MSAC Application 1763

Amendment of MBS Item 11512 to include the use of portable home spirometry via telehealth

PICO Confirmation

Summary of PICO/PPICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for spirometry performed via video telehealth using a portable spirometry device in patients who require monitoring of lung function

Component	Description
Population	Patients who require spirometry for monitoring lung function and have successfully performed spirometry in a respiratory laboratory previously, including but not limited to: 1. patients with chronic (obstructive or restrictive) lung disease 2. patients who have had a solid organ or allogenic bone marrow transplant
Intervention	Spirometry performed at home using a portable spirometry device with a respiratory scientist in continuous attendance via video telehealth.
Comparator/s	Spirometry performed in a respiratory laboratory as per MBS item 11512 Spirometry performed at home with a general practitioner (GP) in attendance via telehealth as per MBS item 11506
Reference standard	Spirometry performed in a respiratory laboratory as per MBS item 11512
Outcomes	**Test accuracy** • Concordance/agreement between in-laboratory and portable home spirometers (e.g. FEV_1 and FVC) **Test reliability** • Test quality (using ATS/ERS grading criteria) • Overall test failure rate (failure for any reason) • Technical test failure rate (technical failure with equipment or infrastructure) • Repeat tests (due to prior failed test) • Referral for in-laboratory spirometry (following spirometry via telehealth) **Change in management** • Change in treatment (e.g. type, dose, medications added or removed) • Change in monitoring frequency **Health outcomes** • Hospitalisations • Mortality • Change in disease outcomes **Safety** • Direct harms of the test • Hospital-acquired diseases or infections • Harms of management decisions (if full linked evidence approach used) **Healthcare resources** • Cost to deliver the intervention (service provider, patient out-of-pocket costs) • Total Australian Government healthcare costs **Other** • Practicality (ease of use and test interpretation, invasiveness, cost, time, patient adherence)

Component	Description
Assessment questions	What is the safety, effectiveness and cost-effectiveness of spirometry performed at home using a portable spirometry device with a respiratory scientist in continuous attendance via video telehealth versus spirometry performed in a respiratory laboratory as per MBS item 11512 for monitoring lung function in patients with chronic lung disease or following solid organ or allogenic bone marrow transplant?

ATS = American Thoracic Society; ERS = European Respiratory Society; FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity.

Purpose of application

An application requesting amendment of MBS item 11512 to include the use of portable home spirometry via telehealth for monitoring patients with chronic lung disease (obstructive or restrictive) was received from The Thoracic Society of Australia and New Zealand Limited by the Department of Health and Aged Care.

Currently, MBS item 11512 applies to spirometry performed in a respiratory laboratory. There are no restrictions on the use of the item by clinical indication or purpose (i.e. for diagnosis, assessment of acute exacerbations, long-term monitoring).

The clinical claim made by the applicant is that portable spirometry performed at home with a respiratory scientist in continuous attendance via telehealth results in non-inferior health outcomes compared to spirometry performed in a respiratory laboratory.

Regarding clinical need, the applicant has proposed that portable home spirometry via telehealth may improve patient satisfaction by reducing patient burden (including financial and time) in addition to eliminating the risk of hospital-acquired diseases or infections.

PICO criteria

Population

The proposed population represents a sub-group of the population currently eligible for spirometry under MBS item 11512. The current item is not restricted by age and does not specify the purpose (i.e. diagnosis or monitoring) or the clinical indication for which spirometry is being performed.

Portable home spirometry via telehealth is proposed for use in patients who require spirometry for monitoring lung function and who have successfully performed spirometry in a respiratory laboratory previously, including but not limited to:

a. patients with chronic obstructive or restrictive lung disease, such as chronic obstructive pulmonary disease (COPD), bronchiectasis, asthma, emphysema, bronchiolitis, cystic fibrosis, and drug-induced or autoimmune-induced lung disease
b. patients following solid organ or allogenic bone marrow transplant.

Home spirometry is not intended for diagnosis, which will continue to be performed under MBS item 11512 in a respiratory laboratory.

In patients with chronic obstructive or restrictive lung diseases, monitoring lung function with spirometry allows the treating doctor to assess or monitor response to therapy, monitor disease exacerbations and recovery, make decisions regarding change in patient management, and monitor the course of the disease (Graham et al. 2019; National Asthma Council Australia March 2023). Frequency of monitoring varies depending on multiple factors such as the type of lung disease and individual patient characteristics. For adults with asthma for example, some patients may only require spirometry during periodic review (every 1-2 years for most patients), whilst for adults with severe asthma or those with poor perception of airflow limitation, spirometry is recommended at every follow-up consultation for asthma (National Asthma

Council Australia 2023). In patients already diagnosed with COPD, spirometry is used to confirm disease exacerbations and should be performed regularly as part of an assessment of disease severity (Yang et al. 2023).

For patients following lung transplant, regular monitoring with spirometry is required indefinitely post-operatively (Yang et al. 2023). For patients receiving other solid organ or allogenic bone marrow transplants, spirometry may be required to monitor for graft-versus-host disease, a multisystem disorder that can involve the lungs and manifest as interstitial pneumonitis (Varelias et al. 2015). According to the applicant, spirometry monitoring for graft-versus-host disease in the post-transplant population would be more likely to occur in patients who develop respiratory symptoms. For all allogenic hematopoietic cell transplantation recipients, spirometry has been recommended pre-transplant, at day 100 post-transplant, at 6, 9 and 12 months post-transplant, then yearly (Kitco et al. 2021). For patients with newly diagnosed chronic graft-versus-host disease, spirometry every three months has been recommended (Kitco et al. 2021).

In developing the PICO Confirmation, consideration was given to whether occupational lung diseases should be specifically discussed. It was considered that these diseases would meet the aforementioned criteria of either obstructive or restrictive lung diseases, and that aetiology may not be relevant.

The applicant has indicated that the telehealth service could be used for children and adults who are capable of performing spirometry. According to the National Asthma Council of Australia *Spirometry handbook for primary care* (March 2023), nearly all adults and most children aged 6 years or older attending general practice are able to perform spirometry with appropriate coaching by a trained operator. The American Thoracic Society (ATS) and European Respiratory Society (ERS) technical statement on standardisation of spirometry (Graham et al. 2019) advises that children as young as 2.5 years old with normal cognitive and neuromotor function are capable of performing acceptable spirometry with appropriate coaching. The applicant has indicated that patients would need to have successfully performed spirometry in a respiratory laboratory before being considered for home spirometry via telehealth. Assessment of suitability for telehealth spirometry is likely to occur collaboratively between the referring doctor and the respiratory laboratory, taking into account the factors outlined in Figure 4.

In the 2022 calendar year, 55,752 claims were made under MBS item 11512 (see Table 2). The general downward trend in utilisation of the item between 2018 and 2022 is hypothesised to be related to:

- a decrease in the number of services delivered due to the COVID-19 pandemic
- an increase in utilisation of telehealth services due to the COVID-19 pandemic that were not claimed under this item number
- changes to the MBS items for respiratory function tests in November 2018.

From 1 November 2018, changes to the MBS diagnostic services for respiratory function tests were introduced (Department of Health and Aged Care n.d.). The changes were made to introduce improved quality requirements, update the list of MBS funded complex lung function tests, and encourage well performed spirometry in general practice. Of relevance to MBS item 11512, the issuing of written reports on tests performed under this item number was restricted to consultant respiratory physicians only. Some practitioners who were previously able to report on these tests were no longer able to, likely contributing in part to the reduced utilisation seen after 2018.

In addition, a new MBS item for exhaled nitric oxide spirometry (11507) and a new higher rebated item for spirometry performed in general practice (11505) were introduced and may have resulted in some claims previously made under MBS item 11512 being rediverted to these new items.

The utilisation of MBS item 11512 for monitoring purposes cannot be determined based on Medicare data, which includes claims for both diagnostic and monitoring purposes.

Table 2 Utilisation of MBS item 11512 from January 2018 to December 2022

MBS Item no.	2018	2019	2020	2021	2022
11512	78,761	76,625	54,543	57,896	55,752

MBS = Medicare Benefits Schedule; no. = number.
Source: Services Australia Medicare item reports (accessed 27 September 2023).

PASC raised the issue of whether the patient populations specified in the PICO would capture all patients who may benefit from the proposed telehealth service, noting that the descriptor for in-laboratory spirometry (MBS item 11512) currently does not restrict use of the item to particular patient groups or by medical condition. The applicant explained that the main requirement for a patient to be considered eligible for home spirometry is that they are able to demonstrate proficiency in performing spirometry in an in-laboratory setting using MBS item 11512. This requirement obviates the need to specify the patient population (e.g. on the basis of a specific medical condition) for home spirometry in the proposed item descriptor. The applicant acknowledged it may not be possible or necessary to define all subpopulations who require lung function monitoring.

PASC agreed that the population did not need to be explicitly defined in the item descriptor, consistent with how MBS item 11512 is currently specified. However, PASC noted that it would be necessary to identify all relevant subpopulations for the purpose of the health technology assessment (HTA). For instance, PASC noted that the increased clinical complexity associated with eligible transplant patients would have implications for the economic modelling in the HTA.

Intervention

The proposed intervention is spirometry performed at home using a portable spirometry device with a respiratory scientist in continuous attendance via video telehealth.

Spirometry is a test used to assess lung function. It provides objective information to diagnose lung diseases and monitor lung health (Graham et al. 2019). The main parameters measured with spirometry include forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), FEV_1/FVC (ratio) and peak expiratory flow (PEF) (National Asthma Council Australia March 2023). These measures provide an indication of lung capacity (FVC), airway calibre (FEV_1), and whether expiratory airflow obstruction is present (by assessing the FEV_1/FVC ratio), and can also be used to assess effort (PEF) (National Asthma Council Australia March 2023).

In Australia, the Global Lung Initiative (GLI) 2012 reference ranges (Quanjer et al. 2012) are recommended for interpreting spirometry results and results are interpreted in the context of both reference values and the individual's personal best or prior results (National Asthma Council Australia March 2023). The shape of the flow-volume and volume-time curves produced by spirometry are also assessed for abnormal ventilatory patterns including obstructive (limited ability to expire air quickly, for example in asthma and

COPD), restrictive (small lung volume, for example in interstitial pulmonary fibrosis) and mixed obstructive and restrictive (small lung volume and inability to expire quickly, for example in cystic fibrosis) (National Asthma Council Australia March 2023).

There are currently five MBS items for spirometry (11503, 11505, 11506, 11507 and 11512). The items cover various settings (primary care, respiratory laboratory), purposes (diagnosis, monitoring), and levels or complexities of testing. The item descriptors and fees for the spirometry items are summarised in Table 10 (Appendix A).

In developing the PICO Confirmation, the Assessment Group considered the two main settings in which spirometry is performed; that is, primary care and in a respiratory laboratory. It was hypothesised that the populations undertaking spirometry in these two settings are likely to be different. Patients primarily under the care of a respiratory physician for their respiratory condition may be more likely to have more complex lung disease and therefore be referred to a respiratory laboratory for spirometry performed under the supervision of, and reported by, a specialist or consultant physician. Those primarily under the care of a general practitioner (GP) for their respiratory condition may have less complex lung disease and be more likely to have spirometry performed by their GP.

Under the proposed amendment, patients having spirometry under MBS item 11512 could perform spirometry at home using a portable spirometry device with a respiratory scientist in continuous attendance via video telehealth. The respiratory scientist would observe the patient's technique and correct as required, provide encouragement and feedback to the patient to facilitate optimal performance, and ensure that acceptable data has been obtained prior to concluding the telehealth assessment. All other requirements of the current MBS item would remain unchanged. The intended use of portable home spirometry via telehealth under the proposed amendment is summarised in Table 3.

Table 3 Proposed use of portable home spirometry via telehealth under amended MBS item 11512

Criteria	Description
Purpose	Monitoring lung function in patients who require monitoring via spirometry and who have successfully performed spirometry in a respiratory laboratory previously, as an alternative to spirometry performed in a respiratory laboratory under MBS item 11512
Referral	No change from existing MBS item 11512
Frequency of use	Multiple times per year. The applicant has indicated that most patients would use the service between 2 and 5 times per year, while some patients may require the service approximately 10 times per year (e.g. transplant patients).
Mode of delivery	Telehealth (with video)
Clinical setting	Home (i.e. out-of-laboratory)
Specialist training	No change from existing MBS item 11512
Provider type	No change from existing MBS item 11512
Required infrastructure (health system)	• Secure telehealth (with video) platform • Equipment and infrastructure to participate in telehealth consultation (e.g. computer or device with speakers, microphone, webcam; reliable internet connection) • Software or Apps, as applicable to the portable spirometry device used
Required infrastructure and equipment (patient) *As applicable to the device used*	• Portable home spirometer[a] and consumables required to use and appropriately maintain the spirometer (e.g. mouthpiece, nose clip, batteries) • Equipment to support use of home spirometer (e.g. computer with appropriate operating system and browser, or mobile device and App) • Equipment and infrastructure to participate in telehealth consultation (e.g. computer or device with speakers, microphone, webcam; reliable internet connection) • Equipment to accurately measure patients' height and weight • Equipment to accurately measure temperature, barometric pressure and humidity at testing location (or accurate source of this information)
Current funding	Telehealth services are currently not funded for MBS item 11512

MBS = Medicare Benefits Schedule.
[a] It is estimated that a replacement spirometer will need to be purchased after approximately 5 years based on the typical service life indicated by the applicant.
Source: prepared for the PICO Confirmation based on information provided by the applicant and patient resources from The Royal Children's Hospital Melbourne.

PASC queried whether the potential requirement for information such as barometric pressure at the testing location extended to portable home spirometry for telehealth, as this information is typically required for in-laboratory spirometry. The applicant clarified that this information is not required for portable spirometry devices because they use different technology to laboratory-based spirometers and are not as impacted by ambient conditions.

The applicant has advised that portable home spirometry via telehealth will provide the same amount and type of data for interpretation by the respiratory physician as in-laboratory spirometry. The data will be interpreted by the respiratory physician in the same way for both home spirometry via telehealth and in-laboratory spirometry (i.e. normal ranges, thresholds etc. will remain unchanged).

While there are currently no spirometry items on the MBS that specify telehealth as an option for the mode of delivery, the wording of some items such as 11505 and 11506, does not preclude performance of spirometry via telehealth. In contrast, MBS item 11512 specifies that the service must be performed in a respiratory laboratory. Diagnostic spirometers are included in the Australia Register of Therapeutic Goods

(ARTG) under Global Medical Device Nomenclature (GMDN) 13680. There were 28 devices listed on the ARTG under GMDN 13680 on the 26 September 2023. A summary of these devices is provided in Table 12 Appendix B, including suitability for home use REDACTED. The applicant has advised that patients will be free to choose the device they purchase, provided it is listed on the ARTG and is suitable for home use. Some laboratories may loan spirometers to patients or may provide guidance to patients on suitable spirometers to purchase.

Implementation considerations

Quality assurance

Device quality assurance would need to be considered for portable home spirometers. The explanatory note for MBS item 11512 (DN.1.20, see Table 11 Appendix A) specifies that 'spirometry services billed to the MBS should meet international quality standards'. The note references the 2005 ATS/ERS technical standards for standardisation of spirometry (Miller et al. 2005). This publication was updated in 2019, and the updated guidance (Graham et al. 2019) has been used in the development of this PICO Confirmation.

The 2019 technical statement outlines the minimum device quality assurance requirements for spirometry, such as maintaining a log of calibration results and recording dates of software updates (Graham et al. 2019). Consideration needs to be given as to how respiratory laboratories would ensure that portable home spirometers used in telehealth consultations meet the minimum quality assurance requirements as set out in this statement.

PASC asked the applicant how quality assurance (such as calibration and software updates) of personal home spirometers would be undertaken. The applicant suggested that patients could bring their device to face-to-face appointments or attend the laboratory periodically for the laboratory staff to perform a calibration check. The applicant also indicated that if patient measurements were not repeatable and this could not be explained by clinical factors, then this could also be a general indication of the need for a calibration check. The applicant explained that there is an existing quality standard for in-laboratory spirometry that they would be aiming to comply with for quality assurance of portable home spirometers. The applicant noted one hospital-based respiratory laboratory that is currently in the process of developing a quality framework for telehealth spirometry.

PASC noted concerns that the validity of the results obtained from portable spirometry devices may be impacted by a range of variables, such as quality assurance. The applicant commented that one of the reasons they feel the amended or new item would provide superior spirometry data to MBS item 11506 performed via telehealth is that respiratory scientists, an appropriately trained workforce, will be involved and able to quickly detect any device-related issues. The applicant commented that under the amended or new item, a respiratory scientist would be in attendance via telehealth to guide the patient and detect any systemic issues with the technology that needed addressing. If the device is not performing as expected, the respiratory scientist could ask the patient to bring it to the laboratory for a calibration check.

Patient access to equipment and infrastructure

The infrastructure and equipment required by a patient to participate in telehealth spirometry is listed in Table 3. Patients will need to purchase the required equipment or loan the equipment from a respiratory laboratory (where available). This will involve initial costs to purchase the equipment and ongoing costs for maintenance, including purchasing a replacement spirometer approximately every 5 years based on the service life indicated by the applicant. Patients who do not have access to the required infrastructure and

equipment would need to attend the respiratory laboratory for spirometry. Equity of access issues should be considered in the assessment report.

PASC asked the applicant if patients who are currently using telehealth spirometry are requiring additional support in the community, for example from General Practitioners (GPs). The applicant advised that telehealth spirometry would only be used in a very select group of patients who would be capable of performing spirometry at home, and that a very low threshold would be applied for bringing patients back into the laboratory for a face-to-face consultation if any difficulties arose.

Comparator(s)

The proposed comparator is spirometry performed in a respiratory laboratory as per MBS item 11512 (see Table 4). This is the test that would be replaced (for some patients) by the proposed amendment.

Table 4 MBS item 11512 descriptor, fee and benefit

Item descriptor for MBS item 11512
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; 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
Fee: $67.65 **Benefit**: 75% = $50.75 85% = $57.55
(See para DN.1.20 of explanatory notes to this Category)

MBS = Medicare Benefits Schedule.
Note: Refer to Appendix A for DN.1.20.

During development of the PICO, consideration was given to whether spirometry performed at home with a GP in attendance via telehealth under MBS item 11506 may also be an appropriate comparator. In this scenario the clinical claim would be that spirometry performed at home with a respiratory scientist in continuous attendance via video telehealth results in superior health outcomes compared to spirometry performed at home with a GP in attendance via telehealth. The Assessment Group considered, however, that the two populations are likely to be different. As discussed previously, it was hypothesised that patients primarily under the care of a respiratory physician for their respiratory condition may be more likely to have more complex lung disease and therefore be referred to a respiratory laboratory for spirometry, while those primarily under the care of a GP for their respiratory condition may have less complex lung disease and be more likely to have spirometry performed by their GP.

PASC discussed whether spirometry performed under existing MBS item 11506 would be a suitable comparator for the proposed telehealth service. It was noted that item 11506 is currently claimable for spirometry performed via telehealth and does not stipulate the clinician type able to provide the service.

The discussion focussed on why a new or amended item 11512 is required if item 11506 can already be claimed for telehealth spirometry (see Proposal for public funding). PASC noted that comparative clinical evidence may not be available to support the assessment of an amended item 11512 compared to item 11506. However, given that MBS item 11506 is currently available and relevant to this setting, PASC concluded that MBS item 11506 should be considered as a comparator, if data are available for assessment.

Consideration was also given to whether a second comparator of 'no spirometry' would be appropriate for patients who are not currently being monitored with spirometry but may commence monitoring with the introduction of telehealth due to improved access. Feedback was sought from the applicant on whether there are currently patients who may be in this category. In the applicant's experience with paediatric patients, those who require monitoring with spirometry are undertaking it. The applicant was not able to provide advice in relation to adults. PASC feedback was sought on whether a second comparator of 'no spirometry' should be included. In this scenario, the clinical claim would be that spirometry performed at home with a respiratory scientist in continuous attendance via video telehealth results in superior health outcomes compared to no spirometry.

PASC discussed whether a second comparator of 'no spirometry' may be appropriate for patients who are currently not undertaking spirometry monitoring, but who may commence spirometry monitoring with telehealth due to improved access. In this situation, the clinical claim would be that telehealth spirometry is superior to 'no spirometry'. PASC noted that (i) the applicant confirmed that it is unlikely that 'no spirometry' is relevant for paediatric patients and (ii) it was unclear from discussions with the applicant whether there are adult patients who might fit into this category. PASC further noted that even if 'no spirometry' were accepted as a second comparator, there may not be comparative clinical evidence available to support the claim of superiority of the proposed telehealth service to 'no spirometry'. Therefore PASC concluded that 'no spirometry' was not an appropriate second comparator.

Reference standard

The proposed reference standard is spirometry performed in a respiratory laboratory as per MBS item 11512 (see Table 4).

The proposed reference standard was noted by PASC and no issues were raised.

Outcomes

The applicant claims that portable home spirometry via video telehealth will provide the same information as spirometry performed in a respiratory laboratory. The test accuracy and test reliability outcomes listed in Table 5 have been proposed to assess this claim.

Overall test failure rate captures test failure due to any reason (technical or non-technical), while technical test failure rate captures failures due to technical reasons only (i.e. a technical failure with the equipment or infrastructure). Repeat tests would be due to failed prior tests and may be repeated either at home or in the laboratory depending on the reason for the test failure.

The proposed change in management and health outcomes have been kept necessarily broad due to the diverse patient population and may only need to be assessed if a full linked evidence approach is required (see Assessment Framework)

The cost to deliver the intervention should be considered from both the service provider and patient perspectives, including costs associated with purchasing, maintaining and replacing equipment and infrastructure.

In regard to the clinical need presented by the applicant, patient time and financial burden will be included in the assessment of practicality of the test. Hospital-acquired diseases or infections will be captured as a safety outcome (although it is anticipated that minimal or no evidence will be available for this outcome).

The proposed outcomes were noted by PASC and no issues were raised.

Table 5 Proposed outcomes

Outcome type	Outcome
Test accuracy	Concordance/agreement between in-laboratory and portable home spirometers (e.g. FEV_1 and FVC)
Test reliability	Test quality (using ATS/ERS grading criteria) Overall test failure rate (failure for any reason) Technical test failure rate (technical failure with equipment or infrastructure) Repeat tests (due to failed prior test) Referral for in-laboratory spirometry (following spirometry via telehealth)
Change in management	Change in treatment (e.g. type, dose, medications added or removed) Change in monitoring frequency
Health outcomes	Hospitalisations Mortality Change in disease outcomes
Safety	Direct harms of the test Hospital-acquired diseases or infections Harms of management decisions (only necessary if full linked evidence approach used)
Healthcare resources	Cost to deliver the intervention (service provider, patient out-of-pocket costs) Total Australian Government healthcare costs
Other	Practicality (ease of use and test interpretation, invasiveness, cost, time, patient adherence)

ATS = American Thoracic Society; ERS = European Respiratory Society; FEV_1 = forced expiratory volume in 1 second; FVC = force vital capacity.

Assessment framework

A truncated assessment framework (see Figure 1) is proposed based on the claim of non-inferiority and the nature of the test as a replacement test. The applicant claims that portable home spirometry via telehealth will provide the same information as spirometry performed in a respiratory laboratory. As such, it can be inferred that there would be no difference in management or health outcomes based on whether a patient undergoes portable home spirometry via telehealth or spirometry performed in a respiratory laboratory.

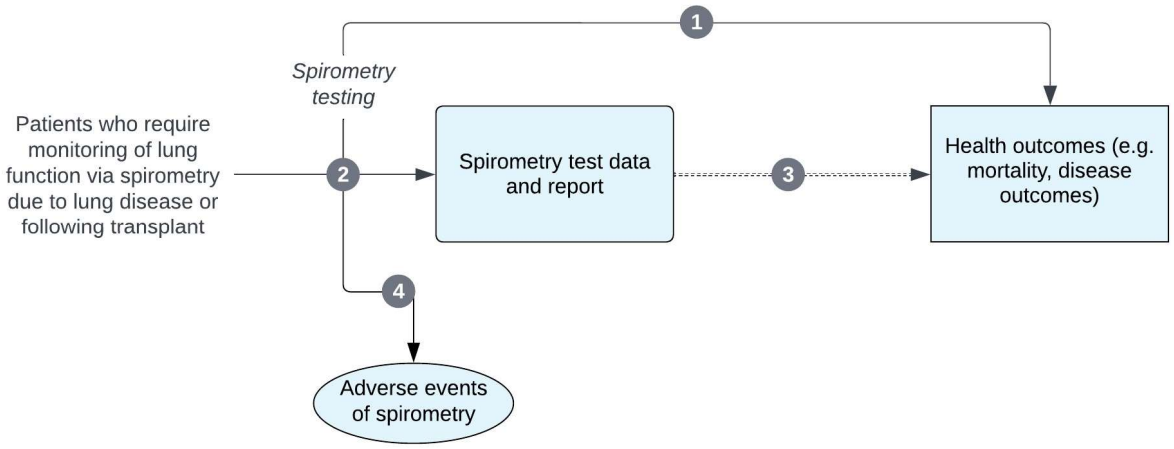

Figure 1 Truncated assessment framework

Figure notes: 1: direct from test to health outcomes evidence; 2: test accuracy; 3: inference of non-inferior health outcomes; 4: adverse events due to testing.

Assessment questions for truncated assessment framework

1. Does the use of portable home spirometry via telehealth for monitoring lung function in patients with chronic lung disease or following transplant result in health outcomes (e.g. mortality, disease outcomes) that are no worse than spirometry performed in a respiratory laboratory?
2. Are the results obtained from portable home spirometry via telehealth for monitoring lung function in patients with chronic lung disease or following transplant concordant with the results obtained from spirometry performed in a respiratory laboratory?
3. Inference that similar test results from both portable home spirometry via telehealth and spirometry performed in a respiratory laboratory will result in the same management decisions, and non-inferior health outcomes.
4. What are the harms of portable home spirometry via telehealth and of spirometry performed in a respiratory laboratory?

If it cannot be demonstrated that portable home spirometry via telehealth provides the same information as spirometry performed in a respiratory laboratory, a full assessment framework may be required (see Figure 2).

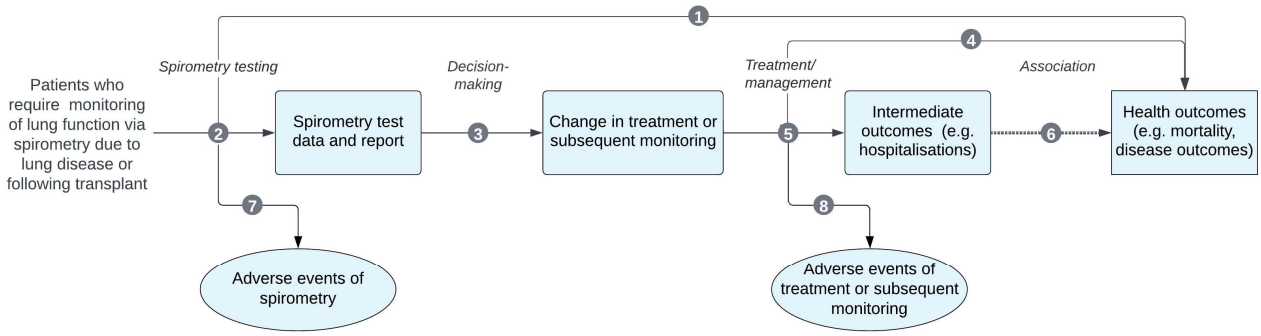

Figure 2 Full assessment framework

Figure notes: 1: direct from test to health outcomes evidence; 2: test accuracy; 3: change in treatment/management; 4: influence of the change in management on health outcomes; 5: influence of the change in management on intermediate outcomes; 6: association of intermediate outcomes with health outcomes; 7: adverse events due to testing; 8: adverse events due to treatment/management.

Assessment questions for full assessment framework

1. Does the use of portable home spirometry via telehealth for monitoring lung function in patients with chronic lung disease or following transplant result in health outcomes (e.g. mortality, disease outcomes) that are no worse than spirometry performed in a respiratory laboratory?
2. Are the results obtained from portable home spirometry via telehealth for monitoring lung function in patients with chronic lung disease or following transplant concordant with the results obtained from spirometry performed in a respiratory laboratory? How does the information from portable home spirometry via telehealth differ from that of spirometry performed in a respiratory laboratory?
3. Does the information from portable home spirometry via telehealth lead to a change in management of the patient that is different compared to the information gained from spirometry performed in a respiratory laboratory?
4. Do the differences in patient management derived from portable home spirometry via telehealth, relative to spirometry performed in a respiratory laboratory, result in non-inferior health outcomes?
5. Do the differences in patient management derived from portable home spirometry via telehealth, relative to spirometry performed in a respiratory laboratory, result in non-inferior intermediate outcomes (e.g. hospitalisations)?
6. Is the observed change in intermediate outcomes associated with a concomitant change in health outcomes, and how strong is the association?
7. What are the harms of portable home spirometry via telehealth and of spirometry performed in a respiratory laboratory?
8. What are the harms associated with the treatments or subsequent monitoring that led from the management decisions informed by portable home spirometry via telehealth and by spirometry performed in a respiratory laboratory?

A scan of the evidence provided by the applicant suggests that there may be limited applicable evidence to support the truncated or full assessment as proposed in the PICO Confirmation. In total seven publications were provided by the applicant, two being conference abstracts.

Of the five published studies, one was a systematic review and meta-analysis that examined the diagnostic accuracy of portable home spirometers in patients with suspected or diagnosed COPD. In all included studies, the portable spirometer operator was a trained technician or a physician or nurse and the spirometry was not performed in a home setting. The review did not report any outcomes proposed in this PICO Confirmation (Zhou et al.).

The remaining four published studies (Doumit et al.; Moor et al.; Dahne et al.; Kruizinga et al.) reported on outcomes relevant to test accuracy and reliability, predominately agreement between in-laboratory and home spirometry. In some studies, applicability concerns relate to test setting (i.e. home spirometry devices tested in a laboratory setting) and supervision/attendance (i.e. home spirometry performed unattended). There are also concerns regarding risk of bias related to methodological limitations in the studies.

Of the two conference abstracts, one provided data on agreement between in-laboratory spirometry devices and portable home spirometry devices; however, both devices were tested in the laboratory setting raising concerns regarding applicability (Kennedy et al.). The second conference abstract examined the impact of technician attendance on home spirometry quality and is therefore not applicable to the proposed PICO due to the incorrect comparator (Long et al.).

A search of the Australian New Zealand Clinical Trials Registry (ANZCTR) and ClinicalTrials.gov was conducted on 10 November 2023 to identify potentially relevant trials in progress. Given the influence of the COVID-19 pandemic on the use of telehealth spirometry, and the time required to conduct clinical trials, it is possible that additional relevant evidence on telehealth spirometry may become available in the near future.

The ANZCTR search identified a highly relevant trial (ACTRN12623000288628) that is being conducted at Royal Prince Alfred Hospital Sydney, Sydney Children's Hospital Randwick, The Children's Hospital at Westmead and The Alfred Hospital Melbourne. The trial will evaluate agreement in spirometry indices between portable personal spirometers and in-laboratory spirometers, as well as ATS/ERS performance grade, in adults and children with a chronic lung disease requiring regular formal spirometry. Both the in-laboratory and portable personal spirometry will be performed during a participant's clinic appointment. This is to ensure that the tests can be conducted within 15 minutes of one another. To replicate the home setting during testing of the portable personal spirometer, the participant will be located in the clinic room and the respiratory scientist will be supervising the test from a different location within the hospital via telehealth. The trial plans to recruit 280 participants and estimates completion of data collection in March 2024. The trial was registered (and last updated) on the ANZCTR in March 2023 and was not recruiting participants at that time.

Two studies were identified from ClinicalTrials.gov that may provide agreement outcomes for in-laboratory versus home spirometry (NCT05219773, NCT05516745). NCT05219773 was reported as currently recruiting participants (accessed 10 November 2023); however, the entry was last updated in February 2022 with an estimated completion date of May 2022. The study was recruiting adults with a diagnosis of asthma or COPD and was being conducted in the United Kingdom. NCT05516745 was reported as currently recruiting participants (accessed 10 November 2023), with a target recruitment of 200 participants and an estimated completion date of March 2025. The study was recruiting males with Duchenne muscular dystrophy aged 7-18 years and was being conducted in Poland.

PASC noted the lack of evidence available to support a HTA using either the truncated or full assessment framework. PASC discussed the limited evidence submitted by the applicant and the trials currently in progress. Two options were proposed; waiting for additional evidence from trials in progress before proceeding to HTA, or the applicant providing additional evidence to support the HTA. The applicant advised that they were involved in the Australian trial currently in progress (ACTRN12623000288628) and expected results to be available in approximately 6 months. The applicant agreed to wait for this evidence to become available before proceeding to HTA.

Clinical management algorithms

The clinical management algorithm showing current practice for spirometry performed under MBS item 11512 is shown in Figure 3. Clinical management under the proposed amendment to item 11512 is shown in Figure 4.

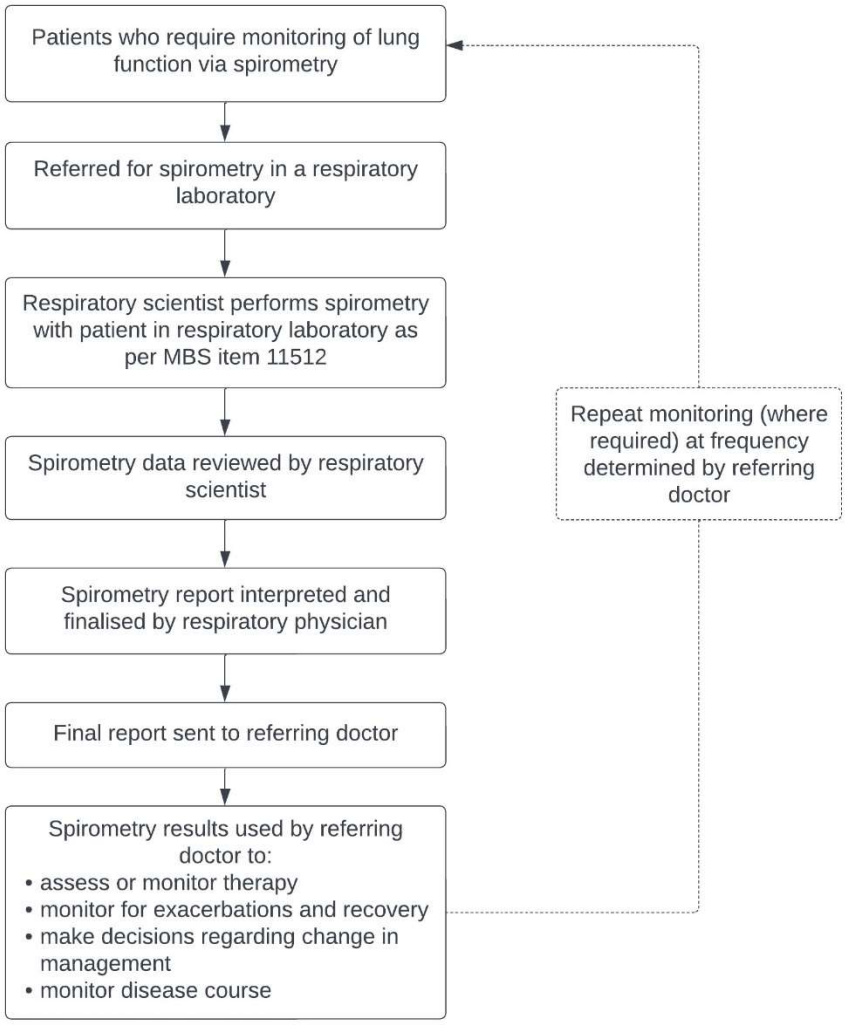

Figure 3 Clinical management algorithm for current practice

Source: adapted from Figure 1 provided by applicant.

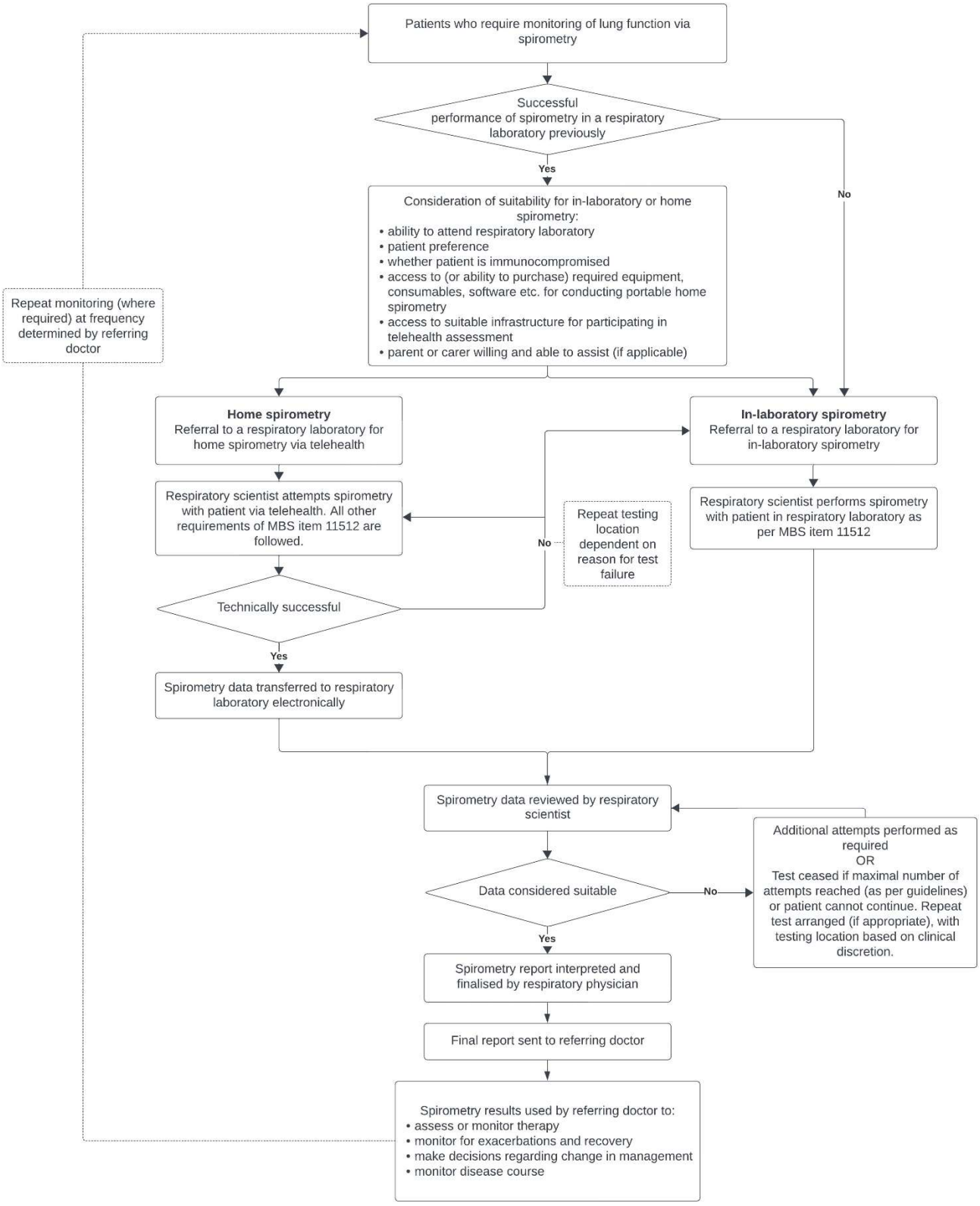

Figure 4 Clinical management algorithm incorporating proposed amendment to MBS item 11512

Source: adapted from Figure 2 provided by applicant.

The clinical management algorithm incorporating the proposed amendment to MBS item 11512 (Figure 4) differs from current management (Figure 3) in the following key ways:

- Patients referred for spirometry for monitoring lung function would be assessed for suitability for home or in-laboratory spirometry and triaged accordingly. Assessment of suitability is likely to occur collaboratively between the referring doctor and the respiratory laboratory. Patients must have successfully performed spirometry in a respiratory laboratory prior to being considered for home spirometry via telehealth.
- Patients referred for home spirometry would complete spirometry at home with a respiratory scientist in continuous attendance via video telehealth, rather than face-to-face in a respiratory laboratory with a respiratory scientist.
- When home spirometry via video telehealth is not successful due to technical issues (with the equipment or infrastructure), patients will be required to repeat spirometry, either in the respiratory laboratory or at home depending on the reason for test failure.
- Data from home spirometry via telehealth will need to be electronically transferred to the respiratory laboratory for review and interpretation.

PASC noted the clinical management algorithms, and no issues were raised.

Proposed economic evaluation

Based on the applicant's clinical claim that the use of portable home spirometry via telehealth results in non-inferior health outcomes compared to spirometry performed in a respiratory laboratory, a cost minimisation analysis (including out-of-pocket costs to the patient) is appropriate.

Table 6 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA = cost-effectiveness analysis; CMA = cost-minimisation analysis; CUA = cost-utility analysis
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis
[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations
[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

It is possible that frequency of monitoring may increase (in line with best practice) with the introduction of telehealth spirometry due to reduced patient burden compared with attending in-laboratory spirometry.

In this scenario, superior health outcomes may be achieved with telehealth spirometry, in which case a cost-effectiveness analysis may be appropriate. It is unlikely that sufficient evidence would be available to support this claim.

While portable home spirometry via telehealth may theoretically have superior safety due to the reduced risk of hospital-acquired diseases or infections, it is unlikely that sufficient evidence will be available to support this claim.

PASC raised no issues with the proposed economic evaluation.

Proposal for public funding

The applicant has requested an amendment to MBS item 11512 to expand the item to include spirometry performed at home using a portable spirometry device with a respiratory scientist in continuous attendance via video telehealth. The proposed amendment is presented in Table 7. The text in grey highlighting is the additional proposed wording and the strikethrough text is the proposed deleted wording. There are no other proposed changes to the item descriptor, fee or explanatory notes.

Table 7 Proposed amendment to MSB item 11512

Category 2 – DIAGNOSTIC PROCEDURES AND INVESTIGATIONS
MBS item 11512 Measurement of spirometry (either face-to-face or via telehealth with video): (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; and (c) that is performed ~~in~~ by 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 (See para DN.1.20 of explanatory notes to this Category)
Fee: $67.65 Benefit: 75% = $50.75 85% = $57.55

DN = diagnostic procedures and investigation note; MBS = Medicare Benefits Schedule.

The applicant has proposed no change to the existing item fee and has indicated that the time required by respiratory laboratory staff and the complexity of testing for telehealth spirometry is at least equivalent to face-to-face testing.

PASC noted that MBS item 11506 could be used for the purpose outlined in the PICO Confirmation and asked the applicant to justify why a new or amended MBS item was required rather than claiming item 11506. The applicant claimed that respiratory scientists are able to obtain technically better spirometry results than spirometry performed in a general practice setting and raised concerns that if the use of MBS item 11506 via telehealth is encouraged for monitoring of lung function, the service provided may not be as high-quality. The applicant explained that MBS item 11512 attracts a higher fee because of the additional

quality requirements associated with this item (attendance by a respiratory scientist and a respiratory physician provides a written report in addition to staff training, supervision and quality assurance). The applicant noted that these same quality requirements would apply to the proposed telehealth spirometry service. The applicant advised that the fee for MBS item 11506 was not appropriate for the proposed service given the expertise and quality assurance involved in the proposed service.

The proposed amendment to MBS item 11512 presented in Table 7, however, would not restrict portable home spirometry via telehealth to use for monitoring purposes. An alternative would be to create a new MBS item (see proposed new item in Table 8). This approach would be advantageous for tailoring the item description as required, adjusting the fee if the telehealth service is not demonstrated to be equivalent to the in-laboratory service, and for monitoring utilisation of the telehealth service.

If the decision is made to amend MBS item 11512, further consideration should be given to:

- how telehealth spirometry will be restricted to use for monitoring purposes (e.g. by further amending the item descriptor)
- whether previous successful performance of spirometry in a respiratory laboratory should be added to the item descriptor as a pre-requisite to undertaking telehealth spirometry
- whether an upper limit to the number of services per patient per annum should be introduced.

Table 8 Proposed new MBS item for spirometry via telehealth for monitoring purposes showing changes from MBS item 11512

Category 2 – DIAGNOSTIC PROCEDURES AND INVESTIGATIONS
MBS item ~~11512~~ XXXXX Measurement of spirometry via telehealth (with video): (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; and (c) that is performed ~~in~~ by 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; and (g) that is performed for the purpose of monitoring lung function; and (h) that is performed in a patient who has successfully completed spirometry in a respiratory laboratory previously each occasion at which one or more such tests are performed to a maximum of 10 services per patient in a 12-month period Not applicable for a service associated with a service to which item 11503 or 11507 applies (See para DN.1.20[a] of explanatory notes to this Category)
Fee: $67.65 Benefit: 75% = $50.75 85% = $57.55

DN = diagnostic procedures and investigation note; MBS = Medicare Benefits Schedule.
[a] DN.1.20 would need to be amended to include the new item number in all locations where item 11512 is mentioned.

It is noted that while the item descriptor for the proposed new item requires the respiratory laboratory to be equipped to perform complex lung function tests, the performance of home spirometry via telehealth using a portable spirometry device may not be considered a complex test. However, it is proposed that this wording is retained to standardise the type of respiratory laboratory eligible to provide this service.

PASC discussed the option of amending the existing MBS item 11512 or alternatively creating a new item for the proposed service. PASC noted the Department's preference for the creation of a new MBS item to enable monitoring of utilisation. The applicant was supportive of this approach and was also keen to monitor uptake. PASC agreed the application should proceed with the creation of a new MBS item rather than amendment to existing item 11512.

PASC considered the proposed item descriptor and agreed to remove the wording regarding patients' specific medical conditions, as noted under the population section. The applicant supported the proposed limit of 10 services per patient per annum for the new item; retaining the reference to a respiratory laboratory equipped to perform complex lung function tests; and the restriction of the item to patients who have successfully completed spirometry in a respiratory laboratory. The applicant proposed that the in-laboratory assessment should have been made within the previous three months.

PASC asked the applicant whether the workforce of respiratory scientists was sufficient to meet demand if the telehealth spirometry service were listed on the MBS. The applicant confirmed that they do not expect an increase in demand for respiratory scientists, as the patients who the item would apply to are already undertaking in-laboratory spirometry. Some of these patients would transition to telehealth spirometry from face-to-face spirometry.

Out-of-pocket costs for patients

According to the Australian Government Medical Costs Finder website (Department of Health and Aged Care n.d.), 42% of patients who received the service relating to MBS item 11512 in a private setting across all of Australia in 2021 – 22 had an out-of-pocket cost. For those patients, the typical out-of-pocket cost for the service was $40. Data by state is summarised in Table 9.

Table 9 Fees and costs for MBS item 11512 in a private setting by state in 2021-22

	NSW	QLD	SA	VIC	WA
Patients with out-of-pocket costs	23%	67%	44%	25%	64%
Typical fee for the service[a]	$100	$90	$105	$115	$100
Amount patients typically paid[a]	$45	$35	$50	$60	$45

NSW = New South Wales; QLD = Queensland; SA = South Australia; VIC = Victoria; WA = Western Australia.
[a] When there was an out-of-pocket cost for the patient.
Source: Australian Government Medical Costs Finder, accessed 17 October 2023.

In addition to the cost of the service, patients having home spirometry via telehealth may incur expenses related to the purchase of the portable home spirometer estimated at approximately $600 - $3,300 (Stark Medical Pty Ltd n.d.; AMA Medical Products n.d.), spirometry consumables, and equipment required to measure other variables as required by the device (e.g. patient's height and weight along with the testing site's temperature and barometric pressure). There will be an initial cost to purchase the equipment and ongoing costs for maintenance, including replacing the spirometer approximately every 5 years based on the service life indicated by the applicant.

It is assumed that patients will have access to equipment required to support the use of the home spirometer (e.g. computer, tablet or mobile device and associated software or App, as applicable to the

device) and equipment and infrastructure required to participate in the telehealth consultation (e.g. device with speakers, microphone, webcam; reliable internet connection).

PASC noted the infrastructure requirements for performing spirometry via telehealth, as well as the out-of-pocket costs for patients. The potential for access and equity issues was raised in relation to patient out-of-pocket costs and digital/technological literacy requirements.

Regarding the cost of the spirometry device, the applicant advised that not all TGA approved spirometers are suitable for home use, and many have additional functions such as oximetry that are not required for spirometry monitoring of lung function. The applicant explained that most laboratories would use app-based (suitable for use with a smartphone) rather than PC-based devices, which tend to be less expensive. The applicant expects a suitable device would cost between $400 and $1,000. Regarding the need for replacement of spirometers, the applicant noted that the replacement cost would vary depending on how often a spirometer is being utilised each year.

Summary of public consultation input

PASC noted and welcomed consultation input from 2 organisations. The 2 organisations that submitted input were:

- Cystic Fibrosis Australia (CFA)
- Lung Foundation Australia (LFA)

The consultation feedback received was all supportive of public funding for the use of portable home spirometry via telehealth. The consultation feedback raised a number of concerns, predominately in relation to education and training for patients and the cost of purchasing and maintaining portable spirometry devices.

Clinical need and public health significance

The main benefits of public funding received in the consultation feedback included easy access to spirometry including for rural and remote areas, minimising infection risk and supporting lifestyle requirements for patients. Cystic Fibrosis Australia (CFA) stated that there is a significant value for families and carers with multiple responsibilities, including families with other children in being able to undertake spirometry in the home. Lung Foundation Australia (LFA) stated that home spirometry may reduce the barrier of access for people in regional or remote areas where access to specialist respiratory services is limited.

The main disadvantages of public funding received in the consultation feedback included out of pocket costs for patients.

Other services identified in the consultation feedback as being needed to be delivered before or after the intervention included sufficient education and training for patients including the maintenance of spirometry equipment.

Indication(s) for the proposed medical service and clinical claim

The consultation feedback agreed with the proposed population, with LFA stating that telehealth spirometry is suitable for people monitoring their lung condition and not diagnosis.

The consultation feedback from CFA agreed with the clinical claim.

Cost information for the proposed medical service

The consultation feedback agreed with the proposed service descriptor, with LFA noting that home spirometry is not suitable for diagnosis.

The consultation feedback raised concerns regarding the high cost of purchasing and maintaining spirometry equipment. CFA agreed with the proposed fee for service and stated that there is already a significant financial burden for people with cystic fibrosis. LFA noted that the high cost of purchasing and maintaining a personal spirometer will be a barrier for some people and may present an equity issue.

PASC noted that consultation feedback was received from Lung Foundation Australia and Cystic Fibrosis Australia. Overall, the responses were supportive of the proposed service with Cystic Fibrosis Australia noting that the proposed service would reduce patient absenteeism from consultations and reduce the need for and hence the risks associated with immunocompromised patients attending hospitals for monitoring, however concerns were raised regarding out-of-pocket costs (upfront and ongoing) to patients and the need to support patients including those with lower technological literacy.

PASC noted the concerns regarding out-of-pocket costs for patients and asked the applicant whether equipment can be hired rather than purchased. The applicant affirmed that equipment can be hired or loaned to patients and gave an example from one hospital in Melbourne, where 200 spirometry devices are available for loan to patients. The spirometers are returned when no longer required (e.g. patient moves interstate). Regarding the burden of consumable costs, the applicant indicated that this would vary depending on who provided the equipment. At home, mouthpieces can be washed and re-used, but need to be replaced in the laboratory setting as patients share the same machine.

Next steps

PASC concluded that there is currently insufficient evidence to proceed to a HTA.

PASC and the applicant agreed to proceed with ratification of the PICO Confirmation but to delay the HTA and review by ESC until additional evidence becomes available (particularly the Australian trial currently in progress [ACTRN12623000288628]).

PASC and the applicant agreed that the application will proceed as the creation of a new MBS item rather than an amendment to the existing MBS item 11512.

PASC noted that there is currently no formal quality assurance process for home spirometry, and that this will need to be addressed.

Applicant Comments on Ratified PICO

In regard to quality assurance for portable home spirometers, patients are able bring their device to face-to-face appointments or attend the laboratory periodically for the laboratory staff to perform a calibration check (verification of calibration) where needed, as per manufacturer's recommendations.

Home spirometers generally cannot be calibrated by the end-users and if they fail to meet verification of calibration they must be returned to the manufacturer for replacement or factory calibration.

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Appendix A MBS spirometry items

There are currently five MBS items for spirometry (see Table 10). All items are in category 2 (Diagnostic procedures and investigations), Group D1 (Miscellaneous Diagnostic Procedures and Investigations), Subgroup 4 (Respiratory). The explanatory notes applicable to the items are presented in Table 11.

Table 10 Summary of MBS spirometry items

Item no. and description	Fee and benefit
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 (See para DN.1.14 of explanatory notes to this Category)	**Fee**: $151.85 **Benefit**: 75% = $113.90 85% = $129.10

Item no. and description	Fee and benefit
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 (See para DN.1.20 of explanatory notes to this Category)	**Fee**: $45.05 **Benefit**: 75% = $33.80 85% = $38.30
11506 Measurement of spirometry, that: (a) involves a permanently recorded tracing, performed before and after inhalation of a bronchodilator; and (b) is performed to: (i) confirm diagnosis of chronic obstructive pulmonary disease (COPD); or (ii) assess acute exacerbations of asthma; or (iii) monitor asthma and COPD; or (iv) assess other causes of obstructive lung disease or the presence of restrictive lung disease; each occasion at which recordings are made (See para DN.1.20 of explanatory notes to this Category)	**Fee**: $22.55 **Benefit**: 75% = $16.95 85% = $19.20
11507 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) fractional exhaled nitric oxide (FeNO) concentration in exhaled breath; if: (c) the measurement is performed: (i) under the supervision of a specialist or consultant physician; and (ii) with continuous attendance by a respiratory scientist; and (iii) in a respiratory laboratory equipped to perform complex lung function tests; and (d) a permanently recorded tracing and written report is provided; and (e) 3 or more spirometry recordings are performed unless difficult to achieve for clinical reasons; each occasion at which one or more such tests are performed Not applicable to a service associated with a service to which item 11503 or 11512 applies (See para DN.1.21 of explanatory notes to this Category)	**Fee**: $109.75 **Benefit**: 75% = $82.35 85% = $93.30

Item no. and description	Fee and benefit
11512 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; 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 (See para DN.1.20 of explanatory notes to this Category)	**Fee**: $67.65 **Benefit**: 75% = $50.75 85% = $57.55

DN = diagnostic procedures and investigation note; MBS = Medicare Benefits Schedule.
Source: MBS Online Medicare Benefits Schedule, accessed 24 October 2023.

Table 11 MBS explanatory notes related to spirometry items

Category 2 - DIAGNOSTIC PROCEDURES AND INVESTIGATIONS
DN.1.14 Respiratory Function Tests - (Item 11503) Specialists and consultant physicians providing services under item 11503 should successfully complete a substantial course of study and training in the relevant test, which has been endorsed by a professional medical organisation. Specialists and consultant physicians should keep appropriate records of this training. Tests should be performed in a respiratory laboratory capable of performing all of, or the majority of the tests listed. Fractional exhaled nitric oxide (FeNO) testing cannot be claimed under item 11503. When laboratory based spirometry (item 11512) is performed on the same day as a test approved under item 11503, then only 11503 must be claimed. When spirometry is the only laboratory test performed then 11512 must be claimed. Maximum inspiratory and expiratory flow-volume loop testing for the purpose of diagnosing central airways obstruction is to be performed under item 11512 not 11503. Item 11503 is not for the purpose of investigation of sleep disorders. Polygraphic data obtained as part of a sleep study item in the range 12203 to 12250 cannot be used for the purpose of claiming item 11503. For the purposes of item 11503, (c) (iii) measurement of airway or pulmonary resistance by any method includes measurement of nasal resistance by rhinomanometry when performed in a respiratory laboratory. Related Items: 11503
DN.1.20 Spirometry (Items 11505, 11506 and 11512) Specialists and consultant physicians providing services under item 11512 should successfully complete a substantial course of study and training in respiratory medicine, which has been endorsed by a professional medical organisation. Specialists and consultant physicians should keep appropriate records of this training. Spirometry services billed to the MBS should meet international quality standards (Eur Respir J 2005; 26: 319–338).

Category 2 - DIAGNOSTIC PROCEDURES AND INVESTIGATIONS
The National Asthma Council's Australian Asthma Handbook (2016) and Lung Foundation Australia's and Thoracic Society of Australia and New Zealand's COPD-X Plan (2016) advise that properly performed spirometry is required to confirm airflow limitation and the diagnosis of asthma and/or COPD. Reversibility testing is the standard required for asthma diagnosis. The diagnosis of COPD is confirmed with post bronchodilator spirometry. Item 11505 should not be repeated when diagnosis has been previously confirmed by properly performed spirometry. To meet quality requirements patients must have three acceptable tests for each testing period (pre/post bronchodilator), and meet repeatability criteria with the best effort recorded. Spirometry should be performed by a person who has undergone training and is qualified to perform it to recommended standards (see Spirometry Handbook, National Asthma Council of Australia (https://www.nationalasthma.org.au/living-with-asthma/resources/health-professionals/information-paper/spirometry-handbook) and ATS/ERS Standardisation of spirometry paper (http://erj.ersjournals.com/content/erj/26/2/319.full.pdf). Related Items: 11505 11506 11512
DN.1.21 Fraction of Exhaled Nitric Oxide (Item 11507) and Cardiopulmonary Exercise Testing (Item 11508) Services billed to item 11507 should meet the following quality standards: • An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FENO) for Clinical Applications: Am J Respir Crit Care Med Vol 184. pp 602–615, 2011 DOI: 10.1164/rccm.912011ST. • ATS/ERS Recommendations for Standardized Procedures for the Online and Offline Measurement of Exhaled Lower Respiratory Nitric Oxide and Nasal Nitric Oxide, 2005: Am J Respir Crit Care Med Vol 171. pp 912–930, 2005 DOI: 10.1164/rccm.200406-710ST Fewer than three traces will be accepted as billable under item 11507 if three reproducible loops are difficult to achieve for clinical reasons. The clinical reason(s) for not achieving three reproducible loops must be documented. Services billed to item 11508 should meet the following quality standards: • Radtke T, Crook S, Kaltsakas G, et al. ERS statement on standardisation of cardiopulmonary exercise testing in chronic lung diseases. Eur Respir Rev 2019; 28: 180101 [https://doi.org/ 10.1183/16000617.0101-2018] • Hallstrand TS, Leuppi JD, Joos G, et al. ERS technical standard on bronchial challenge testing: pathophysiology and methodology of indirect airway challenge testing. Eur Respir J 2018; 52: 1801033 [https://doi.org/10.1183/13993003.01033-2018] For perioperative indications, the test should be conducted according to international guidelines: Perioperative cardiopulmonary exercise testing (CPET): consensus clinical guidelines on indications, organization, conduct, and physiological interpretation for the purpose of preoperative assessment and optimisation for major surgery (published by the Perioperative Exercise and Training Society [POETTS]; British Journal of Anaesthesia, 2018). Specialists and consultant physicians providing services under item 11508 should successfully complete a substantial course of study and training in cardiopulmonary exercise testing, which has been endorsed by a professional medical organisation. Specialists and consultant physicians should keep appropriate records of this training. Related Items: 11507 11508

ATS = American Thoracic Society; COPD = chronic obstructive pulmonary disease; DN = diagnostic procedures and investigation note; ERS = European Respiratory Society; MBS = Medicare Benefits Schedule.
Source: MBS Online Medicare Benefits Schedule, accessed 24 October 2023.

Appendix B Spirometry devices on the ARTG

Table 12 Summary of spirometry devices listed on the ARTG (GMDN code 13680 – Spirometer, diagnostic) as of the 26 September 2023

ARTG ID	Sponsor Name (Manufacturer Name)	Class	Good Name	Product Name	Product Type	Intended Purpose	Suitability for home use REDACTED
405191	Zone Medical Pty Ltd (Safey Medical Devices Private Limited)	Class IIa	Zone Medical Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	Safey Clinic Spirometer shall be used by Healthcare Professionals licensed by law to perform lung function tests of their patients above 5 years of age. This device is intended to be used under Home Healthcare environment and Professional Healthcare Environment. This device should be used under the instructions of a licensed healthcare professional.	**REDACTED**
383496	Stark Medical (MIR Srl - Medical International Research)	Class IIa	Stark Medical - MIR Spirometers with Pulse Oximetry - Spirometer, diagnostic	MIR Spirometers with Pulse Oximetry - Spirometer, diagnostic	Medical device system	Spirometer with optional pulse oximeter is intended to be used by a physician, by a licensed healthcare professional or by a patient. The device is intended to test lung function and can perform spirometry and pulse oximetry tests in adult and paediatric patients, providing a series of parameters relating to human respiratory function.	**REDACTED**
330162	Ecomed Pty Ltd (Vitalograph (Ireland) Limited)	Class IIa	Ecomed Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	To diagnose a patient's lung health and capacity.	**REDACTED**
329202	Bird Healthcare Pty Ltd (Inofab Saglik Teknolojileri Anonim Sirketi)	Class IIa	Bird Healthcare Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	The spirometer is a device intended to measure lung air volume and airflow rate for pulmonary disease diagnosis and screening.	**REDACTED**
319883	Welch Allyn Australia Pty Limited (Medikro Oy)	Class IIa	Welch Allyn Australia Pty Limited – Spirometer Kit - Spirometer, diagnostic	Spirometer Kit - Spirometer, diagnostic	Medical device system	Device that measures lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's previous values. The device is designed for adult and pediatric patients, hospital and clinic use only.	**REDACTED**
308641	Wolfmed Pty Ltd (Geratherm Respiratory GmbH)	Class IIa	Wolfmed Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Medical device system	Is a PC based spirometry system. It is used in pulmonary function testing to determine multiple parameters in spirometry.	**REDACTED**

ARTG ID	Sponsor Name (Manufacturer Name)	Class	Good Name	Product Name	Product Type	Intended Purpose	Suitability for home use REDACTED
300102	Ironbark Creek Investments (VectraCor Inc)	Class IIa	Ironbark Creek Investments - Spirometer, diagnostic	Spirometer, diagnostic	Medical device system	Used to measure and analyse lung function.	**REDACTED**
272599	ACRA Regulatory Services Pty Ltd (NuvoAir AB)	Class IIa	ACRA Regulatory Services Pty Ltd – Spirometer, diagnostic	Spirometer, diagnostic	Procedure Pack	A portable spirometer consisting of three parts – a phone app, detector and disposable turbine mouth piece, intended to be used for monitoring lung function capability by measuring the maximal volume (FVC) and flow of air (FEV1) for the detection, assessment and monitoring of certain lung diseases. The spirometer is used to support the diagnosis of respiratory lung diseases when all function results are verified by a lung specialist before any diagnosis or medical treatment is considered or initiated.	**REDACTED**
242233	MGC Diagnostics Australia Pty Ltd (Medchip Solutions Ltd)	Class IIa	MGC Diagnostics Australia Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	This device is intended to be used by adults and children in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing. The results can be streamed to smartphones, tablets, and computer systems.	**REDACTED**
151991	Point Of Care Diagnostics Australia Pty Ltd (Sibel SA)	Class IIa	Point Of Care Diagnostics Australia Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	The Datospir Mirco is a handheld spirometer for the diagnosis and monitoring of respiratory conditions.	**REDACTED**
142918	Innervate Pty Ltd (NDD Medizintechnik AG)	Class IIa	Innervate Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	A device that measures lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's former values.	**REDACTED**
406037	YES Medical (JNBio Co Ltd)	Class IIa	YES Medical - Spiro Lenis, Model SL503 - Spirometer, diagnostic	Spiro Lenis, Model SL503 - Spirometer, diagnostic	Medical device system	The SL503 spirometer measures and calculates various respiratory function parameters. It is intended for use on patients of any age excluding babies and infants. The mouth piece is disposable and invasive via the mouth.	**REDACTED**

ARTG ID	Sponsor Name (Manufacturer Name)	Class	Good Name	Product Name	Product Type	Intended Purpose	Suitability for home use REDACTED
387682	Emergo Asia Pacific Pty Ltd T/a Emergo Australia (Healthup SA)	Class IIa	Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	The spirometer with pulse oximeter is intended to test and measure lung function in people of all ages excluding neonates and infants and oxygen saturation levels in people of all ages. The spirometer is intended for use by or under the supervision of healthcare professionals as well as for home use by patient.	**REDACTED**
380358	Sonic Equipment Australia Pty Ltd (FIM Medical)	Class IIa	Sonic Equipment Australia Pty Ltd - Spirolyser Q13 - Spirometer, diagnostic	Spirolyser Q13 - Spirometer, diagnostic	Medical device system	The Spirolyser Q13 consists of a hand-piece (into which the QFlow sensor fits), cable (to connect hand-piece to PC/Laptop) and software for the PC/Laptop. The patient blows though the sensor and the readings are displayed and recorded via the software on the PC/Laptop. the Spirolyser test for the following: Slow Vital Capacity, Forced Vital Capacity, Post-medication, Maximal Voluntary Ventilation (MVV)	**REDACTED**
374101	Genesis Biotech Pty Ltd (Contec Medical Systems Co Ltd)	Class IIa	Genesis Biotech Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	The SPIROMETER is a hand-held medical device for checking lung conditions, adopts the infrared signal acquisition mode for measuring items related to FVC, applicable for use in hospitals, clinics, and for routine test.	**REDACTED**
336916	Bydand Trading Pty Ltd T/A Bydand Medical (Medchip Solutions Ltd)	Class IIa	Bydand Trading Pty Ltd T/A Bydand Medical - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	This is a device that is intended to be used to provide spirometry measurements (provides information about a patient's pulmonary function) for diagnosis and management of asthma and chronic obstructive pulmonary disease (COPD). It is for use within a medical clinics, hospitals, and any location where an examination is to take place.	**REDACTED**
332722	Propus Technologies Pty Ltd (PulmOne Advanced Medical Devices Ltd)	Class IIa	Propus Technologies Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	The PumlOne MiniBox+ is intended to measure lung function in adult and pediatric patients, 5 years and older, while at rest (including spirometry, lung volumes, and diffusing capacity. The PulmOne MiniBox+ is to be used by a physician respiratory therapist, or technician in a hospital or clinic setting.	**REDACTED**

ARTG ID	Sponsor Name (Manufacturer Name)	Class	Good Name	Product Name	Product Type	Intended Purpose	Suitability for home use REDACTED
301668	Dalmedi Technologies Pty Ltd (Beijing M&B Electronic Instruments Co Ltd)	Class IIa	Dalmedi Technologies Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	Intended for monitoring peak expired flow rate (PEF) and forced expiratory volume in one second (FEV1).	**REDACTED**
299440	Intermed Medical Pty Ltd (Schiller AG)	Class IIa	Intermed Medical Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	This is a device that is intended to be used to measure lung air volume and airflow rate for pulmonary disease diagnosis and screening. The flow/volume measurement, in- and expiratory vital capacity, partial volumes, second-volume FEV1, maximum voluntary ventilation MVV, peak-flow and more than 40 sub-parameters. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's former values.	**REDACTED**
291176	Uscom Ltd (Thor Laboratories Kft)	Class IIa	Uscom Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	SpiroSonic devices are spirometers that measure a series of parameters relating to human respiratory function. The product is therefore intended for use by a doctor or by a nurse practitioner under the supervision of a doctor.	**REDACTED**
261557	Bird Healthcare Pty Ltd (Medikro Oy)	Class IIa	Bird Healthcare Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Medical device system	The spirometer is a device intended to measure lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's previous values.	**REDACTED**
260028	Philips Electronics Australia Ltd (Philips Medizin systeme Boblingen GmbH)	Class IIb	Philips Electronics Australia Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	The Spirometry module is designed for use with adult, pediatric, and neonatal ventilated patients in range of critical care environments. The module is designed to work with the Philips patient monitors in combination with Philips-branded airway flow sensors and combined CO2/airway flow sensors.It produces real-time waves for flow, volume and pressure of respiratory gases together with numeric for analysis of ventilatory mechanics. The measurement also provides pressure-volume loops, flow-volume loops and pressure-flow loops.	**REDACTED**
184037	MGC Diagnostics Australia Pty Ltd (eResearch Technology GmbH)	Class IIa	MGC Diagnostics Australia Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	A device that measures lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's former values.	**REDACTED**

ARTG ID	Sponsor Name (Manufacturer Name)	Class	Good Name	Product Name	Product Type	Intended Purpose	Suitability for home use REDACTED
181838	Cosmed Asia-Pacific (Cosmed SRL)	Class IIa	Cosmed Asia-Pacific - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	Used to perform pulmonary function tests, by formulating a lung pathology diagnosis, assisting with human physiology studies and contributing to sports medicine applications.	**REDACTED**
176078	GE Healthcare Australia Pty Ltd (NDD Medizintechnik AG)	Class IIa	GE Healthcare Australia Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	This device is intended to provide calibration-free spirometry testing and to measure lung air volume and airflow rate independently of gas composition pressure, temperature and humidity.	**REDACTED**
169380	PulmonX Australia Pty Ltd (Pulmonx Corporation)	Class IIa	PulmonX Australia Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	The console is to be used with the Chartis catheter during a diagnostic bronchoscopy in adult patients with chronic obstructive pulmonary disease and emphysema. The system is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments.	**REDACTED**
156950	Vyaire Medical Pty Ltd (Vyaire Medical GmbH)	Class IIa	Vyaire Medical Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Medical device system	These devices measure lung air volume, airflow rate, spirometry, maximal voluntary ventilation and bronchial responses for pulmonary disease diagnosis and general screening. The various challenge tests can be performed on adults and children. The system consists of (but not limited to), mouthpiece, hose, nose clips, filters and cables.	**REDACTED**
150368	MGC Diagnostics Australia Pty Ltd (MediSoft SA)	Class IIa	MGC Diagnostics Australia Pty Ltd - Spirometer, diagnostic	Spirometer, diagnostic	Single Device Product	A device intended to measure lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's former values.	**REDACTED**

CO_2 = carbon dioxide; FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity.
Source: Australian Register of Therapeutic Goods Search Visualisation Tool (accessed 26 September 2023, filtered by GMDN code 13680).