

MSAC Application 1763

**Amendment of item 11512 to include
the use of portable home spirometry
via telehealth**

Application for MBS eligible service or health technology

ID:

HPP200027

Application title:

Amendment of Item 11512 to include the use of Portable Home Spirometry via Telehealth

Submitting organisation:

THE THORACIC SOCIETY OF AUSTRALIA AND NEW ZEALAND LIMITED

Submitting organisation ABN:

17057925836

Application description

Succinct description of the medical condition/s:

Spirometry is an essential tool for diagnosing and managing a range of obstructive and restrictive lung diseases. Obstructive Lung Disease includes but is not limited to the following, chronic obstructive pulmonary disease (COPD), bronchiectasis, asthma, emphysema, and bronchiolitis. Restrictive lung diseases are a heterogeneous set of lung disorders that can be divided into Intrinsic and extrinsic causes, with the former is related to inflammatory processes within the lung, the later may be related to conditions impacting the chest wall.

Succinct description of the service or health technology:

As per existing item number 11512, with the exception that the patient would be using the device at home with a Scientist in continuous attendance via Telehealth. The technology allows high quality measurement at home.

Application contact details

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

Applicant

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

Organisation

Is the applicant organisation the organisation you are representing in the HPP today?

Yes

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 Prostheses List?

No

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

Amendment

What is the nature of the amendment?

An amendment to the way the service is clinically delivered under the existing item(s)

Justification for amendment:

Telehealth Spirometry is an essential tool utilized by Respiratory Laboratories. It enables high quality measurements performed via Telehealth with a Respiratory Laboratory Scientist in continuous attendance. Spirometry via Telehealth with a Respiratory Scientist would benefit those patients with chronic respiratory disease. These patients will be able to continue to be appropriately monitored while being able to remain in their home environment. Diagnosis will not be made via Home Spirometry, its applications is designed to allow telehealth measurement for monitoring. The ability to undertake Spirometry via Telehealth improves consumer satisfaction for many patients significantly reducing the patient burdens of costs, travel time and social absenteeism. It also eliminates the risk of hospital communicable diseases or infection.

Currently item number 11512 is used by Respiratory Laboratories for testing within the laboratory, We are seeking an amendment to item number 11512 proposing that Respiratory Laboratories can bill for Telehealth Spirometry. We would propose that description (C) be changed from, "that is performed in a respiratory laboratory equipped to perform complex lung function tests; and" To "that is performed in a respiratory laboratory equipped to perform complex lung function tests; either face to face or via telehealth;"

Please select any relevant MBS items.

MBS item number	Selected reason type
11512	Expansion or amendment to existing item

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

Lung function

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	As per item 11512. Patients who are referred for spirometry for diagnosing and monitoring of chronic lung disease.

As per item 11512. Patients who are referred for spirometry for diagnosing and monitoring of chronic lung disease.

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Monitoring

Purpose description:

To monitor a condition over time.

Supporting documentation

Document type	File name(s)
Application PICO set documents	Figures 1 and 2.pdf; Quality of Spirometry in Primary Care.pdf; Summary of Evidence.pdf
Reference list	PICO Reference List.pdf

Population

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

As per item 11512, applicable to patients with chronic lung disease including obstructive and restrictive lung diseases. This would include children and adults capable of performing spirometry. Telehealth spirometry will be specifically performed to monitor lung function in a cohort of patients with existing respiratory diseases.

Spirometry testing will occur via a secure telehealth platform (decided by individual local health districts) under supervision of a respiratory scientist working in a respiratory laboratory-equipped to perform complex lung function testing.

Search and select the most applicable Medical condition terminology (SNOMED CT):

Chronic disease of respiratory system

Intervention

Name of the proposed health technology:

Home Spirometry Via Telehealth

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:

The comparator is the measurement of Spirometry within a Respiratory Laboratory.

Patients with Chronic Respiratory diseases who are referred from a Respiratory Medicine Physician and have a personal spirometer would be eligible to perform Spirometry via telehealth with a Respiratory Scientist. No additional healthcare resources are required. See Figure 1 and Figure 2 attached of Comparative workflows.

GP Spirometry is generally of an insufficient standard when compared to Laboratory measurements performed by a Scientist. Please see References attached. Item number 11506 is used by GP's. We are not proposing a change in this item number. Please see attached evidence file - Quality of Spirometry in primary care.

Outcomes

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

Spirometry via Telehealth with a Respiratory Scientist would benefit those patients with chronic respiratory disease. These patients will be able to continue to be appropriately monitored while being able to remain in their home environment.

The ability to undertake Spirometry via Telehealth improves consumer satisfaction for many patients significantly reducing the patient burdens of costs, travel time and social absenteeism.

Infection Control eliminates the risk of hospital communicable diseases or infection. In a multi-centre randomized controlled trial at 14 Cystic Fibrosis centres with subjects at least 14 years of old, intervention of home monitoring with telehealth spirometry among patients with CF was able to detect more exacerbations than usual care.

The onset of the COVID-19 pandemic was associated with restricted community movement and limited access to healthcare facilities, resulting in changed service delivery in several patient cohorts to telehealth including spirometry. In CF children and adults (3662 individuals), in the 12 months following the onset of the pandemic, there was improvement in clinical outcomes of people with CF when compared to the pre-pandemic period (outcomes included FEV1, number of hospitalizations, BMI). Virtual consultations increased from 8 to 47%.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

11512

Please search and select the proposed category:

DIAGNOSTIC PROCEDURES AND INVESTIGATIONS

Please search and select the proposed group:

MISCELLANEOUS DIAGNOSTIC PROCEDURES AND INVESTIGATIONS

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Measurement of spirometry: (a) that includes continuous measurement of the relationship between flow and volume during expiration or during expiration and inspiration, performed before and after inhalation of a bronchodilator; and (b) that is performed with a respiratory scientist in continuous

attendance (respiratory scientist in the lab; Patient can be located at home and perform spirometry via telehealth, or physically in the lab); and (c) that is performed in a respiratory laboratory equipped to perform complex lung function tests; and (d) that is performed under the supervision of a specialist or consultant physician who is responsible for staff training, supervision, quality assurance and the issuing of written reports; and (e) for which a permanently recorded tracing and written report is provided; and (f) for which 3 or more spirometry recordings are performed; each occasion at which one or more such tests are performed Not applicable for a service associated with a service to which item 11503 or 11507 applies.

Proposed MBS fee:

\$66.00

Indicate the overall cost per patient of providing the proposed health technology:

\$66.00

Please specify any anticipated out of pocket costs:

\$600.00

Provide details and explain:

Cost to the health service/respiratory function lab – No difference when compared to in person attendance.

Cost to the patient includes cost of spirometer and consumables. Spirometers cost approximately \$600. Note however that the typical service life of spirometers is 5 years.

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

no funding

Please provide a cost break down attachment:

Document type	File name(s)
Cost breakdown attachment	Hospital visit vs Home Spirometer (Patient Cost).xlsx; TGA Home Spirometer Costs.xlsx

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)?

Non-inferior

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

Published Data - see Summary of Evidence file

Estimated utilisation

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

As per existing item number 11512.

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

Year 1 estimated uptake(%):

5-10

Year 2 estimated uptake(%):

5-10

Year 3 estimated uptake(%):

5-10

Year 3 estimated uptake(%):

5-10

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

200-300 per hospital with this service (for details see spirometer utilisation 2020-23)

Optionally, provide details:

The attached Home Spirometer Utilisation document is data from a number of Respiratory Laboratories in Australia in the last three years. We would estimate that in years to come it would average 5-10% of the total Spirometry tests performed by those Labs.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Yes, for monitoring (chronic lung disease).

Optionally, provide details:

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

2-3 times per year

Optionally, provide details:

Provide references to support these calculations.

Document type	File name(s)
Estimated utilisation references	Home Spirometer Utilisation 2020-2023.xlsx

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

Professional body name:

AUSTRALIAN AND NEW ZEALAND SOCIETY OF RESPIRATORY SCIENCE LIMITED

Professional body name:

AUSTRALIAN COUNCIL FOR CLINICAL PHYSIOLOGISTS LTD

Professional body name:

THE ROYAL AUSTRALASIAN COLLEGE OF PHYSICIANS

Professional body name:

THE THORACIC SOCIETY OF AUSTRALIA AND NEW ZEALAND LIMITED

List all appropriate professional bodies / organisations representing the group(s) of health professionals who request the health technology/service:

Professional body name:

AUSTRALIAN AND NEW ZEALAND SOCIETY OF RESPIRATORY SCIENCE LIMITED

Professional body name:

THE THORACIC SOCIETY OF AUSTRALIA AND NEW ZEALAND LIMITED

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:

Professional body name:

AUSTRALIAN AND NEW ZEALAND SOCIETY OF RESPIRATORY SCIENCE LIMITED

Professional body name:

AUSTRALIAN COUNCIL FOR CLINICAL PHYSIOLOGISTS LTD

Professional body name:

THE ROYAL AUSTRALASIAN COLLEGE OF PHYSICIANS

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

Number of organisations listed: 1

Professional body name:

LUNG FOUNDATION AUSTRALIA

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

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
GMDN 13680	Spirometer, diagnostic

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes