 67% at 4 years (4), with a reduction of more than 1 point being associated with a significant decrease in mortality.

1.2. **Pulmonary function:**

- **FEV $_1$ (Forced Expiratory Volume in 1 second)** = the volume of air that the patient is able to exhale in the first second of forced expiration. An increase of 12% indicates a meaningful change. A change in FEV1 of 100 mL can be perceived by patients, and correlates with fewer relapses following exacerbations (Donohue et al., 2005).
- **FVC (Forced Vital Capacity)** = the total volume of air that one can forcibly exhale after a full inspiration). Improvement reflects reduced air trapping and improved ventilatory efficiency.
- **RV (Residual Volume)** = the volume of air remaining in the lungs after a full exhalation. The minimally clinical important difference for reduction of the RV is 430 ml) and indicates effective deflation of hyperinflated lobes (Hartman et al., 2012).

- **TLC (Total Lung Capacity)** = the maximum volume of air present in the lungs. Reduction reflects improved chest wall mechanics and decreased hyperinflation.

1.3. **Exercise capacity / functional status:**

- **6MWD (6-minute walking distance test)** = the distance walked in 6 minutes as a sub-maximal test of aerobic capacity or endurance. An increase of 26±2 m for patients with severe COPD indicates a clinically meaningful change (Puhan et al., 2011)
- **mMRC (Modified Medical Research Council**) dyspnoea scale = a measure of perceived respiratory disability ranging from none (grade 0) to almost complete incapacity (grade 4). A change with 1 point suggests a clinically meaningful difference.

1.4. **Quality of life:**

- **St. George's Respiratory Questionnaire (SGRQ)** = a quality-of-life score designed to measure health impairment in patients with respiratory disease. A reduction of 4 points suggests a meaningful change (Cazzola et al, 2008).
- **The CAT (COPD assessment test) =** an 8-question self-completed questionnaire designed to measure the health status of patients with chronic obstructive pulmonary disease (COPD) and their responsiveness to treatment. The CAT has a scoring range of 0 (low impact on daily activities) to 40 (very high impact on daily activities). A change of 2 units suggests a meaningful difference (Kon et al., 2014).

1.5. **Other disease control and secondary prognostic indicators**

- **Exacerbation frequency / hospitalisations** – fewer moderate/severe COPD exacerbations or hospitalisations per patient-year indicate improved disease stability.
- **Oxygen dependence** – reduction or discontinuation of supplemental oxygen reflects improved functional status and prognosis.

2. <u>Health harms</u>

2.1. **All-cause mortality** – proportion of patients who die from any cause within 30 days, 6 months, and 12 months.

2.2. **Procedure-related complication rates:**

- **Pneumothorax** – air in the pleural space due to rapid target-lobe collapse and compensatory expansion of adjacent lung occurs most often within the first 72 hours after BLVR and is considered the predominant early procedure-related event to monitor
- **Valve migration** – displacement, malposition, or expectoration of a valve that compromises lobar occlusion and may reverse atelectasis

- **Infection** – post-procedural pneumonia or increased exacerbation frequency related to mucus retention or post-obstructive changes
- **Haemoptysis** – temporary airway bleeding related to bronchoscopy or valve presence which is usually low-grade but clinically relevant for safety profiling

Proposed MBS items

How is the technology/service funded at present? (e.g., research funding; State-based funding; self-funded by patients; no funding or payments):

BLVR using one-way endobronchial valves is not funded under the MBS. Procedures are mainly self-funded by patients or partly covered by private health insurance in private hospitals. Some public hospitals may offer the service under limited state or research programs, but there is no consistent national funding.

Provide at least one proposed item with their descriptor and associated costs, for each Population/Intervention:

MBS item number (where used as a template for the proposed item)	3xxxx
Category number	3
Category description	Therapeutic procedures (T8 – Surgical Operations; 6 – Cardiothoracic; 5 – Thoracic Surgery)
Proposed item descriptor	Bronchoscopy with endobronchial placement of one-way valves for lung-volume reduction.
Proposed MBS fee	1,167.42
Indicate the overall cost per patient of providing the proposed health technology	See attached cost breakdown.
Please specify any anticipated out of pocket expenses	N/A
Provide any further details and explain	N/A

Algorithms

PREPARATION FOR USING THE HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, before patients would be eligible for the proposed health technology:

As in the "Population" section, patients with severe emphysema would typically undergo a structured diagnostic and optimisation process before being considered for BLVR with EBVs.

Clinical evaluation typically begins with a review by the general practitioner of the patient's history for conditions and symptoms associated with emphysema. This is followed by confirmation of the diagnosis through spirometry and post-bronchodilator lung function testing and a high-resolution CT scan to determine emphysema distribution and exclude alternative pathology.

Before EBV eligibility is assessed, all patients must undergo specialist COPD treatment optimisation in accordance with guideline-based SMM. This includes pharmacotherapy with long-acting bronchodilators, with or without inhaled corticosteroids, a pulmonary rehabilitation programme, and structured smoking cessation support. Optimisation of comorbid conditions is required, and long-term oxygen therapy or non-invasive ventilation may be provided when clinically indicated. Only patients who remain symptomatic and functionally limited despite this comprehensive approach are shortlisted for EBV assessment.

Patient selection

Baseline lung function testing is mandatory to confirm eligibility, including measurement of residual volume, total lung capacity, and diffusion capacity for carbon monoxide (Global Initiative for COPD, 2025). Post-bronchodilator spirometry is used to confirm that forced expiratory FEV_1 is between 15 and 45 percent of predicted values and that RV exceeds 175 percent of predicted values, reflecting severe gas trapping and hyperinflation. High-resolution CT imaging with quantitative fissure analysis is used to identify target lobes and assess fissure completeness.

Imaging and lung function data are typically reviewed by a multidisciplinary team comprising respiratory physicians, interventional pulmonologists, thoracic surgeons, and radiologists to shortlist potential candidates. Chartis collateral ventilation assessment can be performed during the valve procedure if applicable to provides physiologic confirmation of lack of airflow between lobes to confirm appropriate patient selection prior to placement of EBVs.

All assessments are interpreted by clinicians with expertise in interventional pulmonology, and patients must also be free from active pulmonary infection and demonstrate sustained smoking cessation for at least eight weeks prior to the intervention. This preparatory phase requires coordinated multidisciplinary input and ensures that only patients most likely to benefit from EBV therapy are selected, thereby optimizing safety, efficacy, and appropriate resource utilization within the Australian healthcare system.

Is there any expectation that the clinical management algorithm before the health technology is used will change due to the introduction of the proposed health technology?

Yes

Describe and explain any differences in the clinical management algorithm prior to the use of the proposed health technology vs. the comparator health technology:

If BLVR using one-way valves were publicly funded under the MBS, the main change in the pre-procedural clinical management algorithm will be the earlier and more frequent consideration of a bronchoscopic intervention in the treatment pathway for eligible patients. Currently, in the absence of MBS-funded BLVR, this option is either unavailable or offered only on a self-funded or research basis. This creates a barrier to timely intervention and limits access to superior alternatives.

Under the proposed funding model, once a patient fails to achieve adequate symptom relief and functional improvement with SMM, testing for valve candidacy might be undertaken more routinely to determine BLVR eligibility. This step, which is already part of international best-practice algorithms, would be integrated earlier and more systematically into Australian practice. The rest of the preparatory algorithm, including diagnosis and optimisation of medical therapy, would remain unchanged.

In addition (as stated above), the introduction of the National Lung Cancer Screening Program (NLCSP) is expected to increase the incidental detection of emphysema, as patients screened for lung cancer are also at high risk for other conditions such as emphysema, which is easily revealed on low-dose CT scans (Bonney 2025). Only a small proportion of patients are expected to have clinically signficant disease but these patients create an opportunity for more appropriate care, inclusive of advanced interventions such as BLVR.

USE OF THE HEALTH TECHNOLOGY

Explain what other healthcare resources are used in conjunction with delivering the proposed health technology:

As described in the "Intervention" section, BLVR is a bronchoscopic procedure performed under general anaesthesia in a bronchoscopy suite or operating theatre. Each procedure typically requires an average of four valves, a flexible bronchoscope and one disposable endobronchial delivery system / catheter.

The intervention is carried out by an interventional pulmonologist with the support of an anaesthetist, bronchoscopy nursing staff, and recovery personnel. Following valve placement, patients are admitted for inpatient monitoring over three nights according to international best practice guidelines, during which chest X-rays are performed at four and twenty-four hours to screen for early complications such as pneumothorax. If pneumothorax occurs, a protocol-driven management pathway which may include observation only, chest tube insertion, or removal of a valve is performed. Importantly, published evidence indicates that these adverse events do not negate the long-term clinical benefits of the procedure, with patients continuing to experience clinically meaningful improvements in lung function, symptom relief, and quality of life. After this observation period, patients revert to standard outpatient COPD follow-up with their respiratory physician

Explain what other healthcare resources are used in conjunction with the comparator health technology:

Optimised SMM relies on a sustained and prolonged use of healthcare resources across primary, specialist and community care. For severe emphysema, this can include inhaled maintenance therapies (LAMAs, LABAs and ICS where indicated), rescue bronchodilators, smoking-cessation pharmacotherapy and counselling, structured pulmonary rehabilitation and exercise training.

Additionally, SMM requires ongoing outpatient consultations with general practitioners and respiratory specialists. Many patients also require home-based healthcare resources such as long-term oxygen therapy or non-invasive ventilation equipment, particularly as the COPD continues to progress.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:

BLVR with EBVs would be provided in addition to SMM, so any differences in healthcare resources used in the delivery of BLVR with EBVs represent the additional incremental resources used vs. the comparator.

CLINICAL MANAGEMENT AFTER THE USE OF HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, after the use of the proposed health technology:

After undergoing BLVR treatment with EBVs, patients remain in hospital typically for three nights. During this period, they receive daily medical assessments and chest X-rays to monitor for early complications, such as pneumothorax (Global Initiative for COPD, 2025). Where pneumothorax is detected, protocol-driven management pathway which may include observation only, chest tube insertion, or removal of a valve is performed.. Patients are managed until stable. Following discharge, patients attend at least one structured outpatient review at approximately four to eight weeks after treatment. This review can include spirometry, chest x-ray, or high-resolution CT imaging to confirm lobar atelectasis, assess improvements in lung function, and determine valve positioning and function.

At this time, the patient's COPD pharmacotherapy is optimised.. Thereafter, patients continue with standard COPD management, including regular specialist consultations and access to pulmonary rehabilitation or supportive services as needed. Importantly, BLVR therapy does not require lifelong additional specialist monitoring or treatment beyond what is standard for severe COPD. Thus, clinical management after BLVR is characterised by a short inpatient stay with protocolised monitoring, followed by one structured imaging and functional follow-up visit, before reverting to the patient's usual chronic care pathway.

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, after the use of the comparator health technology:

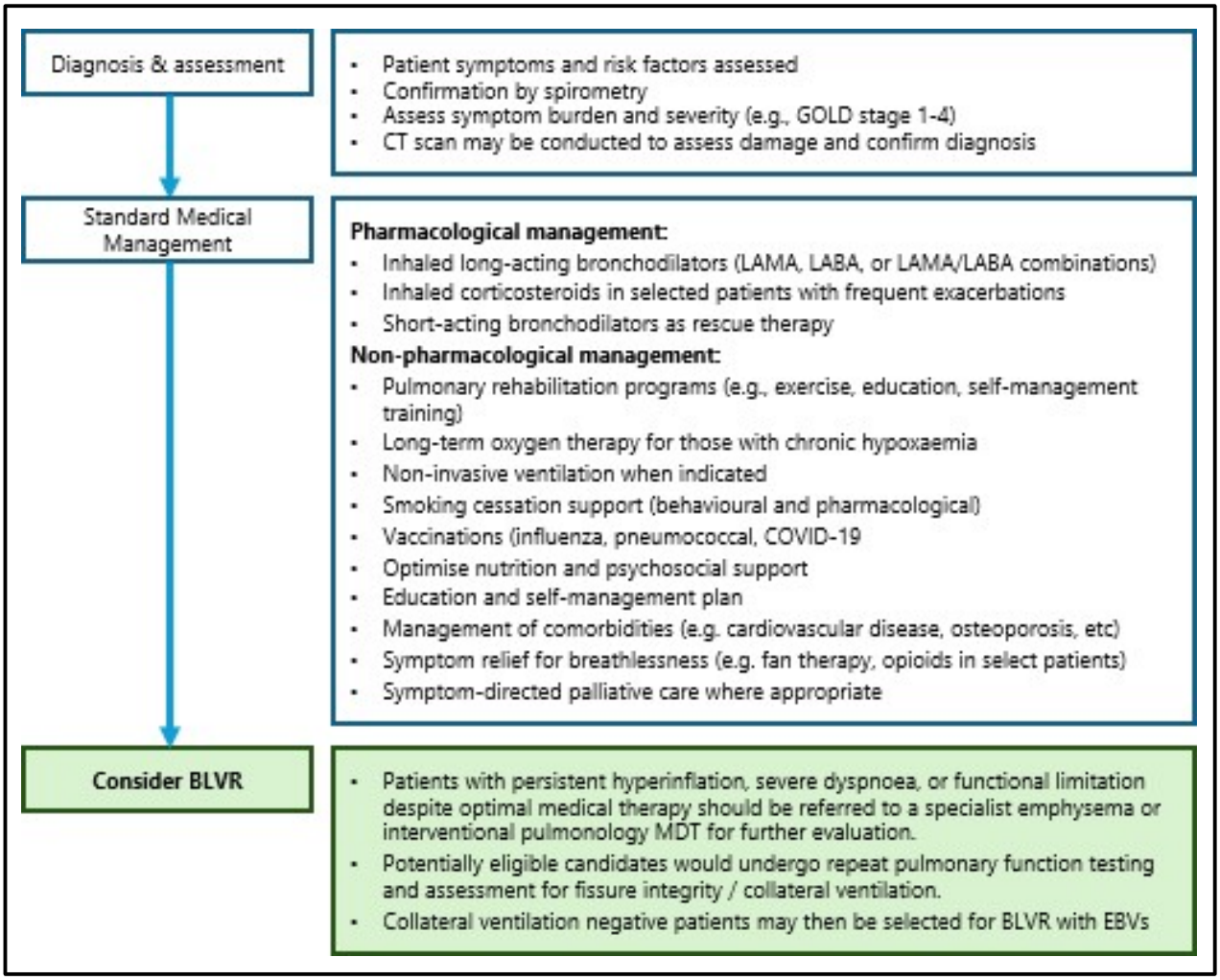
For patients managed with optimised SMM, post-treatment care remains chronic and resource intensive. Patients continue daily use of inhaled pharmacotherapy, structured programmes to maintain exercise tolerance. General practitioners and respiratory

physicians monitor disease progression through regular consultations, while long-term oxygen therapy and non-invasive ventilation are initiated or escalated as hypoxaemia or hypercapnic respiratory failure worsen.

Describe and explain any differences in the healthcare resources used after the proposed health technology vs. the comparator health technology:

Compared to optimised SMM, BLVR constitutes an additional cost for the intervention and post-operative care. However, patients experience a gain in lung function, quality of life, and exercise capacity, and the long-term rate of exacerbations may be significantly reduced.

Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:



Management of emphysema always begins with optimized standard medical management for all patients. This includes smoking cessation and vaccinations**Error! Bookmark not defined.**, inhaled bronchodilators (with or without inhaled corticosteroids when indicated), pulmonary rehabilitation**Error! Bookmark not defined.**, long-term oxygen therapy (LTOT) in hypoxemic patients, and a clinical support team. Only patients who remain symptomatic with hyperinflation despite best medical management enter the interventional and surgical decision pathway. From this point, the algorithm first assesses whether a large bulla is present, in which case bullectomy may be considered.

With the addition of funding for BLVR with EBVs, patients could then alternatively be considered for BLVR treatment if they have intact fissures and low/absent collateral ventilation while medical therapy continues in the background. As described in the comparator section, LVRS or other forms of BLVR (e.g., coils, sealants, thermal ablation) are not yet routinely available in Australia.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

☒ Superior
☐ Non-inferior
☐ Inferior

Please state what the overall claim is, and provide a rationale:

The overall claim is that BLVR with one-way endobronchial valves provides clinically meaningful and statistically significant improvements in lung function, dyspnoea, exercise capacity, and health-related quality of life when compared to optimised SMM alone, while carrying a manageable and well-characterised increase in the risk of procedure-related pneumothorax.

These benefits have been consistently demonstrated in multiple randomised controlled trials and meta-analyses, where both the treatment and control groups received SMM, showing improvements in FEV_1, six-minute walk distance (6MWD), modified Medical Research Council (mMRC) dyspnoea scores, and St. George's Respiratory Questionnaire (SGRQ) scores.

Unlike pharmacological optimisation, which plateaus in advanced emphysema, BLVR directly targets the underlying mechanical problem of hyperinflation. The predictable risk profile, particularly pneumothorax within the early post-procedural period, is offset by protocol-driven inpatient monitoring and does not negate long-term efficacy. This makes BLVR a high-value intervention that complements, rather than replaces, existing COPD management strategies in Australia.

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?

BLVR on top of SMM delivers superior outcomes in terms of lung function, dyspnoea, and exercise capacity when compared to optimised SMM. The improved BODE index demonstrated in the RCTs indicates a better survival prognosis compared to SMM alone.

For patients already optimised on pharmacotherapy and pulmonary recovery, BLVR offers meaningful, additive benefits in symptom relief and functional status. Importantly, it preserves the reversibility option, valves can be removed if clinically indicated, something not possible with LVRS or transplantation.

Identify how the proposed technology achieves the intended patient outcomes:

As described in the "Intervention" section, BLVR using one-way valves are placed into targeted segmental or subsegmental bronchi via minimally invasive bronchoscopy. EBVs act as one-way valves which blocks inflow or air into the diseased lobe during inspiration. During expiration, it opens to vent trapped gas and permit secretion egress.

Progressive emptying of the occluded lobe reduces its volume and promotes atelectasis, thereby decreasing hyperinflation and improving mechanics of the remaining, healthier lung regions. The result is less hyperinflation, improved breathing mechanics, and more efficient gas exchange. These physiological changes translate into significant improvements in patient-relevant outcomes, including improved lung function (higher FEV_1), increased exercise tolerance as measured by six-minute walk distance, and better quality of life captured through validated instruments such as the SGRQ. An improved BODE index demonstrates an improved prognosis for survival.

For some people, compared with the comparator(s), does the test information result in:

A change in clinical management? Yes

A change in health outcome? Yes

Other benefits? No

Please provide a rationale, and information on other benefits if relevant:

Compared with standard medical management, bronchoscopic lung volume reduction (BLVR) leads to meaningful changes in clinical management and health outcomes for patients with severe emphysema who remain symptomatic despite optimal therapy.

Management

BLVR provides a minimally invasive treatment option alongside SMM where none previously existed. In addition to long-term medical therapy alone, eligible patients can undergo to a minimally invasive, one-time interventional procedure that targets and collapses the most diseased lung segments, reducing hyperinflation. This results in measurable improvements in lung mechanics, exercise capacity, and quality of life in an otherwise progressive disease. Clinical follow-up also changes — with post-procedure imaging, valve review, and multidisciplinary follow-up incorporated into ongoing management.

Health outcomes

BLVR using one-way endobronchial valves produces significant and clinically meaningful improvements in key health outcomes, with studies consistently demonstrating that appropriately selected patients experience sustained gains in lung function, exercise capacity, and health-related quality of life. Patients also report reduced dyspnoea and improved daily functioning, reflected in lower mMRC scores and improved BODE indices. Importantly, these benefits are achieved without an increase in all-cause mortality compared with medical management, confirming that BLVR provides measurable clinical benefit while maintaining an acceptable safety profile.

Despite a short-term increase in exacerbations immediately following the procedure, in the longer term (e.g. out to a year) serious COPD exacerbations and respiratory failure event rates tended to be lower in the EBV treatment group compared to controls (Criner 2018).

Several trials demonstrate an improvement in BODE index, which is a strong indicator for improvement in the survival prognosis.

In terms of the immediate costs of the proposed technology (and immediate cost consequences, such as procedural costs, testing costs etc.), is the proposed technology claimed to be more costly, the same cost or less costly than the comparator?

Please select your response below

☒ More costly
☐ Same cost
☐ Less costly

Provide a brief rationale for the claim:

In terms of immediate procedural costs, BLVR using one-way valves is more costly than optimised SMM alone. The initial intervention requires a bronchoscopy under general anaesthesia, use of an average of four valves, and one disposable delivery catheter per case, as well as inpatient observation for approximately three nights. These elements contribute to a higher expenditure compared with routine outpatient care and ongoing standard medical management pathway.

If your application is in relation to a specific radiopharmaceutical(s) or a set of radiopharmaceuticals, identify whether your clinical claim is dependent on the evidence base of the radiopharmaceutical(s) for which MBS funding is being requested. If your clinical claim is dependent on the evidence base of another radiopharmaceutical product(s), a claim of clinical noninferiority between the radiopharmaceutical products is also required.

N/A

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement',

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
1.	Randomised Controlled Trial	"A Multicenter Randomized Controlled Trial of Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema (LIBERATE)", Criner et al, 2018.	A multicentre RCT of 190 patients with heterogeneous emphysema comparing Zephyr valves plus medical therapy versus medical therapy alone; reported significant improvements in FEV_1, 6MWD, SGRQ, mMRC at 12 months.	doi: 10.1164/rccm.201803-0590OC.	2018
2.	Randomised Controlled Trial	"Endobronchial Valve (Zephyr) Treatment in Homogeneous Emphysema: One-Year Results from the IMPACT Randomized Clinical Trial (IMPACT)", Eberhardt et al., 2021	A 93-patient RCT evaluating Zephyr valves in homogeneous emphysema vs. medical therapy alone ; demonstrated a significant improvement of FEV_1, SGRQ, 6MWD, mMRC at 6 months with acceptable safety profile.	doi: 10.1159/000517034	2016

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
3.	Randomised Controlled Trial	"Endobronchial valve therapy in patients with homogeneous emphysema: results from the IMPACT study" Valipour et al., 2016	93 patients RCT evaluating Zephyr valves in homogeneous emphysema vs. medical therapy alone ; demonstrated a significant improvement of FEV_1, SGRQ, 6MWD, mMRC at 3 months. Secondary outcomes included changes in FEV1, SGRQ, 6MWD, and target lobe volume reduction.	DOI: 10.1164/rccm.201607-1383OC	2016
4.	Randomised Controlled Trial	"Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema(TRANSFORM)", Kemp et al. 2017.	A 97-patient RCT vs. medical therapy alone demonstrated a significant improvement of FEV_1, SGRQ, 6MWD, mMRC at 6 months in the Zephyr arm versus controls.	DOI: 10.1164/rccm.201707-1327OC	2017
5.	Randomised Controlled Trial	"Endobronchial Valves for Emphysema without Interlobar Collateral Ventilation(STELVIO)", Klooster et al., 2015	A single-centre RCT of 68 patients demonstrated a significant improvement of FEV_1, SGRQ, 6MWD, mMRC with Zephyr valve placement versus no valve at 6 months.	doi: 10.1056/NEJMoa1507807	2015

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
6.	Randomised Controlled Trial	"Endobronchial valves for patients with heterogeneous emphysema and without interlobar collateral ventilation: open label treatment following the BeLieVeR-HIFi study", Davey et al. 2015	A sham-controlled RCT of 50 patients demonstrating significant gains in FEV_1, quality of life and 6MWD in the Zephyr arm vs. sham controls at 3 months post-implantation.	doi: 10.1016/S0140-6736(15)60001-0	2015
7.	Randomised Controlled Trial	"Lung volume reduction surgery *versus* endobronchial valves: a randomised controlled trial (CELEB)", Buttery et al., 2023	A head-to-head RCT comparing Zephyr valves versus LVRS in 88 patients demonstrated LVRS does not produce superior results compared to Zephyr. Shorter length of stay and fewer complications in the Zephyr group.	doi.org/10.1183/13993003.02063-2022	2023

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
8.	Randomised Controlled Trial	"The REACH Trial: A Randomized Controlled Trial Assessing the Safety and Effectiveness of the Spiration® Valve System in the Treatment of Severe Emphysema" Li et al, 2018	A multicentre RCT of 107 patients demonstrated a significant improvement of FEV_1, SGRQ, 6MWD and reduction in target lobe volume with Spiration valve placement versus no valve at 3 and 6 months.	https://doi.org/10.1159/000494327	2018
9.	Randomised Controlled Trial	"Improving Lung Function in Severe Heterogenous Emphysema with the Spiration Valve System (EMPROVE). A Multicenter, Open-Label Randomized Controlled Clinical Trial." Criner et al, 2019	A multicentre RCT of 172 patients demonstrated a significant improvement of FEV_1, SGRQ, mMRC and reduction in target lobe volume with Spiration valve placement versus no valve at 6 and 12 months.	doi: 10.1164/rccm.201902-0383OC	2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
10.	Prospective Single-Arm Study	"Reduction of Lung Hyperinflation Improves Cardiac Preload, Contractility, and Output in Emphysema: A Prospective Cardiac Magnetic Resonance Study in Patients Who Received Endobronchial Valves", Van der Molen et al., 2022	A 24-patient study assessing cardiac hemodynamic changes post-EBV implantation, measuring right ventricular preload and output at 8 weeks.	doi: 10.1164/rccm.202201-0214OC	2022
11.	Prospective Single-Centre Study	"Two-year Results of Bronchoscopic Lung Volume Reduction Using One-Way Endobronchial Valves: Real-World Single Center Data", Bivort et al. 2025	Prospective cohort of 83 patients treated with BLVR with Zephyr valves, assessing long-term lung function, 6MWD, SGRQ and BODE index at 3, 6, 12 and 24 months post-EBV.	doi.org/10.2147/COPD.S509468	2025
12.	Registry-Based Observational	"Real-Life Nationwide Outcomes of Bronchoscopic Lung Volume Reduction with Endobronchial Valves in Severe Chronic Obstructive Pulmonary Disease ",Borg et al., 2024	Retrospective registry analysis of 122 EBV-treated versus 471 controls, demonstrated a reduction in exacerbation rates, hospitalisations over 12 months.	DOI: 10.1159/ 000543010	2024

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
13.	Retrospective Single-Arm Study	"Endobronchial lung volume reduction with valves reduces exacerbations in severe emphysema patients", Brock et al., 2023	Evaluation of 129 EBV-treated patients comparing exacerbation frequency before and after valve therapy over a 1-year period.	DOI: 10.1016/j.rmed.2023.107399	2023
14.	Retrospective Cohort Study	"Long-term follow-up after bronchoscopic lung volume reduction valve treatment for emphysema", Hartman et al., 2022	Analysis of 280 patients treated with BLVR showing sustained improvements in FEV_1, 6MWD and SGRQ up to three years post-EBV, thereby demonstrating durable clinical benefit and identifying predictors of long-term survival.	DOI: 10.1183/23120541.00235-2022	2022

Identify yet-to-be-published research that may have results available in the near future (that could be relevant to your application).

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
1.	Randomised Controlled Trial	"Endobronchial Valve in Patients With Heterogeneous Emphysema", Chen Liang An, 2016	Multicentre RCT investigating Zephyr® valve efficacy versus standard care in heterogeneous emphysema patients; recruitment ongoing	https://clinicaltrials.gov/ct2/show/NCT02823223	Unknown status
2.	Randomised Controlled Trial	"EBV in Life-threatening Haemoptysis", Allwood, 2018	RCT evaluating endobronchial valves for inoperable patients with refractory haemoptysis following embolization.	https://clinicaltrials.gov/ct2/show/NCT02816229	Unknown status
3.	Randomised Controlled Trial	"Systemic Effects of BLVR", Slebos, 2023	Prospective RCT assessing systemic hemodynamic and inflammatory effects of BLVR with Zephyr® valves.	https://clinicaltrials.gov/ct2/show/NCT03474471	Unknown status

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
4.	Observational (Patient registry)	Zephyr Valve Registry (ZEVR), Pulmonx Corporation, 2025	Global post-market registry tracking safety and effectiveness outcomes in routine clinical use of Zephyr® valves across multiple centres.	https://clinicaltrials.gov/ct2/show/NCT04186546?term=Zephyr&cond=emphysema&draw=2&rank=1	Unknown status
5.	Observational	"Post-Market Clinical Evaluation of Zephyr Valve 5.5-LP", Pulmonx Corporation, 2023	Single-arm evaluation of safety and efficacy of the latest Zephyr® valve model in diverse patient populations.	https://clinicaltrials.gov/ct2/show/NCT04161235?cond=Zephyr+valves&draw=2&rank=2	Unknown status
6.	Randomised Controlled Trial	Video Assisted Thoracic Surgery (VATS) Fissure Completion Prior to Zephyr® Endobronchial Valve Insertion (COVE), Pulmonx Corporation, 2025	RCT comparing the addition of VATS fissure completion technique prior to EBV placement versus valve placement alone.	https://clinicaltrials.gov/ct2/show/NCT04465461?cond=Zephyr+valves&draw=2&rank=4	Unknown status

References

AIHW. Chronic respiratory conditions – COPD. Canberra: Australian Institute of Health and Welfare; 2024. Available from: https://www.aihw.gov.au/reports/chronic-respiratory-conditions/copd

Australian Commission on Safety and Quality in Health Care. COPD Clinical Care Standard. Sydney: ACSQHC; 2025. Available from: https://www.safetyandquality.gov.au/standards/clinical-care-standards/chronic-obstructive-pulmonary-disease-clinical-care-standard

Bonney, A., Pascoe, D.M., McCusker, M.W., Steinfort, D., Marshall, H., McWilliams, A., Brims, F.J., Stone, E., Fogarty, P., Silver, J.D., Milner, B., Silverstone, E., Hsu, E., Nguyen, D., Rofe, C., White, C., Hu, X., Mayo, J., Myers, R. & Lam, S. (2025) 'Incidental findings during lung low-dose computed tomography cancer screening in Australia and Canada, 2016-21: a prospective observational study', Medical Journal of Australia, 222(8), pp. 403–411

Borg M, Ibsen R, Hilberg O, Løkke A. Real-life nationwide outcomes of bronchoscopic lung volume reduction with endobronchial valves in severe chronic obstructive pulmonary disease. Respiration. 2025;104(5):322–31.

Buttery, S.C., Banya, W., Bilancia, R., Boyd, E., Buckley, J., Greening, N.J., Housley, K., Jordan, S., Kemp, S.V., Kirk, A.J.B., Latimer, L., Lau, K., Lawson, R., Lewis, A., Moxham, J., Polkey, M.I., Pavitt, M., Rathinam, S., Shah, P.L., Steiner, M.C., Tenconi, S., Waller, D., Hopkinson, N.S. & the CELEB investigators 2023, 'Lung volume reduction surgery versus endobronchial valves: a randomised controlled trial', European Respiratory Journal, 61(4), 2202063.

Cazzola M, MacNee W, Martinez FJ, Rabe KF, Franciosi LG, Barnes PJ, et al. Outcomes for COPD pharmacological trials: from lung function to biomarkers. Eur Respir J. 2008;31(2):416–69.

Celli, B. R., Calverley, P. M. A., Rennard, S. I., Wouters, E. F. M., Agustí, A., Anthonisen, N., MacNee, W., Jones, P., Pride, N., Rodriguez-Roisin, R., Rossi, A. & Wanner, A. 2005, 'Proposal for a multidimensional staging system for chronic obstructive pulmonary disease', Respiratory Medicine, 99(12), pp. 1546–1554.

Celli, B.R., Cote, C.G., Marin, J.M., Casanova, C., Montes de Oca, M., Mendez, R.A., Pinto Plata, V. & Cabral, H.J. 2004, 'The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease', The New England Journal of Medicine, 350(10), pp. 1005–1012.

Criner, G.J., Sue, R., Wright, S., Dransfield, M., Rivas-Perez, H., Wiese, T., Sciurba, F.C., Shah, P.L., Wahidi, M.M., de Oliveira, H.G., Morrissey, B., Cardoso, P.F.G., Hays, S., Majid, A., Pastis Jr, N., Kopas, L., Vollenweider, M., McFadden, P.M., Machuzak, M., Hsia, D.W., Sung, A., Jarad, N., Kornaszewska, M., Hazelrigg, S., Krishna, G., Armstrong, B., Shargill, N.S. & Slebos, D.-J. 2018, 'A multicenter randomized controlled trial

of Zephyr® endobronchial valve treatment in heterogeneous emphysema (LIBERATE)', American Journal of Respiratory and Critical Care Medicine, 198(9), pp. 1151–1164

Criner, G.J., Delage, A., Voelker, K., Thomas, C.F., Pompilus, F., Shah, P.L., Wheaton, J.D., et al. 2019, 'Improving lung function in severe heterogeneous emphysema with the Spiration® Valve System (EMPROVE): a multicentre open-label randomised controlled clinical trial', American Journal of Respiratory and Critical Care Medicine, 200(11), pp. 1354–1362

Donohue JF. Minimal clinically important differences in COPD lung function. COPD. 2005;2(1):111–24.

Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2025 report. GOLD; 2025.

Gore JM, Brophy CJ, Greenstone MA. How well do we care for patients with end stage chronic obstructive pulmonary disease? A comparison of palliative care and quality of life in COPD and lung cancer. Thorax. 2000;55(12):1000–6.

Güder G, Brenner S, Angermann CE, Ertl G, Held M, Sachs AP, Lammers JW, Zanen P, Hoes AW, Störk S, Rutten FH. GOLD or lower limit of normal definition? A comparison with expert-based diagnosis of chronic obstructive pulmonary disease in a prospective cohort study. Eur Respir J. 2012;40(3):684–91.

Hartman JE, Klooster K, Gortzak K, ten Hacken NHT, Slebos DJ. Survival in COPD patients treated with bronchoscopic lung volume reduction. Respir Med. 2022;196:106835.

Hartman JE, ten Hacken NHT, Klooster K, Boezen HM, de Greef MH, Slebos DJ. The minimal important difference for residual volume in patients with severe emphysema. Eur Respir J. 2012;40(5):1137–41.

Kemp, S.V., Slebos, D.J., Kirk, A., Kornaszewska, M., Carron, K., Ek, L., Broman, G., Hillerdal, G., Mal, H., Pison, C., Briault, A., Downer, N., Darwiche, K., Rao, J., Hübner, R.H., Ruwwe-Glosenkamp, C., Trosini-Desert, V., Eberhardt, R., Herth, F.J.F., Derom, E., Malfait, T., Shah, P.L., Garner, J.L., Ten Hacken, N.H., Fallouh, H., Leroy, S. & Marquette, C.H. 2017, 'A multicenter randomized controlled trial of Zephyr® endobronchial valve treatment in heterogeneous emphysema (TRANSFORM)', American Journal of Respiratory and Critical Care Medicine, 196(12), pp. 1535–1543

Klooster K, Hartman JE, ten Hacken NHT, Slebos DJ. Improved predictors of survival after endobronchial valves treatment in patients with severe emphysema. Am J Respir Crit Care Med. 2017;195(9):1277–84.

Klooster K, ten Hacken NHT, Hartman JE, Kerstjens HAM, van Rikxoort EM, Slebos DJ. Endobronchial valves for emphysema without interlobar collateral ventilation. N Engl J Med. 2015;373(24):2325–35.

Kon, Canavan, Jones, Nolan, Clark et al; Minimum clinically important difference for the COPD Assessment Test: a prospective analysis; Lancet Respir.

Labarca, G., Uribe, J.P., Pacheco, C., Folch, E., Kheir, F., Majid, A., Jantz, M.A., Mehta, H.J., Patel, N., Herth, F.J.F. & Fernández-Bussy, S. 2019, 'Bronchoscopic lung volume reduction with endobronchial Zephyr® valves for severe emphysema: a systematic review and meta-analysis', Respiration, 98(3), pp. 268–278

Li, S., Wang, G., Wang, C., Gao, X., Jin, F., Yang, H., Han, B., Zhou, R., Chen, C., Chen, L., Bai, C., Shen, H., Herth, F.J.F. & Zhong, N. 2019, 'The REACH Trial: A randomized controlled trial assessing the safety and effectiveness of the Spiration® Valve System in the treatment of severe emphysema', Respiration, 97(5), pp. 416–427.

Martini K, Frauenfelder T. Advances in imaging for lung emphysema. Ann Transl Med. 2020;8(21):1467.

Martinez, F. J., Sternberg, A., DeCamp, M., Gumpel, J., Fishman, A., Wisniewski, L., Donohue, J., Alberts, R., Formation of BODE Index Changes Study Group 2008, 'Longitudinal change in the BODE index predicts mortality in severe emphysema', American Journal of Respiratory and Critical Care Medicine, 178(5), pp. 491-499.

uhan, M.A., Chandra, D., Mosenifar, Z., Ries, A., Make, B., Hansel, N.N. & Wise, R.A. 2011, 'The minimal important difference of exercise tests in severe COPD', European Respiratory Journal, 37(4), pp. 784–790.

Sandhaus, R.A., Turino, G., Brantly, M.L., Campos, M., Cross, C.E., Goodman, K., Hogarth, D.K., Knight, S.L., Stocks, J.M., Stoller, J.K., Strange, C., Teckman, J. 2016, 'The diagnosis and management of alpha-1 antitrypsin deficiency in the adult', Chronic Obstructive Pulmonary Diseases: Journal of the COPD Foundation, 3(3), pp. 668–682.

Schünemann HJ, Griffith L, Jaeschke R, Goldstein R, Stubbing D, Guyatt GH. Evaluation of the minimal important difference for the feeling thermometer and the St George's Respiratory Questionnaire in patients with chronic airflow obstruction. J Clin Epidemiol. 2003;56(12):1170–6.

Valipour, A., Herth, F.J.F., Gompelmann, D., Schuhmann, M., Ficker, J.H., Shah, P.L., et al. 2016, 'Endobronchial Valve Therapy in Patients with Homogeneous Emphysema: Results from the IMPACT Study', American Journal of Respiratory and Critical Care Medicine, 194(9), pp. 1073–1082.

van Geffen WH, Slebos DJ, Herth FJ, Kemp SV, Weder W, Shah PL. Surgical and endoscopic interventions that reduce lung volume for emphysema: a systematic review and meta-analysis. Lancet Respir Med. 2019;7(4):313–24.

Welling J, Hartman JE, ten Hacken NHT, Klooster K, Slebos DJ. Eligibility for lung volume reduction in COPD patients in clinical practice. Respiration. 2020;99(3):241–8.

World Health Organization. Chronic obstructive pulmonary disease (COPD) – WHO fact sheet, 2024: https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd)

Yang IA, Hancock K, George J, McNamara R, McDonald CF, McDonald VM, et al. COPD-X handbook: summary clinical practice guidelines for the management of COPD. Milton (QLD): Lung Foundation Australia; 2024.