MSAC application 1814

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

Application for MBS eligible service or health technology

HPP Application number:

HPP200363

Application title:

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

Submitting organisation:

THE THORACIC SOCIETY OF AUSTRALIA AND NEW ZEALAND LIMITED

Submitting organisation ABN:

17057925836

Application description

Succinct description of the medical condition/s:

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. 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.

Succinct description of the service or health technology:

Bronchoscopic lung volume reduction surgery with one way endobronchial valves involves the insertion of multiple valves into target areas of the lung. 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 result of doing this is less hyperinflation and gas trapping, improved breathing mechanics, and more efficient gas exchange.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Consultant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name:

THE THORACIC SOCIETY OF AUSTRALIA AND NEW ZEALAND LIMITED

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

New

What is the type of service or health technology?

Therapeutic

PICO sets

Application PICO sets:

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

Population

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

Bronchoscopic lung volume surgery via insertion of endobronchial valves is intended as a treatment for patients with severe emphysema. Per the COPD X guidelines, the

subgroup most appropriate for referral to BLVR 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.

Select the most applicable Medical condition terminology (SNOMED CT):

Pulmonary emphysema

Intervention

Name of the proposed health technology:

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

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 health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Optimised standard medical management

Outcomes

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

Key outcomes discussed in the PICO set include:

> Survival prognosis:
>>> BODE Index for COPD survival prognosis

> Pulmonary function
>>> FEV_1 (Forced Expiratory Volume in 1 second)
>>> FVC (Forced Vital Capacity)
>>> RV (Residual Volume)
>>> TLC (Total Lung Capacity)

> Exercise capacity / functional status:
>>> 6MWD (6-minute walking distance test)
>>> mMRC (Modified Medical Research Council)

> Quality of life:
>>> St. George's Respiratory Questionnaire (SGRQ)
>>> The CAT (COPD assessment test)

> Other disease control and secondary prognostic indicators
>>> Exacerbation frequency / hospitalisations
>>> Oxygen dependence

> All-cause mortality

> Procedure-related complication rates:
>>> Pneumothorax
>>> Valve migration
>>> Infection
>>> Haemoptysis

Proposed MBS items

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

NA

Category number:

THERAPEUTIC PROCEDURES

Category description:

SURGICAL OPERATIONS

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:

$22,607.42

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

Note: overall cost per patient includes estimated costs for main capital components, estimated consumables costs, and proposed service fee. Cost information is indicative of a reasonable estimate intended to provide an appropriate order of magnitude will depend on manufacturer, supplier, and local procurement arrangements and would require further verification through detailed economic modelling conducted as part of an assessment report.

How is the technology / service funded at present? (For example: 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.

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

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.

Estimated Utilisation

Estimate the prevalence and/or incidence of the proposed population:

The estimated prevalence of COPD is c.2.400/100,000. Within that population, it's estimated that c.33% have an emphysema predominant phenotype (i.e. a prevalence of c.800/100,000 across the entire population). However, major reviews emphasise that only a small fraction of patients meet the full anatomic, physiologic and clinical criteria, and thus BLVR is applicable only to a highly selected subgroup (c.0.2% of the whole COPD patient population). Additional, initial uptake will likely be limited even further by the number of tertiary sites with the necessary skilled staff and infrastructure required to deliver the procedure, thus this assumption has been used to derive initial estimated uptake among the prevalent COPD population.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

0-1%

Year 2 estimated uptake (%):

0-1%

Year 3 estimated uptake (%):

0-1%

Year 4 estimated uptake (%):

0-1%

Estimate the number of patients who will utilise the proposed technology for the first full year:

30-100

Will the technology be needed more than once per patient?

No, once only

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entities who provide the health technology/service:

Thoracic Society of Australia & New Zealand (TSANZ)

Royal Australasian College of Physicians (RACP)

Royal Australasian College of Surgeons (RACS)

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

Lung Foundation Australia

Entities who produce similar products:

Olympus

Pulmonx

Entities who may be impacted by the health technology/service:

Australian and New Zealand College of Anaesthetists (ANZCA)

Australian College of Nursing (ACN)

Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)

Royal Australian and New Zealand College of Radiologists (RANZCR)

Australian Physiotherapy Association (APA)

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?
Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?
Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?
No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
165980	Prosthesis, internal, stent, bronchial
188455	Endobronchial valve