Medicare Benefits Schedule Review Taskforce

Report from the Thoracic Medicine Clinical Committee

August 2016

Important note

The views and recommendations in this review report from the clinical committee have been released for the purpose of seeking the views of stakeholders.

This report does not constitute the final position on these items which is subject to:

- stakeholder feedback;

then

- Consideration by the MBS Review Taskforce;

then *if endorsed*

- Consideration by the Minister for Health; and
- Government.

Stakeholders should provide comment on the recommendations via the online consultation tool.

Confidentiality of comments:

If you want your feedback to remain confidential please mark it as such. It is important to be aware that confidential feedback may still be subject to access under freedom of information law.

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1. Executive Summary

The Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) is undertaking a program of work that considers how more than 5,700 items on the MBS can be aligned with contemporary clinical evidence and practice and improves health outcomes for patients. The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.

The Taskforce is committed to providing recommendations to the Minister that will allow the MBS to deliver on each of these four key goals:

- Affordable and universal access
- Best practice health services
- Value for the individual patient
- Value for the health system.

The Taskforce has endorsed a methodology whereby the necessary clinical review of MBS items is undertaken by Clinical Committees and Working Groups. The Taskforce has asked the Clinical Committees to undertake the following tasks:

1. Consider whether there are MBS items that are obsolete and should be removed from the MBS.
2. Consider identified priority reviews of selected MBS services.
3. Develop a program of work to consider the balance of MBS services within its remit and items assigned to the Committee.
4. Advise the Taskforce on relevant general MBS issues identified by the Committee in the course of its deliberations.

The recommendations from the Clinical Committees are released for stakeholder consultation. The Clinical Committees will consider feedback from stakeholders and then provide recommendations to the Taskforce in a Review Report. The Taskforce will consider the Review Report from Clinical Committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

The Thoracic Medicine Clinical Committee (the Committee) was established in 2015 to undertake a review of relevant MBS items. This review relied upon the clinical expertise of the members who sought advice from colleagues as necessary, as well as independent, targeted rapid evidence reviews of certain services.

The Taskforce identified two priorities for the Committee – lung function tests and diagnostic sleep studies.

1.1 Areas of responsibility of the Thoracic Medicine Clinical Committee

The Taskforce identified 19 MBS items for review by the Committee.

Δ Respiratory function tests (5 items)

11500 Bronchospirometry

11503 Complex Lung Function Tests

11506 Office based Spirometry

11509 Spirometry in a respiratory laboratory

11512 Spirometry in a respiratory laboratory

Δ Sleep studies (7 items)

12203 Adult sleep study in a laboratory

12250 Adult sleep study, unattended

12207 Adult sleep study in a laboratory (4th study)

12210 Paediatric sleep study in a laboratory (Aged 0-12)

12213 Paediatric sleep study in a laboratory (Aged 12-18)

12215 Paediatric sleep study in a laboratory (Aged 0-12, 4th study)

12217 Paediatric sleep study in a laboratory (Aged 12-18, 4th study)

Δ Therapeutic procedures—biopsy of lung cancers (2 items)

30696 Endoscopic Ultrasound Guided Fine Needle Aspiration Biopsy(s)

30710 Endobronchial Ultrasound Guided Biopsy(s)

Δ Therapeutic procedures—bronchus or trachea (5 items)

41889 Bronchoscopy

41892 Bronchoscopy with Endobronchial biopsies or diagnostic/therapeutic procedures

41895 Bronchus, removal of foreign body

41898 Fibreoptic Bronchoscopy

41905 Trachea or Bronchus, dilatation of stricture and endoscopic insertion of stent

A full description of all items is at Appendix A.

1.2 Key recommendations

The Committee recommended amendments in the following areas:

Recommendation 1: Spirometry

The Committee recommends:

- Changes to the item descriptor for item 11506 (office-based reversibility testing) to better target its use to diagnose asthma and chronic obstructive pulmonary disease (COPD). It is recommended that the item be available once a year and that the fee and rebate be doubled to $40 to encourage use in primary care.
- Introduction of a new item for pre or post bronchodilator spirometry to be used to confirm diagnosis of COPD, assess acute asthma episodes and monitor patients with asthma, COPD and other cause of airflow limitation. The recommended fee of $20 is the same as current item 11506.
- Subsume item 11509 (laboratory based spirometry) into current item 11512 (more complex laboratory based spirometry).
- Introduce enhanced quality requirements for all spirometry items.

Further detail is at section 4.

Recommendation 2: Other Respiratory Function Tests

The Committee has revised the list of respiratory function tests that are able to be claimed under item 11503. It suggests that the list represents those tests that are necessary in contemporary practice. It does not include some niche tests used in research settings. The Committee recommends that the list be included in the item descriptor to remove any discretion about what tests are claimable. The tests are:

(a) Absolute lung volumes by any method.

(b) Carbon monoxide diffusing capacity by any method.

(c) Measurement of airway or pulmonary resistance by any method.

(d) Inhalation provocation testing, including pre-provocation spirometry, the construction of a dose response curve, using recognised direct or indirect bronchoprovocation agent and post-bronchodilator spirometry.

(e) Provocation testing involving sequential measurement of lung function at baseline and after exposure to specific sensitising agents, including drugs, or occupational asthma triggers.

(f) 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.

(g) Measurement of the strength of inspiratory and expiratory muscles at multiple lung volumes.

(h) 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.

(i) Six minute walk test for the purpose of determining eligibility for medications subsidised under the Pharmaceutical Benefits Scheme or eligibility for the provision of portable oxygen.

The Committee has also recommended that the claiming rules make clear the following:

1. Laboratory based spirometry is not a test that can be claimed under 11503
2. Laboratory based spirometry cannot be separately claimed on the same day as 11503
3. Respiratory function tests under 11503 cannot be claimed on the same day as sleep studies
4. Flow volume loop testing for central airways obstruction should be claimed under 11512.

The Committee recommends two new items:

- Laboratory based spirometry with FeNO with a MBS fee set between the current fee for 11512 and 11503.
- Cardio pulmonary exercise testing (CPET) in defined clinical circumstances with a fee of approximately $300.

Further detail is at section 5.

Recommendation 3: Sleep Studies

The Committee recommended a number of changes to adult attended and unattended sleep studies which aim to better identify patients who are suitable for direct GP referral; better triage patients to the most suitable testing; and better describe the circumstance when repeat testing following a diagnostic test may have clinical value. These recommendations are:

- GP referral without need for pre-test specialist attendance for patients who have a high pre-test probability for moderate to severe obstructive sleep apnoea (OSA) using validated assessment tools.
- Referral to testing for a wider range of sleep disorders than currently permitted when the patient has been assessed by a respiratory or sleep specialist.
- Better triage of patients to the most suitable test, noting that patients who have high pre-test probability for uncomplicated OSA are generally suitable for unattended sleep studies.
- Better use of follow up studies with closer involvement of sleep physicians in determining the need for follow up testing.
- Addition of new items to the MBS for APAP titration and vigilance testing following MSAC appraisal. The Committee recommends that these new services should be considered once the impact of the other proposed changes to sleep study items can be assessed.

Further detail is at section 6.

Recommendation 4: Diagnostic and therapeutic procedures – lung, trachea and bronchus

The Committee recommends that no changes be made to the items relating to diagnostic and therapeutic procedures for lung, trachea and bronchus 30696, 30710, 41889, 41892, 41893, 41898 and 41905.

Further detail is at section 7.

Recommendation 5: Obsolete items

The Committee recommended that the following items be removed from the MBS:

- **11500** – Bronchospirometry, including gas analysis
- **11509** – Measurement of respiratory function involving a permanently recorded tracing and written report performed before and after inhalation of a bronchodilator

Following public consultation, the MBS Reviews Taskforce has endorsed the recommendation to remove item 11500.

The Committee suggests that Item 11509 should be subsumed into item 11512, which also provides for spirometry performed in a respiratory laboratory. Further detail is at section 8.

Recommendation 6: Generic issues identified by the Committee

The Committee identified a number of issues which were not specific to Thoracic Medicine. These issues relate to low value care; services being undertaken out of Australia and undertaking a review of recommended changes. These issues are being considered by the Taskforce. Further detail is at section 9.

1.3 Consumer engagement

The Committee undertook one of the first clinical reviews. Committee members include health professionals and a consumer representative. The Committee found that many MBS items for thoracic medicine work well and do not require any change. However, some items for people with breathing problems like asthma, emphysema and sleep apnoea (stopping breathing when you are asleep) do require some changes.

The Committee believes it is important to find out from consumers if they will be helped or disadvantaged by the recommendations – and how, and why. Following the public consultation, the Committee will assess the advice from consumers and decide whether any changes are needed to the recommendations. The Committee will then send the recommendations to the MBS Taskforce. The Taskforce will consider the recommendations as well as the information provided by consumers in order to make sure that all the important concerns are addressed. The Taskforce will then provide the recommendations to government.

2. About the Medicare Benefits Schedule (MBS) Review

2.1 Medicare and the MBS

What is Medicare?

Medicare is Australia's universal health scheme which enables all citizens (and some overseas visitors) to have access to a wide range of health services and medicines at little or no cost.

Introduced in 1984, Medicare has three components, being free public hospital services for public patients, subsidised drugs covered by the Pharmaceutical Benefits Scheme, and subsidised health professional services listed on the Medicare Benefits Schedule (MBS).

What is the Medicare Benefits Schedule (MBS)?

The Medicare Benefits Schedule (MBS) is a listing of the health professional services subsidised by the Australian government. There are over 5,700 MBS items which provide benefits to patients for a comprehensive range of services including consultations, diagnostic tests and operations.

2.2 What is the MBS Review Taskforce?

The government has established a Medicare Review Taskforce to review all of the 5,700 MBS items to ensure they are aligned with contemporary clinical evidence and practice and improve health outcomes for patients.

What are the goals of the Taskforce?

The Taskforce is committed to providing recommendations to the Minister that will allow the MBS to deliver on each of these four key goals:

- **Affordable and universal access**— the evidence demonstrates that the MBS supports very good access to primary care services for most Australians, particularly in urban Australia. However, despite increases in the specialist workforce over the last decade, access to many specialist services remains problematic with some rural patients being particularly under-serviced.
- **Best practice health services**— one of the core objectives of the Review is to modernise the MBS, ensuring that individual items and their descriptors are consistent with contemporary best practice and the evidence base where possible. Although the Medical Services Advisory Committee (MSAC) plays a crucial role in thoroughly evaluating new services, the vast majority of existing MBS items pre-dates this process and has never been reviewed.
- **Value for the individual patient**—another core objective of the Review is to have a MBS that supports the delivery of services that are appropriate to the patient's needs, provide real clinical value and do not expose the patient to unnecessary risk or expense.
- **Value for the health system**—achieving the above elements of the vision will go a long way to achieving improved value for the health system overall. Reducing the volume of services that provide little or no clinical benefit will enable resources to be redirected to new and existing services that have proven benefit and are underused, particularly for patients who cannot readily access those services currently.

2.3 Methods: The Taskforce's approach

The Taskforce is reviewing the existing MBS items, with a primary focus on ensuring that individual items and usage meet the definition of best practice.

Within the Taskforce's brief there is considerable scope to review and advise on all aspects which would contribute to a modern, transparent and responsive system. This includes not only making recommendations about new items or services being added to the MBS, but also about a MBS structure that could better accommodate changing health service models.

The Taskforce has made a conscious decision to be ambitious in its approach and seize this unique opportunity to recommend changes to modernise the MBS on all levels, from the clinical detail of individual items, to administrative rules and mechanisms, to structural, whole-of-MBS issues.

The Taskforce will also develop a mechanism for the ongoing review of the MBS once the current Review is concluded.

As the Review is to be clinician-led, the Taskforce has decided that the detailed review of MBS items should be done by Clinical Committees. The Committees are broad based in their membership and members have been appointed in their individual capacity, not as representatives of any organisation. This draft report details the work done by the specific Clinical Committee and describes the Committee's recommendations and their rationale.

This report does not represent the final position of the Clinical Committee. A consultation process will inform recommendations of the Committee and assist it in finalising its report to the MBS review Taskforce.

Following consultation, the Clinical Committee will provide its final advice to the MBS Review Taskforce. The Taskforce will consider the Review Report from Clinical Committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

2.4 Prioritisation process

All MBS items will be reviewed during the course of the MBS Review. However, given the breadth of and timeframe for the Review, each Clinical Committee has needed to develop a work plan and assign priorities keeping in mind the objectives of the Review. With a focus on improving the clinical value of MBS services, the Clinical Committees have taken account of factors including the volume of services, service patterns and growth and variation in the per capita use of services, to prioritise their work. In addition to MBS data, important resources for the Taskforce and the Clinical Committees have included:

- The Choosing Wisely recommendations, both from Australian and internationally
- National Institute for Health and Care Excellence (NICE UK) Do Not Do recommendations and clinical guidance
- Other literature on low value care, including Elshaug et al's[1] Medical Journal of Australia article on potentially low value health services

- The Australian Commission on Safety and Quality in Health Care's (ACSQSHC) Atlas of Healthcare Variation.

3. About the Thoracic Medicine Committee

The Committee was established to make recommendations to the MBS Review Taskforce on the review of MBS items within its remit, based on rapid evidence review and clinical expertise.

3.1 Thoracic Medicine Clinical Committee members

Table 1: Thoracic Medicine Clinical Committee members

Name	Position/Organisation	Declared conflict of interest
Professor Christine Jenkins (Chair)	Senior Staff Specialist, Thoracic Medicine, Concord Hospital; Head of Respiratory Trials, The George Institute; Clinical Professor & Head of Respiratory Discipline, University of Sydney	Provider of MBS services
Professor Nick Antic	Clinical Director, Adelaide Institute for Sleep Health Staff Specialist, Sleep and Respiratory Medicine, Repatriation General Hospital and Flinders Medical Centre	Provider of MBS services
Dr Phillip Antippa	Director, Lung Cancer Services, Royal Melbourne Hospital	Provider of MBS services
Dr Maree Barnes	Institute for Breathing and Sleep, Austin Hospital President, Australasian Sleep Association	Provider of MBS services
Dr Chris Dalton	National Medical Director, Bupa Australia and New Zealand. Ear, Nose and Throat Surgeon, Private practice	Provider of MBS services
Associate Professor Garun Hamilton	Respiratory and Sleep Medicine Physician, Monash Health Adjunct Professor, School of Clinical Sciences, Monash University	Provider of MBS services
Associate Professor Craig Hukins	Director, Department of Respiratory and Sleep Medicine, Princess Alexandra Hospital	Provider of MBS services
Dr Kerry Hancock	General Practitioner, private practice, Executive Member Coordinating Committee COPD National Programme, Lung Foundation Australia. Member, GP Asthma Group, National Asthma Council, Board Member, Asthma Foundation SA	Provider of MBS services
Professor Matthew Peters	Head of Respiratory Medicine, Concord Hospital Professor of Respiratory Medicine, Faculty of Medicine and Health Sciences, Macquarie University	Provider of MBS services
Associate Professor Hiran Selvadurai	Head, Department of Respiratory Medicine, The Children's Hospital, Westmead, Sydney Children's Hospital Network	Provider of MBS services

Name	Position/Organisation	Declared conflict of interest
Dr Ronald Tomlins	Adjunct Associate Professor, Discipline of General Practice, University of Sydney, General Practitioner, Private Practice. President, International Primary Care Respiratory Group	Provider of MBS services
Ms Debra Kay	Consumer Representative	None

3.2 Paediatric Thoracic Working Group members

Table 2: Paediatric Thoracic Working Group members

Name	Position/Organisation	Declared conflict of interest
Associate Professor Hiran Selvadurai (Chair)	Head, Department of Respiratory Medicine, The Children's Hospital, Westmead, Sydney Children's Hospital Network	Provider of MBS services
Dr Chris Dalton	National Medical Director, Bupa Australia and New Zealand. Ear, Nose and Throat Surgeon, Private practice	Provider of MBS services
Associate Professor Gillian Nixon	Paediatric Respiratory and Sleep Physician, Monash Children's Hospital and Department of Paediatrics, Monash University	Provider of MBS services
Dr Sadasivam Suresh	Consultant Respiratory and Sleep Paediatrician, Lady Cilento Children's Hospital and Queensland Children's Lung & Sleep Specialists	Provider of MBS services

3.3 Conflicts of interest

All members of the Taskforce, Clinical Committees and Working Groups are asked to declare any conflicts of interest at the start of their involvement and reminded to update their declarations periodically.

4. Respiratory Function Tests – Spirometry

Three spirometry items are considered in this section:

- **11506** – Office based spirometry
- **11509** – Spirometry in a respiratory laboratory
- **11512** – Spirometry in a respiratory laboratory

4.1 Priority review of respiratory function tests

Respiratory function tests were identified by the Taskforce for priority review, based on concern expressed internationally about the clinical value of spirometry.

These sources included:

- Choosing Wisely
- National Institute for Health and Care Excellence (NICE UK)
- Elshaug et al's[1] Medical Journal of Australia article on potentially low value health services.

The Choosing Wisely and Elshaug et al[1] recommendations relate to the use of spirometry for COPD. These sources suggest that performing spirometry during a COPD exacerbation is of little value and although it is indicated to monitor disease progression, optimal intervals have not been established and clinical judgment should be used. In regard to using spirometry for COPD screening it is not recommended that respiratory spirometry be used for large population screening for COPD, but that it be focused through a case finding approach on those most likely to be at risk.

The National Institute for Health and Care Excellence (NICE) has published clinical guidance on the use of spirometry in relation to COPD, but also more broadly about use in general practice[2].

At its first meeting the Committee confirmed that these items should undergo a detailed review because of concerns about appropriate use (underuse), particularly in primary care.

MBS context

There are three MBS items for spirometry, items 11506, 11509 and 11512. The Committee suggests that item 11509 is redundant – this is discussed in more detail in section 8. Items 11506 and 11512 have similar requirements with both providing for pre and post bronchodilator spirometry. Item 11506 is an office based test and the higher rebated 11512, is a study performed in a respiratory laboratory, under the supervision of a respiratory specialist and requires a written report. These items have been MBS listed and unchanged since at least 1991 (noting that all existing MBS items were renumbered in 1991 – therefore this is the date stored as the item/descriptor start date in the database, however a large proportion of these items have been on the MBS for a long period before this date).

Item 11506 is used principally in primary care with 80 per cent of services in 2014-15 being provided by GPs. Conversely, item 11512 is almost exclusively provided by specialist respiratory physicians.

The item descriptors for items 11506 and 11512 are set in Appendix A and relevant MBS data in Appendix D.

It should be noted that less complex spirometry (pre or post bronchodilator spirometry or spirometry performed without reference to bronchodilation) does not currently have a MBS item. Many less complex tests and procedures do not attract specific MBS items and are covered under the accompanying consultation, however spirometry is a complex test even when performed before or after bronchodilator. The volume of less complex office-based spirometry is unknown.

MBS data relating to item 11506

Table 3: High level MBS data on spirometry item 11509, 2014-15 (date of processing)

Statistic	Amount
Schedule fee	$20.55
Total benefits paid 2014-15	$5,372,888
Number of services 2014-15	270,258
% of services provided out-of-hospital 2014-15	99.80%
Bulk-billing rate for out-of-hospital services 2014-15	83.90%
Total patient count 2014-15	231,878
Total provider count 2014-15	18,358
Benefits change (%) from 2009-10 to 2014-15	37.00%
Service change (%) from 2009-10 to 2014-15	14.40%

Unpublished data (Department of Health)

Table 4: Number of services by jurisdiction, item 11506, 2014-15

Jurisdiction	Estimated residential population*	Number of Services	Service rate per 1,000
NSW	7,565,497	109,903	14.5
VIC	5,886,436	29,228	5.0
QLD	4,750,513	78,751	16.6
SA	1,691,503	17,226	10.2
WA	2,581,250	25,436	9.9
TAS	515,235	6,559	12.7
NT	244,265	1,199	4.9
ACT	387,640	1,934	5.0
AUSTRALIA	23,625,561	270,258	11.4

* Estimated residential population at December 2014 (ABS). Note that NSW and QLD have a service rate greater than 1 standard deviation from the mean, and NT and ACT have a service rate of less than 1 standard deviation. Unpublished data (Department of Health).

MBS data relating to item 11512

Table 5: High level MBS data on spirometry item 11512, 2014-15 (date of processing)

Statistic	Amount
Schedule fee	$61.75
Total benefits paid 2014-15	$4,381,468
Number of services 2014-15	82,705
% of services provided out-of-hospital 2014-15	95.50%
Bulk-billing rate for out-of-hospital services 2014-15	72.60%
Total patient count 2014-15	57,659
Total provider count 2014-15	467
Benefits change (%) from 2009-10 to 2014-15	26.80%
Service change (%) from 2009-10 to 2014-15	18.60%

Unpublished data (Department of Health)

Table 6: Number of services by jurisdiction, item 11512, 2014-15

Jurisdiction	Estimated residential population *	Number of Services	Service rate per 1,000
NSW	7,565,497	24,741	3.3
VIC	5,886,436	23,161	3.9
QLD	4,750,513	18,246	3.8
SA	1,691,503	3,301	2.0
WA	2,581,250	11,586	4.5
TAS	515,235	1,045	2.0
NT	244,265	83	0.3
ACT	387,640	535	1.4
AUSTRALIA	23,625,561	82,705	3.5

* Estimated residential population at December 2014 (ABS). Note that WA has a service rate greater than 1 standard deviation from the mean, and NT has a service rate of less than 1 standard deviation. Unpublished data (Department of Health).

Issues identified by the Committee – Spirometry

Underuse of spirometry in primary care

In Australia and internationally it is accepted that well performed spirometry is underused in primary care. Pre and post bronchodilator spirometry ("reversibility testing") has an important role in confirming the diagnosis of asthma, COPD and other causes of airflow limitation. Underuse of testing means that these conditions are both under and over diagnosed and as a consequence, patients are under and over medicated. Both situations generate avoidable healthcare costs.

In primary care, spirometry may be performed by the GP or a practice nurse. A number of studies have identified barriers to the uptake of testing including lack of training, lack of confidence in interpreting results, interruption to workflows, beliefs that other clinical assessment is preferred and lack of remuneration.[3] Ownership of spirometers in Australian general practice is high,[4] but performance is low relative to the prevalence of obstructive lung disease and other diseases (such as restrictive lung diseases) for which this test is clinically indicated.

Item 11506 covers office based reversibility testing and is the only MBS item available for spirometry that is performed outside of a respiratory laboratory. In 2014-15, there were 270,258 services provided to 231,878 patients (Table 3). Over 90 percent of these services were provided by GPs, with respiratory physicians providing most of the remaining services. For the year 2014-15, the average number of services for each GP who performed spirometry was 11 over 12 months. For specialists the average was 75. Relatively few patients have repeat testing with approximately 20 percent of patients having more than one service over a five-year period. Although the MBS data do not disclose the overall volume of office based spirometry these data are consistent with the expressed concern internationally that spirometry is underused.

To address the problem of underuse of spirometry particularly in primary care settings and for the purpose of better diagnosing and managing asthma and COPD, the Committee has proposed:

1. The MBS fee and rebate for reversibility testing (item 11506) should be increased.
2. An item for less complex spirometry (pre or post bronchodilator) should be introduced.
3. The MBS item for laboratory based spirometry be retained.
4. A new item for a laboratory based spirometry plus FeNO be introduced.

To enable better consideration of these proposals, the Committee commissioned a rapid evidence review.

Rapid Evidence Review: Questions and summary of report findings

The rapid evidence review was undertaken by HealthConsult Pty Ltd. The evidence review was restricted to Level 1 evidence (systematic reviews), Clinical Practice Guidelines (CPGs) and evidence from international Health Technology Assessment agencies. The research questions and findings are summarised below.

Questions and summary of Rapid Evidence Review findings

Q1. Does the use of spirometry improve diagnostic accuracy and health outcomes in people presenting with respiratory symptoms?

- The review found that high-quality spirometry may reduce rates of under-diagnosis and misdiagnosis of asthma, COPD and other causes of airflow limitation.
- Pre-bronchodilator spirometry, post-bronchodilator spirometry, and reversibility testing (pre- and post-bronchodilator spirometry) all have a role in the diagnosis of patients presenting with respiratory symptoms suggestive of asthma, COPD or other causes of airflow limitation.
- International CPGs recommend use of reversibility testing in the diagnosis of asthma in adults and children (>5 years of age) with evidence of airflow limitation (according to pre-bronchodilator spirometry). For the diagnosis of COPD, international CPGs recommend the use of post-bronchodilator spirometry, however, bronchodilator reversibility testing may have a place where diagnostic doubt remains, or both COPD and asthma are suspected, particularly in elderly patients.

Q2. In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for:

1. assessing acute exacerbations?
   - While some asthma and COPD CPGs advised that spirometry is of little value in the management of acute exacerbations, others suggested that it may be useful for categorising severity and assessing patients during recovery.
2. long-term monitoring?
   - For asthma, there is evidence to suggest that low Forced Expiratory Volume (FEV1) is a strong independent predictor of risk of exacerbations. This therefore supports the use of lung function testing as part of long-term monitoring.
   - For COPD, FEV1 is a poor predictor of disease status and prognosis, but spirometry may still have a role alongside other tests in long-term monitoring because worsening airflow limitation is associated with an increasing frequency of exacerbations and adverse events.

Q3. What is the published evidence for the cost-effectiveness of spirometry for the diagnosis of people presenting with respiratory symptoms?

- A recent economic evaluation commissioned by the National Institute for Health and Care Excellence (NICE, 2016) found that the cost-effectiveness of diagnostic strategies using spirometry and reversibility testing was contingent on further diagnostic tests being performed downstream.
- No literature was identified to provide evidence for the cost-effectiveness of a spirometric diagnosis of COPD.

Q4. What is the evidence that an increase in spirometry service fees (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

Q5. What is the evidence that financial incentives for performing spirometry over and above a fee for service (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

Q6. What is the evidence that introduction of an outcome based payment model that links provider payment to accurate diagnosis of asthma or COPD (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

- There is evidence from the United Kingdom to suggest that a financial incentive to undertake spirometry (over and above a fee for service) increases the quantity, but not necessarily the quality, of spirometry in primary care.
- No literature was identified that assessed the impact of financial incentives for the use of spirometry in primary care, on diagnostic accuracy or patient health outcomes.

Other observations and conclusions described in the rapid evidence review

Δ Pre-bronchodilator spirometry is not reimbursed through the MBS but is recommended in international CPGs as a first line objective test to confirm airflow obstruction in adults and

children (>5 years) who present with respiratory symptoms suggestive of asthma; bronchodilator reversibility testing should only follow if airflow limitation is detected.

- Δ Post-bronchodilator spirometry as a standalone service is not reimbursed through the MBS but is recommended in international CPGs for the diagnosis of COPD, in cases where asthma or asthma-COPD overlap syndrome (ACOS) are not suspected.
- Δ Despite a lack of clear evidence of benefit, international CPGs generally support the use of spirometry (pre- or post-bronchodilator) for long-term monitoring of asthma or COPD; a role for spirometry in the assessment of acute exacerbations is less clear.
- Δ Australian CPGs tend to support the use of reversibility testing, which is currently reimbursed on the MBS, to a greater extent than international CPGs.
- Δ Financial incentives may increase the use of spirometry in primary care, but the extent to which it improves diagnosis and health outcomes is unknown.

A copy of the full rapid evidence review report is at Appendix C**.**

The Committee's findings on the Rapid Evidence Review

The Committee accepted that the rapid evidence review properly summarised the current evidence and answered the research questions. The Committee concluded that:

- Δ There is moderate quality evidence and a high degree of concordance between national and international clinical practice guidelines to support the use of pre and post bronchodilator testing to confirm the diagnosis of asthma and other causes of airflow limitation.
- Δ There is moderate quality evidence and a high degree of concordance between national and international clinical practice guidelines to support the use of post bronchodilator testing to confirm the diagnosis of COPD.
- Δ There is some evidence that spirometry is useful in long term monitoring of asthma and COPD (expert consensus/CPGs).
- Δ There is little evidence on the utility of spirometry for the assessment of acute exacerbations in asthma and COPD.
- Δ Although not noted in the evidence review, some CPGs recommend using spirometry to grade severity and thus treatment of COPD. Both GOLD and COPD X use FEV1% predicted ranges to recommend specific therapies.
- Δ Evidence from the UK NICE indicates that financial incentives increase the number of spirometry services provided in primary care.
- Δ There is a lack of published studies addressing whether financial incentives to perform spirometry in primary care improve diagnosis and health outcomes.
- Δ Evidence from the UK NICE indicates that the cost-effectiveness of using spirometry and bronchodilator reversibility testing to diagnose asthma and COPD is variable (contingent on further diagnostic tests being performed downstream (eg FeNO, bronchial provocation). It should be noted that UK evidence on cost effectiveness is not necessarily translatable to Australia because input costs are different.

- Δ The emphasis on reversibility testing in Australian CPGs is likely a consequence of MBS funding which currently reimburses reversibility testing but not less complex spirometry (pre or post-bronchodilator only).

MBS fees for spirometry

Spirometry in primary care is funded through the MBS (item 11506), the Practice Incentive Program (PIP) Asthma Incentive and the Practice Nurse Incentive Program (PNIP). PIP Asthma Incentive is designed to encourage GPs to better manage the clinical care of people with moderate to severe asthma while the PNIP provides incentive payments to practices to support an expanded role for nurses working in general practice. The Committee suggested that these funding arrangements are insufficient and do not adequately encourage the use of spirometry for diagnosing and monitoring asthma and COPD in primary care. The MBS fee for existing item 11506 is $20.55.

The Cranston Research Paper[5] examined models of chronic disease management in primary care for patients with mild to moderate asthma or COPD and gave an estimated cost of providing pre and post bronchodilator spirometry in primary care in South Australia (Table 7). The figures from the Cranston Research Paper have been adjusted to reflect current costs (2015). The table also includes an estimate of costs provided by the Committee and incorporates information from the Lung Health Alliance.

Table 7: Estimate of the cost of pre and post bronchodilator spirometry in primary care for South Australia

Source	Cost per test when provided by a practice nurse	Cost per test when provided by a General Practitioner
Cranston et al	$43.69	$98.69
Committee/Lung Health Alliance	$64.90	$110.49
Average	$54.30	$104.60

Taking account of the current MBS fee for 11506 and the evidence above, the Committee recommended a revised MBS fee in the range of $40-45.

The Committee also recommended adding a new MBS item for less complex spirometry (pre or post bronchodilator) for the diagnosis of COPD; assessment of acute exacerbations of asthma but not COPD; and long term monitoring of both asthma and COPD. The Committee, incorporating information from the Lung Health Alliance, has provided an estimate of the cost of pre or post spirometry in primary care.

Table 8: Estimate of the cost of pre or post bronchodilator spirometry in primary care for South Australia

Source	Cost per test when provided by a practice nurse	Cost per test when provided by a General Practitioner
Committee / Lung Health Alliance	$37.08	$53.90

The Committee recommended a MBS fee for this service equivalent to the existing MBS fee for item 11506.

The Committee agreed that the fee for existing MBS item 11512 ($61.00) should be retained.

Recommendations – spirometry

Following this discussion and acknowledgement of the evidence presented in the review, the Committee makes the following recommendations:

Better target and incentivise use of spirometry (item 11506)

Pre- and post-bronchodilator spirometry is a first line test to confirm airflow limitation in patients over 5 years of age who present with respiratory symptoms suggestive of asthma or COPD. Item 11506 requires operator skill and minimum 20 minutes time, and the MBS fee should be revised to reflect this and increased to incentivise testing. The item should be available in all care settings with a frequency of one test in a 12-month period. As this is diagnostic test, interval limits are reasonable and it should be payable once in 12 months.

New MBS item for pre or post bronchodilator spirometry

A new MBS item should be introduced to reimburse the use of pre or post bronchodilator spirometry for diagnosis of COPD; assessment of acute exacerbations of asthma but not COPD; and long term monitoring of both asthma and COPD. Although not the subject of specific evidence review, the Committee recommends that this new service be available for the assessment of other causes of obstructive lung diseases and restrictive lung disease. This new service should have no interval limits because of the variable use in practice. A fee of $20.00 has been proposed and the current volume of testing and likely utilisation is unknown, although it is likely that some current 11506 claims would transfer to this test.

Enhance quality of spirometry services

To enhance quality, all spirometry services should have a requirement that at least three expiratory manoeuvres that meet acceptable and repeatable criteria are necessary per test and that the results of testing should be recorded and a record retained.

Spirometry billed under item 11512 should be performed in a laboratory that is equipped to perform a minimum range of respiratory function tests to distinguish this service from office based spirometry.

The Committee rejected proposals to:

- Restrict the proposal for a higher fee for pre- and post-bronchodilator spirometry to the primary care setting.
- Introduce testing frequency intervals for the monitoring of asthma and COPD. It was flagged with the Committee that a lack of restrictions on the number of services would risk a high volume of testing without a clear link to clinical benefit and very uncertain estimates of future MBS expenditure. The consumer representative expressed concern that a restriction may mean that the cost of additional testing would be passed onto consumers. Conversely, as less complex spirometry is not currently reimbursed, it may be that currently the testing is performed without explicit charge to patients. A new MBS item may expose patients to out of pocket expense, where none exists now, particularly in primary care or specialist practice where bulk billing rates are low.

Recommendation 1: *Spirometry*

The Committee recommends amendments to item 11506 as follows:

Current Item Descriptor

MEASUREMENT OF RESPIRATORY FUNCTION involving a permanently recorded tracing performed before and after inhalation of bronchodilator - each occasion at which 1 or more such tests are performed

Fee: $20.55

Benefit: 75% = $15.45; 85% = $17.50

Proposed new Item Descriptor

MEASUREMENT OF SPIROMETRY involving a permanently recorded tracing performed before and after inhalation of bronchodilator to confirm diagnosis of asthma, COPD or other causes of airflow limitation - each occasion at which three or more recordings that meet acceptable and repeatable criteria, are performed

Payable once in 12 months.

Fee: $40-45

Benefit: 75% = $TBC; 85% = $TBC

The Committee recommends a new item descriptor for a new spirometry item as follows:

Proposed new item descriptor

MEASUREMENT OF SPIROMETRY involving a permanently recorded tracing, performed before OR after inhalation of bronchodilator to

1) confirm diagnosis of COPD
2) assess acute exacerbations of asthma

3) monitor asthma and COPD.
4) assess other causes of obstructive lung disease or the presence of restrictive lung disease

- each occasion at which three or more spirometry recordings are performed.

Fee: $20

Benefit: 75% = $15; 85% = $17

The Committee has proposed the following changes to the descriptor for item 11512:

Current Item Descriptor

CONTINUOUS MEASUREMENT OF THE RELATIONSHIP BETWEEN FLOW AND VOLUME DURING EXPIRATION OR INSPIRATION involving a permanently recorded tracing and written report, performed before and after inhalation of bronchodilator, with continuous technician attendance in a laboratory equipped to perform complex lung function tests (the tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital) - each occasion at which 1 or more such tests are performed.

Fee: $61.75

Benefit: 75% = $46.35 85% = $52.50

Proposed new Item Descriptor

MEASUREMENT OF SPIROMETRY including continuous measurement of the relationship between flow and volume during expiration or during expiration and inspiration, performed before and after inhalation of bronchodilator, which meets the following quality requirements:

1. continuous technician attendance in a respiratory laboratory equipped to perform complex lung function tests
2. the test is performed under the supervision of a consultant physician practising respiratory medicine who is responsible for staff training, supervision , quality assurance and the issuing of written reports

Δ a permanently recorded tracing and written report is provided
Δ three or more spirometry recordings are performed

Each occasion at which 1 or more such tests are performed, not being a service associated with a service to which items 11503, new item (spirometry plus FeNO) or 22018 applies

Fee: $61.75

Benefit: 75% = $46.35 85% = $52.50

Proposed explanatory notes for items 11506, 11512 and the new item are as follows:

Δ The Australian Asthma Handbook (2015) and Lung Foundation Australia (2015) COPD-X guidelines 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 11506 should not be repeated when diagnosis has been previously confirmed by properly performed spirometry. To meet quality requirements patients should 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 AAH and NAC Spirometry Handbook).

5. Complex respiratory function tests

One item for complex respiratory function tests is considered in this section:

Δ **11503** Complex Lung Function Tests

5.1 Item 11503 – Complex respiratory function tests

Item 11503 provides for more complex respiratory function tests that are performed in a respiratory laboratory under the supervision of a specialist. The list of tests rebated under this item have changed over time and the current list was proposed by the Thoracic Society of Australia and New Zealand some years ago. The Committee recommended the list needs to be updated to reflect current practice. An issue that emerged during discussion was the relationship between this item and the spirometry items.

Refer to Recommendation 2.2: Complex lung function – changes to item 11503 for the current item descriptor, Appendix A for the explanatory notes and Appendix D for further data.

As this item covers a number of different tests and can only be claimed once per day, no matter how many tests are performed, there are no MBS data on the relative use of the tests or the usual numbers of tests done per service. It is acknowledged that the tests vary in their complexity.

MBS data on respiratory function test – item 11503

Table 9: High level MBS data on respiratory function test item 11503, 2014-15 (date of processing)

Statistic	Amount
Schedule fee	$138.65
Total benefits paid 2014-15	$31,462,655
Number of services 2014-15	267,688
% of services provided out-of-hospital 2014-15	90.90%
Bulk-billing rate for out-of-hospital services 2014-15	81.00%
Total patient count 2014-15	207,017
Total provider count 2014-15	888
Benefits change (%) from 2009-10 to 2014-15	67.30%
Service change (%) from 2009-10 to 2014-15	57.20%
Item description start date	1 March 2013

Unpublished data (Department of Health)

Discussion and recommendations

The Committee found that the current MBS item 11503 provides for a broad range of tests that vary in frequency, complexity and purpose with the tests for the item outlined in the explanatory note. It was agreed that the tests claimed under item 11503 should reflect common complex lung function tests that are supported by clinical evidence and should be listed in the item descriptor. The Committee agreed that tests that are rarely used or only used for research purposes or are not supported by evidence should be removed from item 11503.

The Committee recommended that the following tests should be removed from the list of tests covered under item 11503 as they no longer support best practice or are only used in a research environment. These tests (noting current numbering in MBS explanatory notes) are:

(c) Assessment of arterial carbon dioxide tension or cardiac output - re breathing method

(d) Assessment of pulmonary distensibility involving measurement of lung volumes and oesophageal pressure

(f) Measurement of respiratory muscle strength involving the measurement of trans-diaphragmatic or oesophageal pressures

(g) Assessment of phrenic nerve function involving percutaneous stimulation and measurement of the compound action potential of the diaphragm

(h) Measurement of the resistance of the anterior nares or pharynx

(k) Tests of distribution of ventilation involving inhalation of inert gases

(l) Measurement of gas exchange involving simultaneous collection of arterial blood and expired air with measurements of the partial pressures of oxygen and carbon dioxide in gas and blood

(m) Multiple inert gas elimination techniques for measuring ventilation perfusion ratios in the lung

(n) Continuous monitoring of pulmonary function other than spirometry, tidal breathing and minute ventilation, of at least 6 hours duration

(o) Ventilatory and/or occlusion pressure responses to progressive hypercapnia and progressive hypoxia

(p) Monitoring pulmonary arterial pressure at rest or during exercise

(r) Measurement of the respiratory muscle endurance/fatigability by any technique.

The Committee also considered whether some tests that are currently performed should be explicitly included under item 11503. It is not clear whether some providers are currently billing these tests under item 11503. These tests are the six-minute walk test (6MWT), the exhaled fraction of nitric oxide (FeNO), maximum inspiratory flow volume loop and mucociliary function. It was agreed that mucociliary function does not currently warrant inclusion in item 11503 and the other tests are discussed below.

The Committee considered the current quality practice requirement for these tests and for some tests have recommended some minor wording changes to enhance quality. The Committee recommends that the list of tests permitted under 11503 should be included in the item descriptor. The previous list of tests described in explanatory notes was advisory only whereas listing the tests in the item limits use of the item to the nominated tests.

The new list is found in the proposed item descriptor under Recommendation 2.2: Complex lung function – changes to item 11503.

Six-minute walk test (6MWT)

The Committee suggested that the six-minute walk test (6MWT) is currently claimed under item 11503 and should be explicitly added to the list of tests permitted. A short evidence review was

commissioned that outlined the clinical scenarios where the 6MWT is used currently and appears to have clinical utility. The Committee noted that the potential indications for the test are broad. For instance, outside of respiratory laboratories it is used by allied health professionals and others as part of pulmonary rehabilitation. It is not intended that MBS rebates should be provided for this purpose. However, the Committee noted that determining eligibility for certain Pharmaceutical Benefit Schedule medications for pulmonary arterial hypertension require the results of a 6MWT and members supported inclusion of 6MWT in 11503 for this purpose. The Committee suggested that at a suitable time the 6MWT be assessed by MSAC to determine whether there should be MBS funding for other indications. This test is commonly undertaken in respiratory laboratories to assess breathlessness, exercise capacity (distance walked) and desaturation, but does not have an item number for this purpose.

Fraction of Exhaled Nitric Oxide (FeNO)

The Committee advised that FeNO is relatively simple and inexpensive to perform but requires skill to interpret. Measurement of FeNO concentration in exhaled breath is a quantitative, non-invasive, simple, and safe method of measuring airway inflammation that provides a complementary tool to other ways of assessing airways disease, including asthma. The test carries little risk to the patient and has high utilisation. At present, it appears that FeNO may be billed under item 11503 on basis that it is 'analysis of exhaled gas'. Members agreed that FeNO is clinically validated but not complex enough to warrant the MBS fee associated with item 11503. Members agreed that FeNO is likely to become simpler and cheaper to administer over time and is likely to become a test administered in the primary care setting.

The Committee agreed that FeNO should be performed in association with spirometry and is not clinically useful as a standalone test.

The Committee discussed the following options for funding FeNO:

- Include FeNO, when done, under item 11512 (laboratory spirometry)
- Develop a new item for spirometry with FeNO
- Include spirometry with FeNO as a test available under 11503 (recognising that spirometry alone is not a test available under 11503).

Members expressed concern that option three might provide incentive to request FeNO when laboratory based spirometry was requested given the fee difference between 11503 and 11512. Conversely, members thought that additional rebate was warranted when FeNO was performed in addition to spirometry because there is a real cost in staff time and consumables.

A majority of members favoured option two believing that FeNO in combination with spirometry was not of sufficient complexity to warrant inclusion under 11503. One member dissented favouring option three.

Further advice is required to make a recommendation regarding the MBS fee for the combined spirometry/FeNO service. Some stakeholders have already expressed their wish to see a dedicated MBS item for FeNO in response to concerns about the removal of this test from item 11503.

Recommendation 2.1: Complex respiratory tests – new item for FeNO

The Committee recommends a new item for fractional exhaled nitric oxide (FeNO) as follows:

Proposed new Item Descriptor for new FeNO item

Measurement of:

(a) spirometry including continuous measurement of the relationship between flow and volume during expiration or during expiration and inspiration, performed before and after inhalation of bronchodilator; and

(b) fractional exhaled nitric oxide (FeNO) concentration in exhaled breath

The tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital, with continuous technician attendance in a respiratory laboratory equipped to perform complex lung function tests:

(c) a permanently recorded tracing and written report is provided

(d) three or more spirometry recordings are performed unless difficult to achieve for clinical reasons

(e) each occasion at which 1 or more such tests are performed, not being a service associated with a service to which items 11503, 11512 or 22018 applies.

Fee: $TBD

Benefit: 75% = $TBD; 85% = $TBD

Flow-volume loop testing for central airways obstruction

At present flow-volume loop testing may be performed under item 11512 or in a laboratory under item 11503. This test is used to diagnose clinically significant central airway obstruction. It is not a complicated test and members agreed it is most appropriately performed under item 11512. The Committee agreed that an explanatory note is required to advise practitioners that flow-volume loop testing (including expiratory and inspiratory curves) is to be performed under item 11512 rather than item 11503.

The Committee noted that there may be occasions where three flow-volume loop tests cannot be achieved for clinical reasons. They agreed this should not affect the ability to bill for the item as the billing reflects the physician's attendance and test reporting, not the reproducibility of the test.

The Committee also discussed whether the supervision requirements associated with item 11512 should be removed from the descriptor and placed in an explanatory note. However, the Committee agreed to retain the supervision requirements in the descriptor.

The revised item descriptor for item 11512 is in Recommendation 1 –Spirometry, towards the end of Section 4. The explanatory note for items 11503 and 11512 relevant to this issue as follows.

Proposed explanatory notes for items 11503 and 11512

Maximum inspiratory and expiratory flow-volume loop testing for the purpose of diagnosing central airways obstruction is to be performed under MBS item 11512. Fewer than three traces will be accepted as billable under this item if three reproducible loops are difficult to achieve for clinical reasons.

5.2 Other Issues

Paediatric respiratory function tests

There was discussion about whether these tests should attract higher fees recognising that additional resources are sometimes required to undertake the tests. It was acknowledged that the additional resources relate to laboratory staff assisting in setting up or performing the test rather than the time to undertake the test. No additional medical professional time is required to interpret the test. It was acknowledged that these tests are largely provided within a public hospital setting where non-medical staff costs are hospital funded.

The Committee agreed that the recommended changes to lung function tests should cover paediatric and adult patients. The Committee does not support the introduction of a fee loading for paediatric tests at this time.

Co-claiming of spirometry (items 11506 and 11512) with More Complex Laboratory Based Tests (item 11503)

The Committee noted that currently, spirometry performed in a laboratory is being billed under items 11509 (recommended for removal), 11512 or 11503 (complex). The Committee noted that there are no regulations that directly prevent providers from claiming 11503 for laboratory based spirometry nor is there direct restriction on same day co-claiming of the spirometry items with 11503. MBS data (see Appendix D – Top 10 same day item combinations - item 11503 with other MBS items, 2014-15) confirms that in general spirometry items are not claimed on the same day as item 11503.

The Department of Health advised that same day co-claiming of items has increased over time and is quite widespread across the MBS. The absence of a restriction on co-claiming does not indicate that the circumstance has been specifically considered nor does it indicate agreement that co-claiming is legitimate. At the present time, co-claiming is assessed according to the particular service under review. In addition, where an MBS item describes a specific service, that is the item that should be billed rather than a more general item.

The Committee noted that spirometry services could be provided in a variety of settings from a relatively simple, office based service to spirometry as part of suite of complex lung function testing performed in a laboratory. The escalation in the complexity of service (and available rebates) means that the more complex services encompass the simpler service. For example, if spirometry is performed under MBS item 11503, it should not also be billed under item 11512.

The Committee noted that item 11512 should be billed when spirometry is the only laboratory test preformed. However, if spirometry is performed with another approved lung function test in a laboratory, then it would be appropriate to bill MBS 11503, noting that 11503 has one MBS rebate no matter how many tests are performed. The Committee agreed that it is not appropriate to bill item 11503 when spirometry is the only laboratory test performed. To do so would mean that item 11512 is redundant, when clearly it is contemplated that laboratory spirometry should attract MBS rebates that are less than the rebate for item 11503.

The Committee has recommended that regulations and explanatory notes be amended to make it clear that spirometry items cannot be co-claimed on the same day as item 11503 and spirometry is not to be billed under 11503 when it is the only test performed on that day. If laboratory based spirometry is performed with other tests and billed under 11503, the spirometry should meet the quality requirements for 11512.

Co-claiming of MBS item 11503 and 12203

The Committee discussed the same day co-claiming of MBS item 12203 (attended sleep study) with item 11503 (complex lung function testing) noting that in the year to end June 2014 this increased by 150% and in 2014/15, 27% of item 12203 services were claimed with item 11503.

The Committee suggested that some sleep study providers may be performing nasal peak flow in conjunction with a sleep study and billing MBS item 11503. It was agreed that this was opportunistic billing and that there would be no clinical indication for this approach for most patients.

Members recommended that the co-claiming of MBS 11503 for services related to the measurement of sleep or associated factors should be prevented, except for certain clinical indications. It should be noted that previous item under 11503 “Measurement of the resistance of the anterior nares or pharynx” is recommended for deletion. It was recommended that where a patient has clinical indications for an MBS 11503 on the same day as a sleep study, and the service performed under 11503 is separate to the sleep study, then the account may be annotated to reflect this which would enable payment of separate patient rebate. This approach already applies to item 12250.

Recommendation 2.2: Complex lung function – changes to item 11503

The following are recommended draft changes to item 11503. It should be noted that to meet regulatory requirements, further legal drafting will be required.

Current Item 11503 Descriptor

Measurement of the:

(a) mechanical or gas exchange function of the respiratory system; or

(b) respiratory muscle function; or

(c) ventilatory control mechanisms.

Various measurement parameters may be used including any of the following:

(a) pressures;

(b) volumes;

(c) flow;

(d) gas concentrations in inspired or expired air;

(e) alveolar gas or blood;

(f) electrical activity of muscles.

The tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital. Each occasion at which 1 or more such tests are performed, not being a service associated with a service to which item 22018 applies.

(See para D1.14 of explanatory notes to this Category)

Fee: $138.65

Benefit: 75% = $104.00; 85% = $117.90

Proposed new Item Descriptor

Complex measurement of properties of the respiratory system including the lungs and respiratory muscles performed in a respiratory laboratory under the supervision of a specialist in Respiratory Medicine who is responsible for staff training, supervision, quality assurance and the issuing of written reports on tests performed. Tests for this service are:

(a) Absolute lung volumes by any method

(b) Carbon monoxide diffusing capacity by any method

(c) Measurement of airway or pulmonary resistance by any method

(d) Inhalation provocation testing, including pre-provocation spirometry, the construction of a dose response curve, using recognised direct or indirect bronchoprovocation agent and post-bronchodilator spirometry

(e) Provocation testing involving sequential measurement of lung function at baseline and after exposure to specific sensitising agents, including drugs, or occupational asthma triggers

(f) 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

(g) Measurement of the strength of inspiratory and expiratory muscles at multiple lung volumes

(h) 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

(i) Six minute walk test for the purpose of determining eligibility for medications subsidised under the Pharmaceutical Benefits Scheme or eligibility for the provision of portable oxygen

Each occasion at which one or more tests are performed and not to be claimed with spirometry and sleep study items (numbers to be inserted)

Fee: $138.65

Benefit: 75% = $104; 85% = $117.90

Proposed explanatory notes for item 11503

Fractional exhaled nitric oxide (FeNO) testing cannot be claimed under MBS item 11503.

When laboratory based spirometry (item 11512) is performed on the same day as a test approved under item 11503, then 11503 should be claimed. When spirometry is the only laboratory test performed then 11512 should be claimed.

Maximum inspiratory and expiratory flow-volume loop testing for the purpose of diagnosing central airways obstruction is to be performed under MBS item 11512 not 11503.

5.3 Proposed new MBS item - Cardiopulmonary Exercise Testing (CPET)

Cardiopulmonary exercise testing (CPET) provides a relatively non-invasive global assessment of functional capacity involving multiple organ systems, allowing the evaluation of both submaximal and peak exercise responses. It provides data as to respiratory gas exchange, including oxygen uptake (VO_2), carbon dioxide output (VCO_2), tidal volume (VT) and minute ventilation (VE) as well as other variables such as ECG, BP and oxygen saturation.

The Committee has proposed that there be a new MBS item for CPET recognising that it is highly specialised, high risk and valuable test with low utilisation and more complex than other tests available under item 11503. Currently it is performed under MBS item 11503. Some practitioners bill 11503 in combination with item 11712 (cardiac exercise testing) with MBS data demonstrating that this combination was billed on 2,699 occasions in 2014-15.

To consider the proposal a concise high level evidence review was commissioned. The review suggested that there are numerous potential indications for CPET including:

- Evaluation of breathlessness where specialist assessment and other testing has not revealed a cause.
- Evaluation of exercise capacity in response to therapy or for rehabilitation.
- Assessment of suitability for major surgery.

The review is at Appendix F.

The Committee considered the report and recommends that there be a new item for CPET recognising that CPET is much more resource intensive than other tests available under item 11503. Based on the evidence review the Committee recommend that the indications for CEPT be limited to an evaluation of breathlessness where an initial diagnosis is inconclusive and for pre-operative evaluation of high risk patients.

Recommendation 2.3: Proposed new item - Cardiopulmonary Exercise Testing (CPET)

The Committee proposes a new item with a MBS fee equal to existing items 11503 plus 11712. Based on the current use of items 11712 and 11503 in combination, utilisation is expected to be around 2,700 services per annum.

Proposed new item descriptor for cardiopulmonary exercise testing item

Maximal symptom-limited incremental exercise test utilising a calibrated cycle ergometer or treadmill

(a) performed for the evaluation of

  (i) breathlessness of uncertain cause from tests performed at rest, or
  (ii) breathlessness out of proportion with impairment due to known conditions, or
  (iii) functional status and prognosis in patients with significant cardiac or pulmonary disease where complex procedures such as organ transplantation are considered
  (iv) anaesthetic and peri-operative risks in patients undergoing major surgery who are assessed as substantially above average risk after standard evaluation

AND

(b) the test has been requested by a Consultant Physician following personal assessment, AND

(c) an experienced Respiratory Scientist and Medical Practitioner are in constant attendance during the testing in a respiratory laboratory equipped with airway management and defibrillator equipment,

AND

(d) there is continuous measurement of at least

  (i) work rate
  (ii) pulse oximetry
  (iii) respired oxygen and carbon dioxide partial pressures and respired volumes
  (iv) ECG
  (v) heart rate and blood pressure

AND

(e) interpretation and preparation of a permanent report is provided by a Specialist in Respiratory Medicine who is also responsible for the supervision of technical staff and quality assurance in accordance with the guidelines of the Thoracic Society of Australia and New Zealand.

Fee: $290.80

Benefit: 75% = $218.15; 85% = $244.26

6. MBS Item Group Two – Sleep Studies

Seven items for sleep study are considered in this section:

- Δ **12203** Adult sleep study in a laboratory
- Δ **12250** Adult sleep study, unattended
- Δ **12207** Adult sleep study in a laboratory (4th study)
- Δ **12210** Paediatric sleep study in a laboratory (Aged 0-12)
- Δ **12213** Paediatric sleep study in a laboratory (Aged 12-18)
- Δ **12215** Paediatric sleep study in a laboratory (Aged 0-12, 4th study)
- Δ **12217** Paediatric sleep study in a laboratory (Aged 12-18, 4th study)

6.1 Sleep studies

The decision by Taskforce that MBS funded sleep studies should be a priority review was prompted by international concern from Choosing Wisely about the clinical value of sleep studies, local concern about practice models that have evolved that have supported patient access without appropriate clinical review which potentially compromises quality service provision. There has been above forecast growth in use of sleep studies.

Background

Continuous positive airway pressure (CPAP) is an evidence based therapy for managing obstructive sleep apnoea (OSA). The therapy is generally prescribed by a sleep or respiratory physician after a diagnostic sleep study. Overnight laboratory-based Level 1 testing has been MBS rebated since the early 1990s. Unattended home based diagnostic studies for adults have been MBS listed since October 2008 ahead of MSAC assessment in March 2010 which supported the continuation of MBS funding for Level 2 (seven parameters) unattended studies. MSAC did not support Level 3 or 4 studies but recognised that there was large disease burden which could not be met by laboratory based Level 1 studies and that adult Level 2 studies were acceptably safe and effective (based on diagnostic accuracy). MBS listing was recommended with a number of caveats including;

- Δ Patients referred for testing should have a high pre-test probability of having OSA
- Δ The need for testing should be determined by a qualified sleep practitioner
- Δ The sleep practitioner should establish quality assurance procedures for the data acquisition, personally analyse the data and provide a report
- Δ Rebated testing for level 2 studies should be limited to once in 12 months.

These caveats are reflected in the item descriptors and are consistent with the requirements for Level 1 laboratory based studies (although these MBS services are payable up to 3 times annually).

Essential features of the MBS listing that sought to balance access and quality were that patients did not need personal assessment by a sleep specialist before testing was done but nevertheless a qualified sleep practitioner would authorize the study based on referral and assessment that the patient has high pretest probability of OSA.

At the time of introduction of item 12250, MSAC was uncertain about the likely uptake of Level 2 testing but expected that the availability of Level 2 unattended studies would reduce the volume of Level 1 laboratory based studies. However, at the same time there was growing recognition of the adverse health impacts of OSA and a rising prevalence of OSA. On the other hand, MSAC expressed some concern that positive Level 2 studies may lead to additional confirmatory Level 1 studies despite the accuracy of Level 2 tests.

There are several MBS items for sleep studies but the two main items for adults are item 12203 (Level 1 attended/laboratory based studies) and item 12250 (Level 2 unattended/home based studies).

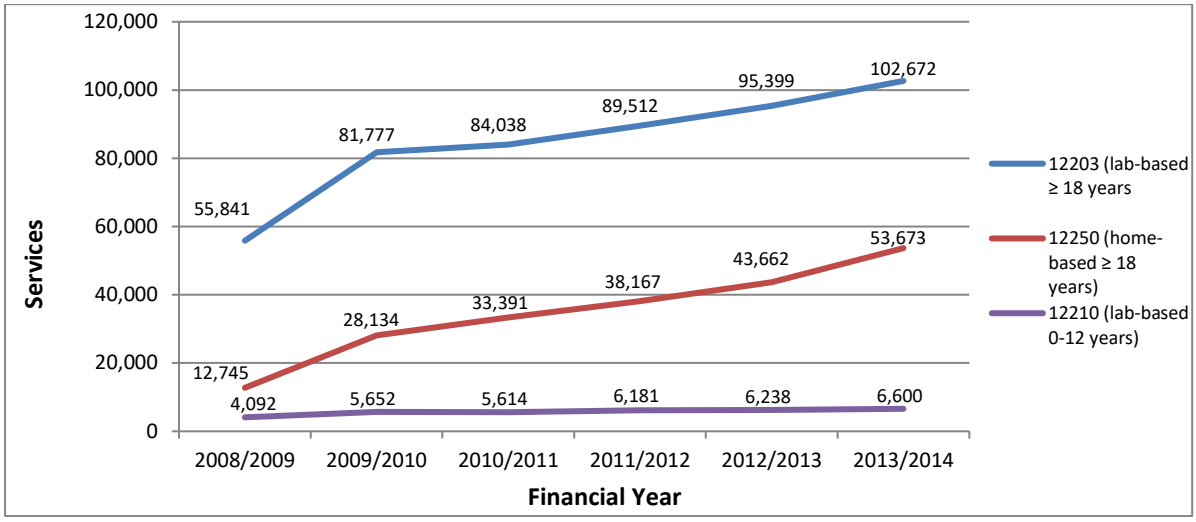
MBS data on sleep studies – items 12203, 12207 and 12250

Table 10: High level MBS data on sleep studies – items 12203, 12207 and 12250 (by date of processing)

Statistic	**12203**	**12207**	**12250**
Schedule fee	$588.00	$588.00	$335.30
Total benefits paid 2014-15	$49,134,837	$1,394	$19,506,651
Number of services 2014-15	103,243	3	68,310
% of services provided out-of-hospital 2014-15	49.70%	33.30%	99.60%
Bulk-billing rate for out-of-hospital services 2014-15	90.90%	100.00%	85.50%
Total patient count 2014-15	84,475	3	68,390
Total provider count 2014-15	284	3	224
Benefits change (%) from 2009-10 to 2014-15	34%	234%	158%
Service change (%) from 2009-10 to 2014-15	26%	200%	143%

Unpublished data (Department of Health)

The following describes the use of both laboratory based (item 12203) and home based (item 12250) sleep studies. The analysis is confined mainly to adult studies and to the key items. Testing of children is limited, confined to the laboratory based Level 1 studies and largely linked to therapies other than CPAP. The data look at service growth, geographical variation and use of associated services and in particular consultation with consultant physicians pre and post-testing.



*Item 12250 was MBS-listed on 1 October 2008; Data is by date of processing. Unpublished data (Department of Health).

*FIgure 1. Growth in Services – Sleep Study Items 12203 (adult lab-based), *12250 (adult home-based) and 12210 (child lab-based) – 1 October 2008 to 30 June 2014*

Table 11: Benefits, average fee charged and service growth (2013-14) – Items 12203, 12250 and 12210

Item	*Total benefits paid ($ million)	Average fee charged per service ($)	Average benefit per service ($)	Service growth: 2010-11 to 2013-14 (%)	Service growth: 2012-13 to 2013-14 (%)
12203	$49.0	$614	$477	22%	8%
*12250	$15.3	$307	$286	61%	23%
12210	$3.8	$775	$579	18%	6%

* About 80% of 12250 services are bulk-billed; Data is by date of processing. Unpublished data (Department of Health).

- Since 2010-11, the average annual increase in item 12250 services has been 18%. Service growth from 2012-13 to 2013-14 was even higher at 23% with total benefits paid increasing from $12.4m to $15.3m. This rate of growth is well above the average for all MBS services of 6-7%.
- While annual growth for item 12203 is comparatively lower (about 6% from 2010-11), service growth for this item has not decreased since the listing of item 12250 on 1 October 2008 (benefits paid for this item increased from $45.2m in 2012-13 to $49.0m in 2013-14).
- The data suggest that the majority of item 12250 services are being provided to patients who, prior to the availability of item 12250, may not have received a sleep study (or at least an MBS rebated lab-based study). A confounding factor is that MBS billing of public hospital services has increased over time.
- Average annual growth for paediatric laboratory based sleep studies (item 12210) is also increasing at an average rate of 4% per year since 2010-11.

Services per Patient

In 2012-13, 2,098 patients received both an item 12203 and an item 12250. This makes up only a small proportion of item 12250 services (about 5%) and does not appear to be a driver of the growth of item 12203.

Table12: Number of patients who received an adult lab-based sleep study (12203) and also an adult home-based sleep study (12250) in Financial Year 2012-13

No. of Lab Studies	Patients	*12250 services	12203 services
1	2,098	x 1	x 1
2	178	x 1	x 2
3	8	x 1	x 3

*About 40,503 patients received a service under item 12250 in 2012-13; Data is by date of service. Unpublished data (Department of Health).

The data below indicate that approximately 20% of patients (12,927 patients in 2012-13) receive more than one adult lab-based study (item 12203) in the same 12 month period. Reassessment (post institution of therapy) is MBS rebated for Level 1 but not Level 2 studies.

Table 13: Lab-based sleep study item 12203: Number of services per patient (2012-13)

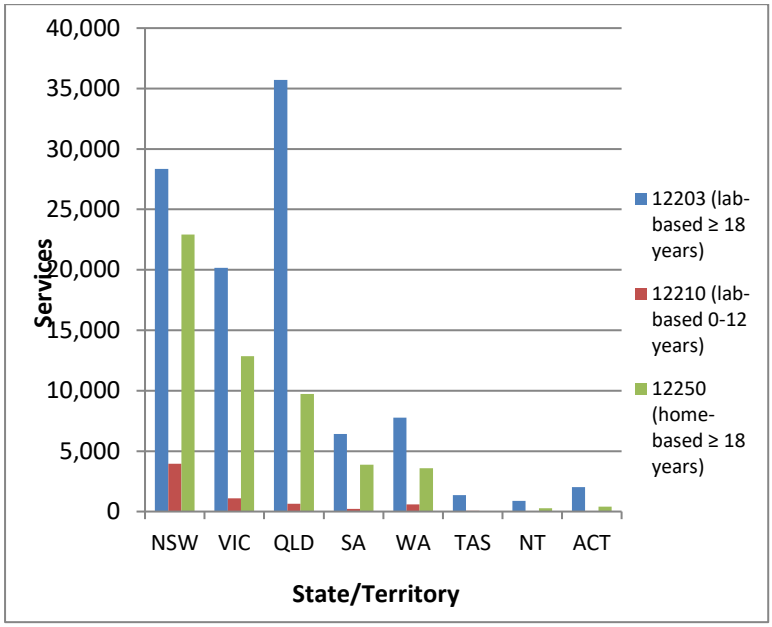
No. of Lab Studies	Approx. Patients
1	46,489
2	12,373
3	554

*Data is by date of service. Unpublished data (Department of Health).

State/Territory Comparison and Provider Variation

Comparison of data for items 12203, 12210 and 12250 shows the following:

- The highest number of item 12203 services occurred in Queensland (35%), followed by NSW (28%) and VIC (20%). The per capita use of item 12203 services (7.53 per 1000) for Queensland is well above other states and territories.
- In Queensland a large proportion of item 12203 services are provided by very few clinicians. Nationally, the average number of item 12203 services (per provider) performed in 2013-14 was roughly 400. A few clinicians perform more than 7000 services annually.
- For item 12250, 43% of services occurred in NSW, followed by Victoria (24%) and Queensland (18%). Similar to item 12203, a large number of services are concentrated in a few providers. The average number of services (per provider) for 2013-14 was 275 with a few clinicians performing more than 2000 studies annually.
- In 2013-14, while 181 sleep physicians billed at least one item 12250 service (totalling about 53,000 services nationally), around 35% of these services were performed by less than 10 providers.



Data is by date of processing. Unpublished data (Department of Health).

FIgure 2. Items 12203, 12210 and 12250 - Services by State/Territory - Provider location (2013-14)

Table 14: Lab-based sleep study items 12203 and 12250: Services per 1,000 population

State/Territory	Item 12203	Item 12250
NSW	3.76	3.04
VIC	3.44	2.19
QLD	7.53	2.05
SA	3.81	2.29
WA	3.00	1.39
TAS	2.63	0.00
NT	3.54	1.14
ACT	5.21	1.06

Consultation items billed with home based sleep studies

The following data look at the relationship between sleep studies and attendance with a sleep or respiratory physician before or after testing. The level of involvement of sleep and respiratory physicians in the decision to undergo testing and the development of a management plan following testing is of interest particularly as testing and management move more into primary care. Group A4 consultations are consultant physician attendances and include items 110 and 116.

Table 15 Patients who received a MBS funded consultation (from a sleep and respiratory specialist) up to 3 weeks prior to a service under item 12250 for home-based studies (2012-13)

Approx. patients receiving a 12250 (adult home-based sleep study)[a]	Approx. patients receiving an A4 item (up to 3 weeks prior)	No Group A4 item billed
40,122	4,412 (11%)	35,710 (89%)

Data is by date of service.
a Data extraction period and methodology will influence patient number. Unpublished data (Department of Health).

Table 16: Patients who received a MBS rebated consultation (from a sleep and respiratory specialist) up to 12 months before and/or after a service under item 12250 for home-based studies (2012-13)

Approx. patients receiving a 12250 (adult home-based sleep study)[a]	Group A4 item billed either before and/or after item 12250	No Group A4 item billed
39,386	13,073 (33%)	26,313 (67%)

Data based on date of service and derived specialty.
a Data extraction period and methodology will influence patient number. Unpublished data (Department of Health).

Table 17 Patients who received a MBS rebated consultation (from a sleep and respiratory specialist) up to 12 months before and/or after a service under item 12203 for adult lab-based studies (2012-13)

Approx. patients receiving a 12203 (adult lab-based sleep study)[a]	Group A4 item billed either before and/or after item 12203[b]	No Group A4 item billed
61,760	44,750 (72%)	17,010 (28%)

Data based on date of service and derived specialty.
a A patient may receive up to 3 lab-based studies under item 12203 in a 12 month period.
b Based on the initial 12203 service received. Unpublished data (Department of Health).

Table 18: Patients who received a MBS rebated consultation (from a sleep and respiratory specialist) up to 12 months before and/or after a service under item 12210 for paediatric lab-based studies (2012-13)

Approx. patients receiving a 12210 (child lab-based sleep study)[a]	Group A4 item billed either before and/or after item 12210[b]	No Group A4 item billed
5,839	4,962 (85%)	877 (15%)

Data based on date of service and derived specialty.
a A patient may receive up to 3 lab-based studies under item 12210 in a 12 month period.
b Based on the initial 12210 service received. Unpublished data (Department of Health).

- Approximately, 35,710 patients (89%) did not have a MBS rebated consultant physician consultation (an A4 consultation) in the 3 weeks prior to the home-based investigation.
- Furthermore, about 26,313 patients (67%) did not have a MBS rebated physician consultation within the twelve months (before or after) of the home-based investigation. Of the patients who did have a consultation, about 55% attended the same sleep specialist who billed item 12250.
- Patients who undergo laboratory based studies have a different claiming pattern. Most adult patients undergoing laboratory based studies do attend a physician before or after the test. 44, 750 or 72% of services were associated with a MBS rebated consultation with a sleep or respiratory specialist in the 12 months before or after the sleep study.

Models of care

Generally, but with a few exceptions, laboratory based Level 1 studies have been provided at hospitals, public and private. Home based Level 2 studies are generally community sector services offered by sleep physician practices and, more recently, “sleep disorder businesses”. The provider data below show that most sleep physicians provide largely one or other of the two types of test, rather than offering both. (This is particularly the case with high volume providers).

Table 19: Number of sleep providers who billed item 12203 and/or item 12250 (2012-13)

Item(s) billed	*Providers
12203 only	269
12250 only	180
Both 12203 and 12250	160

*Data based on date of service. Unpublished data (Department of Health).

A large proportion of studies are performed by medical corporates which have varying service models. Most offer testing following GP referral which is typically online, using pro-formas which give information about symptoms and history. This aims to identify patients who have a high pre-test probability for OSA. The technician may elaborate history and record information such as patient weight. The sleep physician has oversight of patient selection and reporting (consistent with MBS requirements). Some practices that perform sleep studies also sell CPAP devices to patients following positive testing. As the MBS data might suggest, the level of involvement of sleep physicians in patient selection for testing and the prescription of therapies is variable.

It should be acknowledged too that large volumes of MBS funded sleep studies are performed in public hospitals. These are usually laboratory based studies (although some public hospitals offer both laboratory and home based studies) and whether patients are admitted or not for the overnight study may depend on whether patients hold private health insurance.

Home based studies can only be MBS rebated once per year and relatively few patients go on to have a laboratory based study following the index home based study. It appears then that patients who have home studies do not undergo formal titration studies when CPAP is fitted. Conversely, many patients who are prescribed CPAP following a laboratory based study undergo MBS rebated overnight laboratory based titration studies.

Discussion and findings

The Committee noted that OSA is a high prevalence condition and the addition of Level 2 sleep studies has enabled better access to testing for adult patients which provides a basis for evidence-based therapies and in particular CPAP.

However, there is concern that better access to testing has been associated with diminished quality for many patients. The Committee noted that a very high proportion of sleep studies are provided by relatively few providers and a very high proportion of patients (67 percent of patients undergoing home studies and 28 percent of patients undergoing laboratory studies) do not have a MBS funded consultation with a specialist physician in the 12 months before or after a sleep study. For these patients, specialist sleep physician input into the assessment and management of patients is limited to remote authorisation of testing and then providing a diagnosis, sometimes with advice about therapy, but without direct clinical assessment.

There is concern that in some sleep study facilities authorisation of testing has occurred in retrospect, often by reporting physicians, and not based on objective clinical assessment or a face to face consultation in clinically uncertain cases.

Further there are reports that advice to proceed to CPAP is made at lower apnoea-hypopnea index (AHI) thresholds than is conventionally recommended as indicative of OSA requiring treatment. Low AHI thresholds are often not supported by evidence of OSA when a clinical assessment is undertaken and other more appropriate treatment modalities may not be considered if a clinical assessment by a qualified sleep physician is not undertaken.

An outcome of the current model of direct GP referral for patients with high pre-test probability of moderate to severe OSA, is that GPs are put at the centre of not only triaging patients to testing but also determining management. The GP members of the Committee suggested that GPs are not confident about managing patients with OSA and, in particular, advising patients on the relative merits of the various therapeutic options including CPAP.

Advice from the Australasian Sleep Association[6] (ASA) suggests that primary care models, whereby *uncomplicated* patients with high pre-test probability of OSA can be managed in a primary care setting using home based studies and without necessarily directly involving a sleep physician, can be appropriate. This model of care requires a "hub and spoke" model with appropriately trained primary care clinicians liaising with and having back-up from sleep medicine specialists. This model is currently not available in Australia but the ASA is working with the RACGP towards the development of a training program.

The Committee agreed that all patients with OSA should have a personalised treatment plan that is directed to managing risk factors as well as, if indicated, appropriate therapies such as CPAP, oral appliances or other measures. Direct GP referred patients who have moderate-high pre-test probability of symptomatic OSA and a well performed sleep study that confirms this, should have a discussion regarding the test results and a treatment plan that is developed following personal attendance with a suitably qualified medical practitioner.

Although many patients with OSA are suitable for direct GP referral to testing, complicated OSA patients, those with overlapping or other sleep disorders and those with low pre-test probability of moderate – severe OSA should be assessed by sleep or respiratory physicians **before** testing. In this setting, follow up would ordinarily occur with the specialist physician who requested the test.

The Committee supports current MBS arrangements that aim to put the sleep or respiratory physician at the centre of determining need for testing (i.e. assessing pre-test probability) and reporting the test. The Committee recommends that appropriately trained medical practitioners discuss the results with the patient and advise on management including CPAP.

The Committee expressed concern about conflicts of interest that arise when sleep study practices that perform tests also sell CPAP devices. This is not limited to medical corporates. The ASA has advocated for the regulated "prescription"' of CPAP devices by sleep physicians and although the Committee accepts that clinician input is desirable it notes that, unlike medicines, there are no existing regulatory levers that could mandate this. However, medical practitioners are bound by the Medical Board of Australia's code of conduct which makes clear the obligations around managing conflicts of interest and the sale or endorsement of medical devices. Clause 8.12 requires "declaring

to your patients your professional and financial interest in any product you might endorse or sell from your practice, and not making an unjustifiable profit from the sale or endorsement". The Committee notes that although a reporting sleep physician may be independent from the company providing the test and selling CPAP equipment, if a high volume of sleep reporting is performed for the company then their interests are closely linked with those of the company.

The Committee agreed that given the lack of outcomes data, it is not known whether the current MBS model delivers both very good access to patients who are well triaged to testing and then the most appropriate treatment that provides benefit; or alternatively, access to low value testing and commencement on CPAP which in some cases is not clinically indicated and does not address their sleep related problem. In this latter scenario, patients purchase CPAP devices that may deliver little benefit, often based on advice from non-health professionals, and with no medical consultation involved. Patients may also be advised by non-health professionals to purchase a more expensive "APAP" machine, when a simpler and cheaper CPAP device may be sufficient.

The Committee expressed concern about the high volumes of testing in some practices. The ASA has developed guidelines about clinical aspects of testing and also practice standards. The ASA supports practice accreditation noting that currently there is no industry wide assurance that the quality of testing is high.

Recommendations

The Committee recommends that there be a number of changes to adult MBS funded sleep studies that aim to improve the clinical value of sleep studies. Specifically, the proposals aim to:

1. Improve the triage of patients to testing, supporting direct GP referral through use of validated clinical assessment tools that identify uncomplicated patients with high pre-test probability of symptomatic moderate to severe OSA. Respiratory physicians will be able to authorise testing as well as qualified sleep medicine practitioners.
2. Retain the ability of respiratory and sleep physicians, following personal consultation with a patient, to determine whether testing is needed and if so what type of test, for patients with an expanded range of sleep disorders. Clinical indications for testing are linked to ASA guidelines.
3. Ensure that patients are triaged to the most appropriate test recognising that many uncomplicated OSA patients should undergo Level 2 unattended diagnostic studies, but that the doctor-patient assessment and interaction is critical to determine the appropriate test for patients and that service models need to evolve to meet this need. Level 1 studies are more resource intensive and with those resources redeployed to providing Level 2 studies, overall more patients who require testing will be able to access testing.
4. Provide a suite of items that distinguish between diagnostic and other studies to provide a stronger link between testing and physician management of patients with proven sleep disorders and to enable better data collection. In particular, identifying laboratory based titration studies will assist in future consideration of CPAP titration in community settings. For instance, technology evolution means that many patients now purchase auto-titration (APAP) devices, or commence CPAP using an APAP device before switching to fixed pressure CPAP. The

Committee recommends the development of an item number for APAP titration to be used for uncomplicated patients as a means of determining fixed pressure CPAP requirements without the need for an in laboratory CPAP titration sleep study (see discussion below).

5. Provide reasonable limits on the frequency of testing with each item payable only once annually. The Committee considers that diagnostic and treatment initiation testing should not be repeated without good clinical indication and it would be rare for patients to have need for further testing within 3 to 5 years of initial diagnostic testing. It suggests that MBS data should be monitored and if concern arises that there is unnecessary repeat testing, then additional limits on testing intervals should be considered.
6. Ensure that patients who have a sleep disorder proven on diagnostic testing are personally assessed in a face to face or video enabled consultation and advised on management options by appropriately skilled medical professionals.
7. Strengthen quality requirements in relation to the performance of testing and the supervision of testing by qualified sleep medicine practitioners (as defined in current regulations that remain unchanged). Practice accreditation as a condition of MBS funding has not been recommended.

Proposed new adult sleep study items

As well as recommending changes to the existing adult sleep study items the Committee discussed and recommends the addition of two new MBS services. The Committee recognise that both proposals require additional development (including evidence gathering) and evaluation that is beyond the scope of the Committee process.

Unattended APAP titration

As noted above, many patients who are recommended CPAP can safely undergo home APAP titration as an alternative to laboratory based titration. Home APAP can be used to determine the pressure for fixed pressure CPAP devices or to set up patients who elect to use a more expensive autotitrating device in the long term. Home based APAP titration has been proven to be cost effective relative to laboratory based titration and in the Australian setting.[7]

APAP titration is already used in Australia but the number of patients who are titrated using this approach is unknown. Currently, unattended diagnostic sleep studies can only be performed annually and very few patients who undergo an unattended study (item 12250) undergo a subsequent attended study (item 12203). It seems that most patients who are prescribed CPAP following an unattended study undergo a titration study as part of the fitting of the CPAP or APAP device and the cost is subsumed into the device cost. In some public sector facilities, home APAP titration is funded through hospital budgets and/or by a small patient fee, noting that most of the input cost is non-medical professional staff time.

The introduction of an unattended APAP titration MBS item would complement a general move to unattended testing for less complex patients. By directing such patients away from Level 1 laboratory based testing, more resources would be available for necessary laboratory based

diagnostic testing and treatment initiation for more complex patients. The availability of unattended APAP would also enable many uncomplicated OSA patients to have both their diagnostic and treatment studies at home, also including clinician assessment for both tests. This is likely to be more time and cost efficient.

The Committee noted that the recommended changes to existing adult sleep studies (item 12203 and 12250) may impact on current service models. For this reason, it may be preferable to review the impact of those changes before adding unattended APAP titration to the MBS, particularly as the unmet need for this item and hence number of new MBS services is uncertain. The Committee recommends that this review takes place 2-3 years after introduction of the revised adult sleep study items.

Vigilance testing

Vigilance testing refers to the assessment of excessive daytime sleepiness or the ability to maintain alertness using tests including the Multiple Sleep Latency Test (MSLT) and the Maintenance of Wakefulness Test (MWT). The usual indication for these tests is to establish a diagnosis of central nervous system hypersomnolence, to assess eligibility for PBS listed medicines in the management of narcolepsy and for the assessment of either hypersomnolence or the ability to maintain alertness where there is a safety concern (for example, commercial drivers with sleep disorders).

There are no MBS items for vigilance testing but practitioners are using combinations of various items to provide MBS rebates for vigilance testing (and sometimes outside of the requirements for these items).

The ASA has proposed that there be specific MBS items for MSLT and MWT that are to be used in combination with existing sleep items to confirm the diagnosis of excessive daytime sleepiness or a patient's capacity to maintain wakefulness. The ASA base their proposal on the standards developed by the American Academy of Sleep Medicine.[8]

One of the challenges in trying to progress this proposal through the Committee process is that the specific proposal is much broader than the commonly understood (and confined) role of these tests. For instance, it is estimated that excessive sleepiness affects approximately 5 percent of the population. It also involves a new test that is not specifically funded currently.

The Committee recommend that vigilance testing be evaluated by MSAC with view to it being specifically MBS funded. It notes that MSAC's evaluation is proportionate to the clinical and financial risk of the proposed new service and if the patient population for the proposed service can be well defined (and confined), a "light touch" appraisal may be appropriate.

The Committee also noted that the MBS does not fund employment related medical services. Assessment of commercial drivers for licensing purposes may not be an MBS rebateable service.

6.2 Paediatric Sleep Studies

A Paediatric Sleep Studies Working Group was convened to review the MBS paediatric sleep items and relevant data and consider whether any amendments are required or whether on balance, the current items are supporting good access to high value services.

Background

The four paediatric attended sleep study items were introduced to the MBS from 1 November 2001. These items recognised that paediatric sleep studies require a different and more complex investigation to that of adults, with broader indications than adult studies. This complexity manifests in several ways:

- Physicians required additional training and accreditation to conduct paediatric sleep studies.
- Assessment of the studies takes longer.
- Additional staff are required for paediatric sleep studies including a paediatric trained nurse for the duration.
- Additional equipment is required.

The paediatric attended sleep study items have higher MBS fees and rebates than the corresponding adult attended items. Within the paediatric grouping the fees and rebates are higher for studies performed on 0 to 12 year olds compared to 12 to 18 year olds reflecting the different resourcing requirements.

In 2011, although MSAC supported MBS funding for unattended Level 2 sleep studies for adults, it did not support MBS funding for unattended studies for paediatric patients.

The MBS item descriptors for the four paediatric sleep study items are at Appendix A and the table below provides relevant MBS data.

MBS data paediatric sleep – items 12210, 12213, 12215 and12217

Table 20: Key statistics for items 12210, 12213, 12215 and 12217 (by date of processing)

Statistic	12210	12213	12215	12217
Schedule fee	$701.85	$632.30	$701.85	$632.30
Total Benefits paid 2014-15	$4,155,302	$965,925	$4,375	$3,246
Number of services 2014-15	7,179	1,842	7	6
% services provided out-of-hospital 2014-15	51.90%	61.50%	100.00%	83.30%
Bulk-billing rate for out-of-hospital services 2014-15	89.80%	91.20%	100.00%	100.00%
Total Patient count 2014-15	6,800	1,728	5	6
Total provider count 2014-15	48	171	4	4
Benefits Change (%) from 2009-10 to 2014-15	33.00%	56.00%	-74.00%	108.00%
Service Change (%) from 2009-10 to 2014-15	27.00%	48.00%	-76.00%	100.00%

Unpublished data (Department of Health)

Discussion and Recommendations

Members agreed that the existing MBS paediatric sleep study item descriptors reflect current clinical practice. In particular, members suggested that it remains appropriate to confine MBS funded testing to attended level one studies. Members agreed that the proposed changes to the principal adult items (12203 and 12250) are not relevant to paediatric practice.

A key concern for providers of paediatric sleep studies is the capacity of current laboratories to meet growing clinical need. Most paediatric sleep studies are performed within public sector childrens' hospitals and capacity constraints mean that the volume of testing has not increased significantly over time. Members noted that paediatric sleep studies are more labour intensive than adult studies and that staffing requirements limit the number of paediatric studies which can be undertaken. It was acknowledged that the additional staffing requirements relate to salaried staff, and in particular nursing staff, rather than a shortfall in paediatric respiratory physicians.

Members discussed whether the current age ranges specified in item descriptors remain clinically appropriate. Age is an important factor in planning and prioritising paediatric patients for sleep studies. Younger children particularly under four year olds, may require higher staffing ratios compared to older (although older children with complex medical conditions also frequently require higher staffing ratios). It has been proposed by some paediatric sleep physicians that the current two tier system of MBS fees and rebates be replaced with a three tier system (age 0 to 6, 6 to 12 and 12 to 18). Members noted that changes to accommodate a revision to the paediatric items to reflect the complexity of services by age of patient could be considered within a cost neutral envelope. For example, the MBS fee for the more straightforward paediatric sleep study items could be reduced, with a commensurate increase to the MBS fee for the more labour intensive items. Overall, the Working Group does not recommend a move away from the current two tiered structure.

The role of overnight pulse oximetry testing for children was discussed (level 4 sleep studies). It was noted that pulse oximetry is commonly used as a tool for triaging long waiting lists for polysomnography. Whilst it is straightforward and usually performed at home after training of a parent, it is prolonged and requires specialist interpretation. It is a useful study when positive as it enables direct referral for surgical intervention (for instance adeno-tonsillectomy) when indicated without the need for attended polysomnography. It is also useful in determining safety of oxygen titration in children with oxygen-dependent complex lung disease. Members noted that a change to support oximetry would support good access to high value services by shortening waiting lists. The paediatric sleep physician members asked if a change in wording to the criteria for 11503 (complex respiratory function testing) would enable such testing to be supported. Other members questioned whether this proposal was relevant to 11503 given that it is not proposed that the pulse oximetry be performed in a respiratory laboratory. The Paediatric Sleep Studies Working Group and the Committee recommend that merits of overnight pulse oximetry (Level 4 sleep studies) in paediatrics should evaluated by MSAC. The Committee do not recommend that pulse oximetry in children be covered under item 11503.

Members considered whether home based sleep studies for patients in the 12-18 age group were appropriate. However, they agreed that the complexities of the clinical conditions being diagnosed and treated rendered home based studies for this group unsuitable for the majority of cases. The Working Group recommends that at the current time, the current age thresholds for home based sleep studies continue.

The Paediatric Sleep Studies Working Group supports the proposal that vigilance testing should be MBS funded, noting that it has a role in the assessment of children as well as adults. The role of APAP titration in children/adolescents should also be assessed as part of the proposal for support of that testing.

Recommendation 3: *Adult sleep study item descriptors and explanatory notes*

The Committee has proposed the following changes to the descriptor for attended sleep study – diagnostic – Item 12203:

Current Item Descriptor – Item 12203

Overnight investigation for sleep apnoea for a period of at least 8 hours duration, for an adult aged 18 years and over where:

(a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG, EOG, submental EMG, anterior tibial EMG, respiratory movement, airflow, oxygen saturation and ECG are performed;

(b) a technician is in continuous attendance under the supervision of a qualified sleep medicine practitioner;

(c) the patient is referred by a medical practitioner;

(d) the necessity for the investigation is determined by a qualified adult sleep medicine practitioner prior to the investigation;

(e) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events and assessment of clinically significant alterations in heart rate and limb movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report ; and

(f) interpretation and report are provided by a qualified adult sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient

payable only in relation to each of the first 3 occasions the investigation is performed in any 12 month period.

(See para D1.18 of explanatory notes to this Category)

Fee: $588.00

Benefit: 75% = $441.00; 85% = $509.60

Proposed new Item Descriptor – 12203

Overnight diagnostic assessment of sleep for a period of at least 8 hours duration in an adult aged 18 years and over to confirm diagnosis of a sleep disorder where:

(a) the patient has been referred by a medical practitioner to a qualified adult sleep medicine practitioner or a consultant respiratory physician who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea using the following screening tools:

  (i) an Epworth Sleepiness Scale score of 8 or more; AND
  (ii) one of the following
    - a STOP-BANG score of 5 or more; or
    - an OSA-50 score of 5 or more; or
    - a high risk score on the Berlin Questionnaire.

OR

(b) Following personal attendance, a qualified adult sleep medicine practitioner or a consultant respiratory physician determines that testing to confirm the diagnosis of a sleep disorder is necessary,

AND

(c) the overnight investigation is performed for:

  (iii) suspected obstructive sleep apnoea syndrome where the patient is assessed as not suitable for an unattended sleep study or
  (iv) suspected central sleep apnoea syndrome; or
  (v) suspected sleep hypoventilation syndrome; or
  (vi) suspected sleep-related breathing disorders in association with non-respiratory co-morbid conditions including heart failure, significant cardiac arrhythmias, neurological disease, acromegaly or hypothyroidism; or
  (vii) unexplained hypersomnolence which is not attributed to inadequate sleep hygiene or environmental factors; or
  (viii) suspected parasomnia or seizure disorder where clinical diagnosis cannot be established on clinical features alone (including associated atypical features, vigilance behaviours or failure to respond to conventional therapy); or
  (ix) suspected sleep related movement disorder, where the diagnosis of restless legs syndrome is not evident on clinical assessment;

AND

(d) a sleep technician is in continuous attendance under the supervision of a qualified sleep medicine practitioner;

AND

(e) continuous monitoring and recording of the following studies which are to be performed in accordance with current Australasian Sleep Association guidelines for the performance of Type I sleep studies:

  (i) airflow;
  (ii) submental electro-myogram (EMG);
  (iii) anterior tibial electro-myogram (EMG);
  (iv) continuous electro-cardiogram (ECG);

(v) continuous electro-encephalogram (EEG);
(vi) electro-oculogram (EOG);
(vii) oxygen saturation;
(viii) respiratory movement (chest and abdomen);
(ix) position;

AND

(f) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events, cardiac abnormalities and limb movements) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report;

AND

(g) interpretation and preparation of a permanent report is provided by a qualified adult sleep medicine practitioner with direct review of raw data from the original recording of polygraphic data from the patient.

Not payable on same occasion of service with items x, y z etc

Payable only once in a 12 month period. A second attended sleep study is permitted, when required immediately prior to vigilance testing.

The Committee has proposed the following changes to the item descriptor for unattended sleep study – diagnostic – Item 12250.

Current Item Descriptor – Item 12250

Overnight investigation for sleep apnoea for a period of at least 8 hours duration for a patient aged 18 years or more, if all of the following requirements are met:

(a) the patient has, before the overnight investigation, been referred to a qualified adult sleep medicine practitioner by a medical practitioner whose clinical opinion is that there is a high probability that the patient has obstructive sleep apnoea; and

(b) the investigation takes place after the qualified adult sleep medicine practitioner has:
(i) confirmed the necessity for the investigation; and
(ii) communicated this confirmation to the referring medical practitioner; and

(c) during a period of sleep, the investigation involves recording a minimum of seven physiological parameters which must include:
(i) continuous electro-encephalogram (EEG); and
(ii) continuous electro-cardiogram (ECG; and
(iii) airflow; and
(iv) thoraco-abdominal movement; and
(v) oxygen saturation; and
(vi) 2 or more of the following:
(A) electro-oculogram (EOG);
(B) chin electro-myogram (EMG);
(C) body position; and

(d) in the report on of the investigation, the qualified adult sleep medicine practitioner uses the data specified in paragraph (c) to:

(i) analyse sleep stage, arousals and respiratory events; and
(ii) assess clinically significant alteration in heart rate; and

(e) the qualified adult sleep medicine practitioner:

(i) before the investigation takes place, establishes quality assurance procedures for data acquisition; and
(ii) personally analyses the data and writes the report on the results of the investigation;

(f) the investigation is not provided to the patient on the same occasion as a service mentioned in any of items 11000 to 11005, 11503, 11700 to 11709, 11713 and 12203 is provided to the patient

Payable only once in a 12 month period

(See para D1.18 of explanatory notes to this Category)

Fee: $335.30

Benefit: 75% = $251.50 85% = $285.05

Proposed new Item Descriptor – 12250

Overnight investigation of sleep for a period of at least 8 hours in a patient aged 18 years or over to confirm diagnosis of obstructive sleep apnoea, where:

(a) the patient has been referred by a medical practitioner to a qualified adult sleep medicine practitioner or a consultant respiratory physician who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea using the following screening tools:

(i) an Epworth Sleepiness Scale score of 8 or more; AND
(ii) one of the following:
- a STOP-BANG score of 5 or more; or
- an OSA-50 score of 5 or more; or
- a high risk score on the Berlin Questionnaire.

OR

(b) Following personal attendance, a qualified adult sleep medicine practitioner or a consultant respiratory physician determines that testing to confirm the diagnosis of obstructive sleep apnoea is necessary;

AND

(c) during a period of sleep, the investigation involves the monitoring of at least seven physiological parameters which must include:

(i) airflow; and
(ii) chin electro-myogram (EMG); and
(iii) continuous electro-cardiogram (ECG); and

(iv) continuous electro-encephalogram (EEG); and
(v) electro-oculogram (EOG); and
(vi) oxygen saturation; and
(vii) respiratory effort.

AND

(d) The investigation is performed under the supervision of an accredited sleep medicine practitioner; AND

(e) The equipment is applied to the patient by trained technicians; AND

(f) Polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events and cardiac abnormalities) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report; AND

(g) Interpretation and preparation of a permanent report is provided by a qualified adult sleep medicine practitioner with direct review of raw data from the original recording of polygraphic data from the patient.

Not to be provided on the same occasion as a service mentioned in any of items 11000 to 11005, 11503, 11700 to 11709, 11713 and 12203 is provided to the patient.

Payable once in a 12 month period.

Proposed explanatory notes for items 12250 and 12203

Items 12250 and 12203 are applicable for patients who have not been previously diagnosed with a sleep disorder. They enable direct GP referral to testing without personal assessment by a sleep or respiratory physician, when validated screening tools suggest a high pre-test probability for diagnosis of symptomatic, moderate to severe OSA. The screening questionnaires must be administered by the referring practitioner. Alternatively, the need for testing can be determined by a sleep or respiratory physician following direct clinical assessment.

Determination of the need for testing should conform with Australasian Sleep Association guidelines.

Unattended sleep studies are suitable for many patients with suspected OSA but patients with other sleep disorders should undergo an attended study.

Assessment for potential contraindications to an unattended sleep study can be undertaken by either the referring practitioner, qualified adult sleep medicine practitioner or consultant respiratory physician. Standardised referrals should request sufficient information to enable such assessment.

In accordance with the Australasian Sleep Association's Guidelines for Sleep Studies in Adults, relative contraindications for an unattended sleep study to investigate suspected OSA include but are not limited to:

(a) intellectual disability or cognitive impairment;

(b) physical disability with inadequate carer attendance;

(c) significant co-morbid conditions including neuromuscular disease, heart failure or advanced respiratory disease where more complex disorders are likely;

(d) suspected respiratory failure where attended measurements are required, including measurement of carbon dioxide partial pressures;

(e) suspected parasomnia or seizure disorder;

(f) suspected condition where recording of body position is considered to be essential and would not be recorded as part of an unattended sleep study;

(g) previously failed or inconclusive unattended sleep study;

(h) unsuitable home environment including unsafe environments or where patients are homeless; and

(i) consumer preference based on a high level of anxiety about location of study or where there is unreasonable cost or disruption based on distance to be travelled, or home circumstances;

Patients who have these features may be suitable for either attended (Level 1) or unattended (Level 2) studies.

The results and treatment options following any diagnostic sleep study should be discussed during a professional attendance with a medical practitioner before the initiation of any therapy. If there is uncertainty about the significance of test results or the appropriate management for that individual then referral to a sleep or respiratory medicine specialist is recommended.

Any personal attendance by a qualified adult sleep medicine practitioner or consultant respiratory physician associated with this service may be undertaken face-to-face or by video conference.

The Committee has proposed the following new item descriptor for new attended adult treatment initiation study item 122XX.

Overnight assessment of positive airway pressure for a period of at least 8 hours duration in an adult aged over 18 where:

(a) the necessity for an intervention sleep study is determined by a qualified adult sleep medicine practitioner or consultant respiratory physician where a diagnosis of a sleep-related breathing disorder has been made; and the patient has not undergone positive airways pressure therapy in the previous 6 months; and

(b) the patient has had a professional attendance (either face-to-face or by video conference) and it is established that the sleep-related breathing disorder is responsible for symptoms; and

(c) a sleep technician is in continuous attendance under the supervision of a qualified sleep medicine practitioner; and

(d) continuous monitoring and recording of the following studies which are to be performed in accordance with current Australasian Sleep Association guidelines for the performance of Type I sleep studies:

    (i) continuous electro-encephalogram (EEG);

(ii) electro-oculogram (EOG);
(iii) submental electro-myogram (EMG);
(iv) anterior tibial (EMG);
(v) respiratory movement;
(vi) airflow;
(vii) oxygen saturation;
(viii) position;

(e) continuous electro-cardiogram (ECG); and

(f) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events, cardiac abnormalities and limb movements) with manual scoring, or manual correction of computerised scoring in epochs not more than one minute, and the data are stored for interpretation and preparation of a report; and

(g) interpretation and preparation of a permanent report are provided by a qualified adult sleep medicine practitioner with direct review of raw data from the original recording of polygraphic data from the patient.

One in a 12-month period.

The Committee has proposed the following item descriptor and explanatory notes for new attended treatment effectiveness study (assessment of specific interventions) item 122XX.

Proposed new Item Descriptor

Follow up study for an adult patient aged over 18 with a sleep- related breathing disorder, following professional attendance with a sleep or respiratory specialist where

Δ there has been a recurrence of symptoms not explained by known or identifiable factors such as inadequate usage of treatment, sleep duration or significant recent illness; or

(i) There has been a significant change in weight or changes in co-morbid conditions that could affect sleep-related breathing disorders, and
(ii) Other means of assessing treatment efficacy (including review of data stored by the therapy device) are unavailable, or have been unhelpful
(iii) The data acquisition and analysis requirements as described in item 12203 are met.

One in a 12 month period.

Proposed explanatory notes for item 122XX

The necessity for a treatment effectiveness sleep study is determined by a qualified adult sleep medicine practitioner or consultant respiratory physician where

(a) the patient has undergone a therapeutic intervention including but not limited to PAP, upper airway surgery, appropriate oral appliance, ≥10% weight loss in the previous 6 months, AND

(b) There is clinical evidence of sub-optimal response, OR uncertainty regarding control of sleep disordered breathing.

7. Diagnostic and therapeutic procedures – lung, trachea and bronchus

Seven items for sleep study are considered in this section:

- Δ **30696** Endoscopic Ultrasound Guided Fine Needle Aspiration Biopsy(s)
- Δ **30710** Endobronchial Ultrasound Guided Biopsy(s)
- Δ **41889** Bronchoscopy
- Δ **41892** Bronchoscopy with Endobronchial biopsies or diagnostic/therapeutic procedures
- Δ **41895** Bronchus, removal of foreign body
- Δ **41898** Fibreoptic Bronchoscopy
- Δ **41905** Trachea or Bronchus, dilatation of stricture and endoscopic insertion of stent

7.1 Therapeutic procedures – bronchus and trachea

These items were only briefly reviewed by the Committee. Members suggested that the fee relativity between items 41895 and items 41892 and 41898 is not correct noting that the complexity of the three services is similar. There could be some room for consolidation of these items. The Committee noted that the MBS fees for these items are low, taking account of the complexity of the services. No specific recommendations were made and it was agreed that these items could be more closely reviewed during a future MBS review.

MBS data on therapeutic procedures - bronchus and trachea

Table 21: High level MBS data on therapeutic procedures - items 41889, 41892, 41895, 41898 and 41905 2014-15

Statistic	41889	41892	41895	41898	41905
Number of services	1,570	10,185	88	1,604	221
Benefits	$196,091	$1,611,556	$21,952	$315,045	$60,182
Number of providers	401	621	46	244	33
Number of patients	1,455	9,069	78	1,502	121
% out of hospital (OOH)	37.26%	21.73%	0.00%	26.50%	0.00%
Bulk-billing rate for out-of-hospital services	99.83%	98.55%	0.00%	99.76%	0.00%
Average fee charged (OOH)	$275.00	$0.00	n/a	$0.00	n/a

Unpublished data (Department of Health)

Table 22 Key statistics on therapeutic procedures - items 41889, 41892, 41895, 41898 & 41905

Item Number	Short item descriptor	Benefits Change (%) from 2009-10 to 2014-15	Service Change (%) from 2009-10 to 2014-15	Item Start Date	Item Description Start Date
41889	Bronchoscopy, as an independent procedure	50%	24%	1 Dec 1991	1 Dec 1991
41892	Bronchoscopy with 1 or more endobronchial biopsies or other diagnostic or therapeutic procedures	50%	44%	1 Dec 1991	1 Dec 1991
41895	Removal of foreign body in bronchus	77%	69%	1 Dec 1991	1 Dec 1991
41898	Fibreoptic bronchoscopy with 1 or more transbronchial lung biopsies, with or without bronchial or bronchoalveolar lavage, with or without the use of interventional imaging	29%	17%	1 Dec 1991	1 Dec 1991
41905	Insertion of stent Trachea or bronchus, dilatation of stricture and endoscopic	479%	531%	1 Nov 1995	1 Nov 1995

Unpublished data (Department of Health)

7.2 Lung cancer biopsy items

Two items for lung cancer biopsy were added to the MBS in 2009 following MSAC appraisal. No specific issues were identified and hence no detailed review undertaken.

MBS data on biopsy of lung cancer items

Table 23: High level MBS data on biopsy of lung cancer items 30696 and 30710, 2014-15

Statistic	30696	30710
Number of services	630	1,823
Benefits	$291,623	$828,283
Number of providers	46	111
Number of patients	630	1,770
% out of hospital (OOH)	62.4%	50.3%
Bulk-billing rate for OOH services	99.7%	99.8%
Average fee charged (OOH)	$813.30	$681.70

Unpublished data (Department of Health)

Recommendation 4: ***Diagnostic and therapeutic procedures – lung, trachea and bronchus***

The Committee recommended no changes to the items in this section:

- Δ **30696** Endoscopic Ultrasound Guided Fine Needle Aspiration Biopsy(s)
- Δ **30710** Endobronchial Ultrasound Guided Biopsy(s)
- Δ **41889** Bronchoscopy
- Δ **41892** Bronchoscopy with Endobronchial biopsies or diagnostic/therapeutic procedures
- Δ **41895** Bronchus, removal of foreign body
- Δ **41898** Fibreoptic Bronchoscopy
- Δ **41905** Trachea or Bronchus, dilatation of stricture and endoscopic insertion of stent.

8. Obsolete items

After a review of the items assigned to the Committee, the associated MBS data and based on consultations with colleagues, the Committee has identified two MBS items as obsolete, i.e. the item has no clinical purpose in contemporary practice as it has been superseded by another service or procedure or the service identified is better covered under another item.

The two items are:

- Δ **11500** Bronchospirometry
- Δ **11509** Spirometry in a respiratory laboratory

8.1 Item 11500 – Bronchospirometry, including gas analysis

The Committee suggested that this low volume item does not describe a contemporary service and clinical need for this is covered by a range of appropriate respiratory function tests provided under items 11503, 11506 and 11512. Following public consultation, in February 2016, the MBS Review Taskforce endorsed this recommendation.

Table 24: High level MBS data on bronchospirometry item 11500, 2014-15 (date of processing)

Statistic	Amount
Schedule fee	$167.00
Total benefits paid 2014-15	$138,808
Number of services 2014-15	1,026
% of services provided out-of-hospital 2014-15	55.70%
Bulk-billing rate for out-of-hospital services 2014-15	54.60%
Total patient count 2014-15	979
Total provider count 2014-15	20
Benefits change (%) from 2009-10 to 2014-15	60.60%
Service change (%) from 2009-10 to 2014-15	55.90%

Unpublished data (Department of Health)

8.2 Item 11509 – Spirometry in a respiratory laboratory

Item 11509 provides for measurement of respiratory function involving a permanently recorded tracing and written report.

MBS data relating to item 11509

Table 25: High level MBS data on spirometry item 11509, 2014-15 (date of processing)

Statistic	Amount
Schedule fee	$35.65
Total benefits paid 2014-15	$519,845
Number of services 2014-15	16,804
% of services provided out-of-hospital 2014-15	99.50%
Bulk-billing rate for out-of-hospital services 2014-15	65.50%
Total patient count 2014-15	11,486
Total provider count 2014-15	254
Benefits change (%) from 2009-10 to 2014-15	7.10%
Service change (%) from 2009-10 to 2014-15	1.50%

Unpublished data (Department of Health)

Rationale

Items 11509 and 11506 describe the same service (pre and post bronchodilator spirometry) performed in different settings. Item 11506 is an office based test mainly used in primary care, while item 11509 must be performed in a laboratory and is largely confined to specialist practice.

Although item 11509 is not a low volume item (16,804 services in 2014-15), the Committee suggests that the item is redundant as technology advances mean that the spirometry devices used in laboratory settings provide what is described in item 11512. More straightforward pre and post bronchodilator spirometry (outside of a laboratory setting) is covered under 11506. Hence, the Committee recommended that item 11509 be removed.

Recommendation 5: *Obsolete items*

The Committee recommended deleting items 11500 and 11509.

9. Generic issues

The Committee identified a number of issues which were not specific to Thoracic Medicine. These issues relate to low value care; services being undertaken out of Australia and undertaking a review of recommended changes. These issues are being considered by the Taskforce.

Recommendation 6: ***Generic issues***

- **Low value care:** The Committee agreed that identifying and reducing the use of health care interventions that deliver marginal benefit, be it through overuse, misuse or waste is important. Conversely, some MBS funded services are underused, which in turn may compromise patient care.
- **Services being undertaken out of Australia:** The Committee understands that data from unattended sleep studies (12250) is being processed outside of Australia and expressed concerns that this practice may compromise quality services provision. The Committee noted that Section 10 of the *Health Insurance Act 1973* (the Act) precludes the payment of a Medicare benefit where any component of a service is performed offshore. The Committee strongly supports the principle that underpins the legislation and in the case of sleep studies advise that the whole service, including the acquisition and reporting of data, should be performed in Australia to provide the necessary quality assurance. The Committee noted however that any concern about services being undertaken outside of Australia is a Medicare compliance issue and is outside their remit.
- **Review of the recommended changes:** The Committee suggests that should its recommendations be endorsed by the MBS Review Taskforce and in turn adopted by government, then the impact of these changes should be evaluated and that a suitable time frame for review would be two to three years following implementation.

10. Recommendations Impact Statement

The recommendations relating to spirometry, complex respiratory function tests and sleep studies will ensure that patients have access to MBS services that reflect modern clinical practices. They also update the MBS items to capture the current scope of the procedure being performed. The removal of MBS items which are out dated and no longer reflect modern clinical practice will encourage practitioners to provide services that are recognised by the relevant profession as reflecting current clinical practice. Practitioners will also benefit from the consolidation of some services which should minimise confusion when billing MBS items.

11. References

This contains references to sources and materials referenced in this report.

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12. Acronyms and Abbreviation

Term	Description
6MWT	Six Minute Walk Test
AAH	Australian Asthma Handbook
ABS	Australian Bureau of Statistics
APAP	Automatic Positive Airway Pressure
ASA	Australasian Sleep Association
ACOS	Asthma-COPD Overlap Syndrome
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous Positive Airway Pressure
CPET	Cardiopulmonary Exercise Testing
CPG	Clinical Practice Guidelines
ECG	Continuous Electro-Cardiogram
EOG	Electro-Oculogram
EMG	Anterior Tibial Electro-Myogram
FeNO	Fraction of Exhaled Nitric Oxide
FEV1	Forced Expiratory Volume
FEV1%	FEV1/FVC Ratio
GOLD	Global Initiative for Obstructive Lung Disease
GP	General Practitioner
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NAC	National Asthma Council
NICE	National Institute for Health and Care Excellence
OOH	Out of Hospital
OSA	Obstructive Sleep Apnoea
PAP	Positive Airway Pressure
PIP	Practice Incentive Program
PNIP	Practice Nurse Incentive Program
RACGP	Royal Australian College of General Practitioners
TMCC	Thoracic Medicine Clinical Committee
VCO_2	Carbon Dioxide Output
VE	Minute Ventilation
VO_2	Oxygen Uptake
VT	Tidal Volume

13. Glossary

Term	Description
ACSQHC	Australian Commission on Safety and Quality in Health Care
COPD-X	Australian and New Zealand Guidelines for the management of Chronic Obstructive Pulmonary Disease
Department, The	Australian Government Department of Health
DHS	Australian Government Department of Human Services
GP	General practitioner
High-value care	Services of proven efficacy reflecting current best medical practice, or for which the potential benefit to consumers exceeds the risk and costs.
Inappropriate use / misuse	The use of MBS services for purposes other than those intended. This includes a range of behaviours ranging from failing to adhere to particular item descriptors or rules, through to deliberate fraud.
Low-value care	The use of an intervention which evidence suggests confers no or very little benefit on patients, or that the risk of harm exceeds the likely benefit, or, more broadly, that the added costs of the intervention do not provide proportional added benefits.
MBS item	An administrative object listed in the MBS and used for the purposes of claiming and paying Medicare benefits, comprising an item number, service descriptor and supporting information, Schedule fee and Medicare benefits.
MBS service	The actual medical consultation, procedure, test to which the relevant MBS item refers.
MSAC	Medical Services Advisory Committee
Multiple operation rule	A rule governing the amount of Medicare benefit payable for multiple operations performed on a patient on the one occasion. In general, the fees for two or more operations are calculated by the following rule: Δ 100% for the item with the greatest Schedule fee Δ plus 50% for the item with the next greatest Schedule fee Δ plus 25% for each other item.
Multiple services rules (diagnostic imaging)	A set of rules governing the amount of Medicare benefit payable for multiple diagnostic imaging services provided to a patient at the same attendance (same day). See MBS Explanatory Note DIJ for more information.
Obsolete services	Services that should no longer be performed as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
Pathology episode coning	An arrangement governing the amount of Medicare benefit payable for multiple pathology services performed in a single patient episode. When more than three pathology services are requested by a general practitioner in a patient episode, the benefits payable are equivalent to the sum of the benefits for the three items with the highest Schedule fees.
PBS	Pharmaceutical Benefits Scheme

Appendix A MBS items, Descriptors and Explanatory Notes

Respiratory function tests

11500

BRONCHOSPIROMETRY, including gas analysis

Fee: $167.00

Benefit: 75% = $125.25; 85% = $141.95

11503

Measurement of the:

(a) mechanical or gas exchange function of the respiratory system; or

(b) respiratory muscle function; or

(c) ventilatory control mechanisms.

Various measurement parameters may be used including any of the following:

(a) pressures;

(b) volumes;

(c) flow;

(d) gas concentrations in inspired or expired air;

(e) alveolar gas or blood;

(f) electrical activity of muscles.

The tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital. Each occasion at which 1 or more such tests are performed, not being a service associated with a service to which item 22018 applies.

(See para D1.14 of explanatory notes to this Category)

Fee: $138.65

Benefit: 75% = $104.00; 85% = $117.90

Explanatory note for Respiratory Function Test Item 11503

D.1.14.

The investigations listed hereunder would attract benefits under Item 11503. This list has been prepared in consultation with the Thoracic Society of Australia and New Zealand.

(a) Carbon monoxide diffusing capacity by any method

(b) Absolute lung volumes by any method

(c) Assessment of arterial carbon dioxide tension or cardiac output - re breathing method

(d) Assessment of pulmonary distensibility involving measurement of lung volumes and oesophageal pressure

(e) Measurement of airway or pulmonary resistance by any method

(f) Measurement of respiratory muscle strength involving the measurement of trans-diaphragmatic or oesophageal pressures

(g) Assessment of phrenic nerve function involving percutaneous stimulation and measurement of the compound action potential of the diaphragm

(h) Measurement of the resistance of the anterior nares or pharynx

(i) Inhalation provocation testing, including pre-provocation spirometry, the construction of a dose response curve, using histamine, cholinergic agents, non-isotonic fluids or powder and post-bronchodilator spirometry

(j) Exercise testing using incremental workloads with monitoring of ventilatory and cardiac responses at rest, during exercise and recovery on premises equipped with a mechanical ventilator and defibrillator

(k) Tests of distribution of ventilation involving inhalation of inert gases

(l) Measurement of gas exchange involving simultaneous collection of arterial blood and expired air with measurements of the partial pressures of oxygen and carbon dioxide in gas and blood

(m) Multiple inert gas elimination techniques for measuring ventilation perfusion ratios in the lung

(n) Continuous monitoring of pulmonary function other than spirometry, tidal breathing and minute ventilation, of at least 6 hours duration

(o) Ventilatory and/or occlusion pressure responses to progressive hypercapnia and progressive hypoxia

(p) Monitoring pulmonary arterial pressure at rest or during exercise

(q) Measurement of the strength of inspiratory and expiratory muscles at multiple lung volumes

(r) Measurement of the respiratory muscle endurance/fatigability by any technique

(s) Measurement of respiratory muscle strength before and after intravenous injection of placebo and anticholinesterase drugs

(t) Simulated altitude test involving exposure to hypoxic gas mixtures and measurement of ventilation, heart rate and oxygen saturation at rest and/or during exercise and observation of the effect of supplemental oxygen

(u) Inhalation provocation testing to specific sensitising agents

(v) Spirometry performed before and after simple exercise testing undertaken as a provocation test for the investigation of asthma, in premises capable of performing complex lung function tests and equipped with a mechanical ventilator and defibrillator

11506

MEASUREMENT OF RESPIRATORY FUNCTION involving a permanently recorded tracing performed before and after inhalation of bronchodilator - each occasion at which 1 or more such tests are performed

Fee: $20.55

Benefit: 75% = $15.45; 85% = $17.50

11509

MEASUREMENT OF RESPIRATORY FUNCTION involving a permanently recorded tracing and written report, performed before and after inhalation of bronchodilator, with continuous technician attendance in a laboratory equipped to perform complex respiratory function tests (the tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital) - each occasion at which 1 or more such tests are performed

Fee: $35.65

Benefit: 75% = $26.75; 85% = $30.35

11512

CONTINUOUS MEASUREMENT OF THE RELATIONSHIP BETWEEN FLOW AND VOLUME DURING EXPIRATION OR INSPIRATION involving a permanently recorded tracing and written report, performed before and after inhalation of bronchodilator, with continuous technician attendance in a laboratory equipped to perform complex lung function tests (the tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital) - each occasion at which 1 or more such tests are performed

Fee: $61.75

Benefit: 75% = $46.35; 85% = $52.50

Sleep studies

12203

Overnight investigation for sleep apnoea for a period of at least 8 hours duration, for an adult aged 18 years and over where:

(a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG, EOG, submental EMG, anterior tibial EMG, respiratory movement, airflow, oxygen saturation and ECG are performed;

(b) a technician is in continuous attendance under the supervision of a qualified sleep medicine practitioner;

(c) the patient is referred by a medical practitioner;

(d) the necessity for the investigation is determined by a qualified adult sleep medicine practitioner prior to the investigation;

(e) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events and assessment of clinically significant alterations in heart rate and limb movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report ; and

(f) interpretation and report are provided by a qualified adult sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient

payable only in relation to each of the first 3 occasions the investigation is performed in any 12 month period.

(See para D1.18 of explanatory notes to this Category)

Fee: $588.00

Benefit: 75% = $441.00; 85% = $509.60

12250

Overnight investigation for sleep apnoea for a period of at least 8 hours duration for a patient aged 18 years or more, if all of the following requirements are met:

(a) the patient has, before the overnight investigation, been referred to a qualified adult sleep medicine practitioner by a medical practitioner whose clinical opinion is that there is a high probability that the patient has obstructive sleep apnoea; and

(b) the investigation takes place after the qualified adult sleep medicine practitioner has:

(i) confirmed the necessity for the investigation; and
(ii) communicated this confirmation to the referring medical practitioner;
and

(c) during a period of sleep, the investigation involves recording a minimum of seven physiological parameters which must include:

(i) continuous electro-encephalogram (EEG); and
(ii) continuous electro-cardiogram (ECG; and
(iii) airflow; and
(iv) thoraco-abdominal movement; and
(v) oxygen saturation; and
(vi) 2 or more of the following:

(A) electro-oculogram (EOG);

(B) chin electro-myogram (EMG);

(C) body position; and

(d) in the report on of the investigation, the qualified adult sleep medicine practitioner uses the data specified in paragraph (c) to:

(i) analyse sleep stage, arousals and respiratory events; and
(ii) assess clinically significant alteration in heart rate; and

(e) the qualified adult sleep medicine practitioner:

(i) before the investigation takes place, establishes quality assurance procedures for data acquisition; and
(ii) personally analyses the data and writes the report on the results of the investigation;

(f) the investigation is not provided to the patient on the same occasion as a service mentioned in any of items 11000 to 11005, 11503, 11700 to 11709, 11713 and 12203 is provided to the patient

Payable only once in a 12 month period

(See para D1.18 of explanatory notes to this Category)

Fee: $335.30

Benefit: 75% = $251.50; 85% = $285.05

12207

Overnight investigation for sleep apnoea for a period of at least 8 hours duration, for an adult aged 18 years and over where:

(a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recordings of EEG, EOG, submental EMG, anterior tibial EMG, respiratory movement, airflow, oxygen saturation and ECG are performed;

(b) a technician is in continuous attendance under the supervision of a qualified sleep medicine practitioner;

(c) the patient is referred by a medical practitioner;

(d) the necessity for the investigation is determined by a qualified adult sleep medicine practitioner prior to the investigation;

(e) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events and assessment of clinically significant alterations in heart rate and limb movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report; and

(f) interpretation and report are provided by a qualified adult sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient

where it can be demonstrated that a further investigation is indicated in the same 12 month period to which item 12203 applies for the adjustment and/or testing of the effectiveness of a *positive pressure ventilatory support device* (other than nasal continuous positive airway pressure) in sleep, in

a *patient with severe cardio-respiratory failure*, and where previous studies have demonstrated failure of continuous positive airway pressure or oxygen - **each additional investigation**

(See para D1.18 of explanatory notes to this Category)

Fee: $588.00

Benefit: 75% = $441.00; 85% = $509.60

12210

Overnight paediatric investigation for a period of at least 8 hours duration for a child aged 0 - 12 years, where:

(a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG (minimum of 4 EEG leads with facility to increase to 6 in selected investigations), EOG, EMG submental +/- diaphragm, respiratory movement must include rib and abdomen (+/- sum) airflow detection, measurement of CO2 either end-tidal or transcutaneous, oxygen saturation and ECG are performed;

(b) a technician or registered nurse with sleep technology training is in continuous attendance under the supervision of a qualified paediatric sleep medicine practitioner;

(c) the patient is referred by a medical practitioner;

(d) the necessity for the investigation is determined by a qualified paediatric sleep medicine practitioner prior to the investigation;

(e) polygraphic records are analysed (for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and the assessment of clinically significant alterations in heart rate and body movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report;

(f) the interpretation and report to be provided by a qualified paediatric sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient.

payable only in relation to the first 3 occasions the investigation is performed in a 12 month period.

(See para D1.18 of explanatory notes to this Category)

Fee: $701.85

Benefit: 75% = $526.40; 85% = $623.45

12213

Overnight paediatric investigation for a period of at least 8 hours duration for a child aged between 12 and 18 years, where:

(a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG (minimum of 4 EEG leads with facility to increase to 6 in selected investigations), EOG, EMG submental +/- diaphragm, respiratory movement must include rib and abdomen (+/- sum) airflow detection, measurement of CO2 either end-tidal or transcutaneous, oxygen saturation and ECG are performed;

(b) a technician or registered nurse with sleep technology training is in continuous attendance under the supervision of a qualified sleep medicine practitioner;

(c) the patient is referred by a medical practitioner;

(d) the necessity for the investigation is determined by a qualified sleep medicine practitioner prior to the investigation;

(e) polygraphic records are analysed (for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and the assessment of clinically significant alterations in heart rate and body movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report;

(f) the interpretation and report to be provided by a qualified sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient.

payable only in relation to the first 3 occasions the investigation is performed in a 12 month period.

(See para D1.18 of explanatory notes to this Category)

Fee: $632.30

Benefit: 75% = $474.25; 85% = $553.90

12215

Overnight paediatric investigation for a period of at least 8 hours duration for children aged 0 - 12 years, where:

(a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG (minimum of 4 EEG leads with facility to increase to 6 in selected investigations), EOG, EMG submental +/- diaphragm, respiratory movement must include rib and abdomen (+/- sum) airflow detection, measurement of CO2 either end-tidal or transcutaneous, oxygen saturation and ECG are performed;

(b) a technician or registered nurse with sleep technology training is in continuous attendance under the supervision of a qualified paediatric sleep medicine practitioner;

(c) the patient is referred by a medical practitioner;

(d) the necessity for the investigation is determined by a qualified paediatric sleep medicine practitioner prior to the investigation;

(e) polygraphic records are analysed (for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and the assessment of clinically significant alterations in

heart rate and body movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report;

(f) the interpretation and report to be provided by a qualified paediatric sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient.

where it can be demonstrated that a further investigation is indicated in the same 12 month period to which item 12210 applies, for therapy with Continuous Positive Airway Pressure (CPAP), bilevel pressure support and/or ventilation is instigated or in the presence of recurring hypoxia and supplemental oxygen is required - each additional investigation.

(See para D1.18 of explanatory notes to this Category)

Fee: $701.85

Benefit: 75% = $526.40; 85% = $623.45

12217

Overnight paediatric investigation for a period of at least 8 hours duration for children aged between 12 and 18 years, where:

(a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG (minimum of 4 EEG leads with facility to increase to 6 in selected investigations), EOG, EMG submental +/- diaphragm, respiratory movement must include rib and abdomen (+/- sum) airflow detection, measurement of CO2 either end-tidal or transcutaneous, oxygen saturation and ECG are performed;

(b) a technician or registered nurse with sleep technology training is in continuous attendance under the supervision of a qualified sleep medicine practitioner;

(c) the patient is referred by a medical practitioner;

(d) the necessity for the investigation is determined by a qualified sleep medicine practitioner prior to the investigation;

(e) polygraphic records are analysed (for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and the assessment of clinically significant alterations in heart rate and body movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report;

(f) the interpretation and report to be provided by a qualified sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient.

where it can be demonstrated that a further investigation is indicated in the same 12 month period to which item 12213 applies, for therapy with Continuous Positive Airway Pressure (CPAP), bilevel pressure support and/or ventilation is instigated or in the presence of recurring hypoxia and supplemental oxygen is required - each additional investigation.

(See para D1.18 of explanatory notes to this Category)

Fee: $632.30

Benefit: 75% = $474.25; 85% = $553.90

Explanatory note for Investigations for Sleep Apnoea

D.1.18.

Claims for benefits in respect of items 12207, 12215 and 12217 should be accompanied by clinical details confirming the presence of the conditions set out above. Claims for benefits for these services should be lodged with the Department of Human Services for referral to the National Office of the Department of Human Services for assessment by the Medicare Claims Review Panel (MCRP) and must be accompanied by sufficient clinical and/or photographic evidence to enable the Department of Human Services to determine the eligibility of the service for the payment of benefits.

Practitioners may also apply to the Department of Human Services for prospective approval for proposed surgery.

Applications for approval should be addressed in a sealed envelope marked "Medical-in-Confidence" to:

The MCRP Officer
PO Box 9822
SYDNEY NSW 2001

In relation to item 12250 for home-based sleep studies, the investigation cannot be provided on the same occasion as a service described in any of items 11000 to 11005, 11503, 11700 to 11709, 11713 and 12203.

Where the date of service for item 12250 is the same as the date of service of any items 11000 to 11005, 11503, 11700 to 11709, 11713 and 12203, for a benefit to be payable, there must be written notation on the account, identifying that the service under any of items 11000 to 11005, 11503, 11700 to 11709, 11713 and 12203 was not provided on the same occasion as item 12250 and was not for a home-based sleep study.

The correct date to specify on the account for item 12250 is the day the home-based sleep study was completed (as opposed to the day it was initiated).

Therapeutic procedures – biopsy of lung cancers

30696

ENDOSCOPIC ULTRASOUND GUIDED FINE NEEDLE ASPIRATION BIOPSY(S) (endoscopy with ultrasound imaging) to obtain one or more specimens from either:

(a) mediastinal mass(es) or

(b) locoregional nodes to stage non-small cell lung carcinoma

not being a service associated with another item in this subgroup or to which items 30710 and 55054 apply (Anaes.)

(See para T8.21 of explanatory notes to this Category)

Fee: $563.30

Benefit: 75% = $422.50; 85% = $484.90

30710

ENDOBRONCHIAL ULTRASOUND GUIDED BIOPSY(S) (bronchoscopy with ultrasound imaging, with or without associated fluoroscopic imaging) to obtain one or more specimens by either:

(a) transbronchial biopsy(s) of peripheral lung lesions; or

(b) fine needle aspiration(s) of a mediastinal mass(es); or

(c) fine needle aspiration(s) of locoregional nodes to stage non-small cell lung carcinoma

not being a service associated with another item in this subgroup or to which items 30696, 41892, 41898, and 60500 to 60509 applies (Anaes.)

(See para T8.21 of explanatory notes to this Category)

Fee: $563.30

Benefit: 75% = $422.50; 85% = $484.90

Explanatory Note for Endoscopic or Endobronchial Ultrasound +/- Fine Needle Aspiration – (Items 30688-30710)

T.8.21.

For the purposes of these items the following definitions apply:

Biopsy means the removal of solid tissue by core sampling or forceps;

FNA means aspiration of cellular material from solid tissue via a small gauge needle.

The provider should make a record of the findings of the ultrasound imaging in the patient's notes for any service claimed against items 30688 to 30710.

Endoscopic ultrasound is an appropriate investigation for patients in whom there is a strong clinical suspicion of pancreatic neoplasia with negative imaging (such as CT scanning). Scenarios include, but are not restricted to:

A middle aged or elderly patient with a first attack of otherwise unexplained (eg negative abdominal CT) first episode of acute pancreatitis; or

A patient with biochemical evidence of a neuroendocrine tumour.

The procedure is not claimable for periodic surveillance of patients at increased risk of pancreatic cancer, such as chronic pancreatitis. However, EUS would be appropriate for a patient with chronic pancreatitis in whom there was a clinical suspicion of pancreatic cancer (eg: a pancreatic mass occurring on a background of chronic pancreatitis).

Therapeutic procedures – bronchus or trachea

41889

BRONCHOSCOPY, as an independent procedure (Anaes.)

Fee: $178.05

Benefit: 75% = $133.55; 85% = $151.35

41892

BRONCHOSCOPY with 1 or more endobronchial biopsies or other diagnostic or therapeutic procedures (Anaes.)

Fee: $235.05

Benefit: 75% = $176.30; 85% = $199.80

41895

BRONCHUS, removal of foreign body in (Anaes.) (Assist.)

Fee: $367.75

Benefit: 75% = $275.85

41898

FIBREOPTIC BRONCHOSCOPY with 1 or more transbronchial lung biopsies, with or without bronchial or bronchoalveolar lavage, with or without the use of interventional imaging (Anaes.) (Assist.)

Fee: $256.95

Benefit: 75% = $192.75; 85% = $218.45

41905

TRACHEA OR BRONCHUS, dilatation of stricture and endoscopic insertion of stent (Anaes.) (Assist.)

Fee: $453.35

Benefit: 75% = $340.05

Appendix B Obsolete Items Data

Item 11500 – Bronchospirometry, including gas analysis

Table B1: Percentage of patients by age groups who received a service under item 11500 in 2014-15

Age Group	Number of Services	% provided to the age group
0-14	18	1%
15-19	43	4%
20-24	60	6%
25-29	36	4%
30-34	37	4%
35-39	38	4%
40-44	46	4%
45-49	49	5%
50-54	63	6%
55-59	78	8%
60-64	142	14%
65-69	114	11%
70-74	129	13%
75-79	99	10%
80-84	46	4%
>=85	28	3%

Unpublished data (Department of Health)
Note: Total number of services is 1,026.

Table B2: Percentage of services by specialty group - 11500, 2014-15

Specialty group	Number of Services	% of total services
Cardiology	70	7%
Respiratory and Sleep Medicine	612	60%
Anaesthetics	332	32%

*some data has been omitted because of low service volumes. Unpublished data (Department of Health)

Table B3: Total number of services and benefits paid for item 11500 by financial year

Financial Year	Services	Benefits Paid
2004/05	782	$91,504
2005/06	700	$81,951
2006/07	334	$39,383
2007/08	341	$42,147
2008/09	522	$68,525
2009/10	658	$86,452
2010/11	493	$65,114
2011/12	482	$64,470
2012/13	906	$121,712
2013/14	900	$122,636.00
2014-15	1,026	$138,808
Total	7,144	$922,706

Public data (Department of Human Services web site)

Item 11509 - Spirometry

Table B4: Percentage of patients by age groups who received a service under item 11509, 2014-15

Age Group	Number of Services	% provided to the age group
0-4	31	0%
5-9	1,135	7%
10-14	1,375	8%
15-19	809	5%
20-24	400	2%
25-29	429	3%
30-34	424	3%
35-39	512	3%
40-44	615	4%
45-49	639	4%
50-54	823	5%
55-59	1,082	6%
60-64	1,467	9%
65-69	1,999	12%
70-74	1,826	11%
75-79	1,636	10%
80-84	1,076	6%
>=85	526	3%

Unpublished data (Department of Health)
Note: Total number of services is 16, 804.

Table B5: Number of services by state, item 11509, 2014-15

Factor	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Australia
Estimated residential population *	7,565,497	5,886,436	4,750,513	1,691,503	2,581,250	515,235	244,265	387,640	23,625,561
11509	7,544	469	6,405	1,772	351	221	13	28	16,804
Service rate per 1,000	1	0.1	1.3	1	0.1	0.4	0.1	0.1	0.7

* Estimated residential population at December 2014 (ABS). Note that states with a service rate greater than 1 standard deviation from the mean are NSW and SA. Unpublished data (Department of Health)

Table B6: Percentage of services by specialty group - 11509, 2014-15

Specialty group	11509	% of total services
Specialist - Respiratory and Sleep Medicine	8,181	49%
Specialist - Internal Medicine	2,524	15%
Specialist - Immunology and Allergy	1,905	11%
Specialist - Pathology	1,344	8%
Specialist - Paediatric Medicine	1,111	7%
GP – Vocationally Registered General Practitioner	465	3%
Specialist - Geriatric Medicine	463	3%
Other	808	4%

*some data has been omitted because of low service volumes Unpublished data (Department of Health)
Note: Total number of services is 16,804.

Table B7: Same day item combinations - item 11509 with other MBS items, 2014-15

Item combination	Number of Episodes	Number of services	% of total episodes	Description of episodes
11509, 00116	8,905	17,820	53%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician) & subsequent consultant physician consultation
11509	2,783	2,797	17%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician) only
12003, 11509, 00110	1,903	5,709	11%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician,) Skin sensitivity testing (more than 20 allergens) & initial consultant physician consultation
11509, 00110	724	1,448	4%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician) & initial consultant physician consultation
11509, 00132	383	766	2%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician) & consultant physician treatment & management plan
11700, 11509, 00132	322	966	2%	Measurement of respiratory function tests after bronchodilator (supervised by

Item combination	Number of Episodes	Number of services	% of total episodes	Description of episodes
				consultant physician), consultant physician treatment and management plan & 12 lead ECG
12003, 11509, 00132	224	672	1%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician,) Skin sensitivity testing (more than 20 allergens) & consultant physician treatment & management plan
11700, 11509	199	398	1%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician) & 12 lead ECG
11509, 00023	198	399	1%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician & Level B GP consultation
12003, 11509	181	362	1%	Measurement of respiratory function tests after bronchodilator (supervised by consultant physician) & Skin sensitivity testing (more than 20 allergens)

Unpublished data (Department of Health)

Appendix C **Spirometry Rapid Review Report**

MBS Review

SPIROMETRY IN THE DIAGNOSIS AND MANAGEMENT OF PEOPLE WITH AIRFLOW LIMITATION

RAPID REVIEW REPORT

February 2016

Suggested Citation

This report was prepared by Ms Kate Applegarth, Dr Diah Elhassen, Dr Sue Campbell, Dr Lisa Fodero and Mr Joe Scuteri from HealthConsult Pty Ltd.

This report should be cited as follows:

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Conflict of Interest Statement

All authors engaged by the MBS Review Taskforce are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the relevant MBS Review Clinical Committee or their Working Groups. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, meta-analyses, and evidence-based clinical practice guidelines.

Systematic reviews, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria, the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to two outcomes.

About the MBS Review Taskforce

The MBS Review Taskforce was established in 2015 as part of the Government's Healthier Medicare initiative. The Taskforce will review the MBS in its entirety, considering individual items as well as the rules and legislation governing their application, with the overarching goal of promoting the provision of the best patient outcomes for our health expenditure.

The Taskforce's membership includes doctors working in both the public and private sectors with expertise in general practice, surgery, pathology, radiology, public health and medical administration, as well as consumer representation and academic expertise in health technology assessment.

Disclaimer

This Rapid Review is the work of HealthConsult and was commissioned by the MBS Review Taskforce and its Thoracic Medicine Clinical Committee. It was developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, MBS data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific

research and is not intended as an exhaustive analysis. HealthConsult, the MBS Review Taskforce and the Thoracic Medicine Clinical Committee assume no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. HealthConsult, the MBS Review Taskforce and the Thoracic Medicine Clinical Committee make no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report.

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Abbreviations

Term	Description
ABS	Australian Bureau of Statistics
ACAM	Australian Centre for Asthma Monitoring
ACCP	American College of Chest Physicians
ACOS	Asthma-COPD Overlap Syndrome
ACP	American College of Physicians
AHRQ	Agency for Healthcare Research and Quality
AMSTAR	Assessment of Multiple Systematic Reviews
APHCRI	Australian Primary Health Care Research Institute
APNA	Australian Primary Health Care Nurses Association
ATS	American Thoracic Society
BEACH	Bettering the Evaluation and Care of Health
BTS	British Thoracic Society
CADTH	Canadian Agency for Drugs and Technologies in Health
COPD	Chronic Obstructive Pulmonary Disease
CPG	Clinical Practice Guideline
CTS	Canadian Thoracic Society
DoD	Department of Defense
EMA	European Medicines Agency
ERS	European Respiratory Society
FeNO	Fractional Exhaled Nitric Oxide
FEV_1	Forced Expiratory Volume in 1 Second
FVC	Forced Vital Capacity
GDG	Guideline Development Group
G-I-N	Guidelines International Network
GINA	Global Initiative for Asthma
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GP	General Practitioner

Term	Description
ADE	Grading of Recommendations Assessment, Development and Evaluation
HTA	Health Technology Assessment
LFA	Lung Foundation Australia
LLN	Lower Limit of Normal
MBS	Medicare Benefits Schedule
MP	Member of Parliament
MSAC	Medical Services Advisory Committee
NAC	National Asthma Council Australia
NCGC	National Clinical Guideline Centre
NHLBI	National Heart, Lung, and Blood Institute
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PCRS	Primary Care Respiratory Society
PEF	Peak Expiratory Flow
PICO	Population, Intervention, Comparator, Outcomes
QALY	Quality-Adjusted Life Year
QOF	Quality and Outcomes Framework
QUADAS-2	Quality Assessment of Diagnostic Accuracy Studies, Version 2
RACGP	Royal Australian College of General Practitioners
RCP	Royal College of Physicians
RCT	Randomised Controlled Trial
SABA	Short-acting $Beta_2$-agonist
SF-36	36-item Short Form Health Survey
SIGN	Scottish Intercollegiate Guidelines Network
TSANZ	Thoracic Society of Australia and New Zealand
UK	United Kingdom
US	United States

Term	Description
VA	Department of Veterans Affairs
WHO	World Health Organization

Executive Summary

Background

This Report presents the collection and analysis of evidence to inform the Thoracic Medicine Clinical Committee in their deliberations regarding the existing MBS item for pre- *and* post-bronchodilator spirometry (MBS item 11506) and subsequent recommendations to the MBS Review Taskforce. Usage of this item is relatively modest, considering that: (i) chronic obstructive lung diseases, such as asthma and chronic obstructive pulmonary disease (COPD), are highly prevalent in Australia and are largely diagnosed and managed in primary care; and (ii) clinical practice guidelines (CPGs) regard spirometry as an essential tool in the diagnosis and management of patients with chronic airflow obstruction.

As a means to improve the diagnosis and management of asthma and COPD within the primary care setting, the Thoracic Medicine Clinical Committee have proposed that consideration should be given to increasing the rebate for item 11506 and/or adding a new MBS item to allow pre- *or* post-bronchodilator testing.

Objectives

To determine best clinical practice for the use of spirometry (with and without bronchodilator reversibility testing) in the diagnosis and management of patients who present to primary care with respiratory symptoms suggestive of asthma, COPD or other causes of airflow limitation.

To review recent published evidence relating to the cost-effectiveness of spirometry for diagnosis or management of asthma and COPD in primary care.

To review recent published evidence relating to the impact on diagnostic accuracy and health outcomes of providing financial incentives for performing spirometry in primary care.

Research methods

Literature search

A literature search for this rapid review was performed on 12th January 2016, using MEDLINE, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effect, Health Technology Assessment Database, and NHS Economic Evaluation Database. Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional studies not identified through the search. A search of CPG databases and the websites of health technology assessments (HTA) agencies and other relevant groups and societies was conducted on 12th January 2016 to identify relevant evidence-based CPGs.

Inclusion criteria

- English-language full reports published between 1st January 2005 and 12th January 2016

- systematic reviews, meta-analyses, HTAs and CPGs
- patients with a diagnosis or symptoms suggestive of airflow obstruction/limitation
- spirometry for diagnosis, assessment of acute exacerbations, or long-term monitoring
- report diagnostic accuracy, patient health outcomes, or cost-effectiveness

Exclusion

- original (primary) studies, editorials, narrative reviews

Results of the literature search

No recent, standalone systematic reviews, meta-analyses or HTAs were identified that *fully* addressed the research questions for this review.

The literature search identified 24 relevant CPGs, of which 11 were selected for inclusion because they were published from 2010 onwards by peak bodies in Australia and overseas. For each included CPG, relevant recommendations, evidence statements and consensus statements were extracted and tabulated. In several CPGs, the guidance relevant to this MBS Review was not developed into formal recommendations; in these cases there was not necessarily a clear link to the underlying evidence base. Several CPGs provided consensus-based recommendations, due to limited or no evidence.

Q1) Does the use of spirometry improve diagnostic accuracy and health outcomes in people presenting with respiratory symptoms?

See Table 28 of the report for a summary of the type of spirometry recommended in CPGs.

- Very low to moderate quality evidence suggests that high-quality spirometry may reduce rates of under-diagnosis and misdiagnosis of asthma, COPD and other causes of airflow limitation.
- According to international CPGs, **pre-bronchodilator spirometry**, **post-bronchodilator spirometry**, and reversibility testing (**pre- *and* post-bronchodilator spirometry**) all have a role in the diagnosis of patients presenting with respiratory symptoms suggestive of asthma, COPD or other causes of airflow limitation.
- On the basis of low quality evidence or consensus, the use of **bronchodilator reversibility testing** is recommended by international CPGs for the diagnosis of asthma in adults and children (>5 years of age) with evidence of airflow limitation according to **pre-bronchodilator spirometry**.
- On the basis of low level evidence or consensus, the use of **post-bronchodilator spirometry** is recommended by international CPGs for the diagnosis of COPD; however, **bronchodilator reversibility testing** may have a place where diagnostic doubt remains, or both COPD and asthma are suspected, particularly in elderly patients.
- Australian CPGs are less clear about a role for **pre- *or* post-bronchodilator spirometry** in the diagnosis of asthma and COPD. It could be interpreted from Australian guidance that **pre-**

***and* post-bronchodilator spirometry** should always be undertaken for the diagnosis of asthma and COPD; this guidance does not appear to be evidence-based.

Q2a) In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for assessing acute exacerbations?

See Table 28 of the report for a summary of the type of spirometry recommended in CPGs.

- Due to a lack of evidence, there are no CPG recommendations relating to the use of spirometry for the assessment of acute exacerbations.
- While some asthma and COPD CPGs advised that spirometry is of little value in the management of acute exacerbations, others suggested that it may be useful for categorising severity and assessing patients during recovery.

Q2b) In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for long-term monitoring?

See Table 39 of the report for a summary of the type of spirometry recommended in CPGs.

- Several asthma guidelines note that there is evidence to suggest that low forced expiratory volume (FEV1) is a strong independent predictor of risk of exacerbations and therefore support the use of lung function testing as part of long-term monitoring.
- For COPD, the general consensus from Australian and international CPGs is that FEV1 is a poor predictor of disease status and prognosis, but that spirometry may still have a role alongside other tests in long-term monitoring because worsening airflow limitation is associated with an increasing frequency of exacerbations and adverse events.
- The only CPG that mentions bronchodilator reversibility testing at follow-up is the National Asthma Council Australia handbook (2015), which notes that MBS reimbursement is only available if pre- and post-bronchodilator readings are taken and a permanently recorded tracing is retained.

Q3) What is the published evidence for the cost-effectiveness of spirometry for the diagnosis of people presenting with respiratory symptoms?

- A recent economic evaluation commissioned by the National Institute for Health and Care Excellence (NICE, 2016) found that the cost-effectiveness of diagnostic strategies using spirometry and bronchodilator reversibility testing was contingent on further diagnostic tests being performed downstream.
- No evidence was identified that assessed the cost-effectiveness of spirometry for the diagnosis of COPD.

Q4) What is the evidence that an increase in spirometry service fees (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

Q5) What is the evidence that financial incentives for performing spirometry over and above a fee for service (a) increases the number of accurate diagnoses of asthma or

COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

Q6) What is the evidence that introduction of an outcome based payment model that links provider payment to accurate diagnosis of asthma or COPD (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

- There is evidence from the United Kingdom to suggest that a financial incentive to undertake spirometry (over and above a fee for service) increases the quantity, but not necessarily the quality, of spirometry in primary care.
- No evidence was identified that addresses the impact of financial incentives for the use of spirometry in primary care, on diagnostic accuracy or patient health outcomes.

Conclusions

- **Pre-bronchodilator spirometry** is not reimbursed through the MBS but is recommended in international CPGs as a first line objective test to confirm airflow obstruction in adults and children (>5 years) who present with respiratory symptoms suggestive of asthma; **bronchodilator reversibility testing** should only follow if airflow limitation is detected.
- **Post-bronchodilator spirometry** is not reimbursed through the MBS but is recommended in international CPGs for the diagnosis of COPD, in cases where asthma or asthma-COPD overlap syndrome (ACOS) are not suspected.
- Despite a lack of clear evidence of benefit, international CPGs generally support the use of spirometry (pre- *or* post-bronchodilator) for long-term monitoring of asthma or COPD; a role for spirometry in the assessment of acute exacerbations is less clear.
- Australian CPGs tend to support the use of **pre- *and* post-bronchodilator spirometry**, which is currently reimbursed on the MBS, to a greater extent than international CPGs.
- Financial incentives may increase the use of spirometry in primary care, but the extent to which it improves diagnosis and health outcomes is unknown.

1 Background

On 22 April 2015, the Australian Minister for Health, the Hon Sussan Ley MP, announced the formation of the Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) as part of the Government's Healthier Medicare initiative. An evidence-based MBS underpins best clinical practice and facilitates better health outcomes for patients. The clinician-led Taskforce will lead an accelerated programme of MBS reviews to align MBS funded services with contemporary clinical evidence.

This Report presents the collection and analysis of evidence to inform the Thoracic Medicine Clinical Committee (the Committee) in their deliberations regarding the existing MBS item for pre- *and* post-bronchodilator spirometry (MBS item 11506). The Committee have proposed that consideration should be given to increasing the rebate for item 11506 and/or adding a new MBS item to allow pre- *or* post-bronchodilator testing, as a means to improve diagnosis, assessment and management of asthma, chronic obstructive pulmonary disease (COPD) and other causes of airflow limitation in primary care.

1.1 Objective of this Rapid Review

The primary objective of this Rapid Review is to determine best clinical practice for the use of spirometry – with and without bronchodilator reversibility testing – in the diagnosis, assessment and management of patients who present to primary care with respiratory symptoms suggestive of asthma, COPD or other causes of airflow limitation.

A secondary objective is to review recent published evidence relating to the cost-effectiveness of spirometry in the primary care setting. A tertiary objective is to review recent published evidence relating to the impact on diagnostic accuracy and patient health outcomes of providing financial incentives for performing spirometry in the primary care setting.

1.2 Clinical Need and Target Population

Spirometry directly and objectively assesses the functional consequences of airway narrowing and is the most widely used test of lung function (Johns et al, 2013). Australian and international clinical practice guidelines (CPGs) recommend the use of spirometry in the diagnosis and management of the most common chronic respiratory diseases, namely asthma and COPD (GOLD, 2016; LFA/TSANZ, 2015; NAC, 2015; NCGC, 2016). Both of these chronic inflammatory lung diseases are characterised by airflow obstruction and spirometry is considered to be the 'gold standard' for detecting obstruction and assessing its severity.

Although airflow obstruction is a hallmark characteristic of both asthma and COPD, differentiation is often relatively easy (LFA/TSANZ, 2015). In asthma, airway obstruction is typically intermittent and substantially – if not completely – reversible, either spontaneously or in response to treatment. In contrast, airflow obstruction is progressive and largely irreversible in patients with COPD.

Furthermore, while asthma usually dates back to a younger age, patients with COPD typically have a late onset of symptoms and a moderately heavy smoking history.

However, there are some patients (particularly older patients and smokers and ex-smokers) in whom it is difficult to distinguish between asthma and COPD as the primary cause of their chronic airflow limitation (ACAM, 2011; GINA, 2015). Longstanding or poorly controlled asthma can lead to chronic, irreversible airway narrowing. Furthermore, it is now recognised that some people may have components of both diseases, known as asthma-COPD overlap syndrome, or ACOS (GINA, 2015; LFA, 2014).

Making a diagnosis therefore relies on clinical judgment based on a combination of symptoms, history, physical examination and confirmation of the presence of airflow obstruction using spirometry (GINA, 2015; GOLD, 2016). As treatments for asthma and COPD are diverging due to substantial improvements in our understanding of the pathogenesis of both diseases, the correct diagnosis is vital in order to maximise the long-term outcome for the patient (Sims and Price, 2012).

1.2.1 Prevalence of Asthma and COPD in Australia

Based on self-reported data from the 2011-12 Australian Health Survey (ABS 2012), approximately 10.2% of the total population (approximately 2.3 million Australians) have asthma, while 5.7% of people aged 55 and over (approximately 310,700 Australians) have symptoms suggestive of COPD (emphysema and/or bronchitis). However, COPD is often under-recognised by doctors and underreported by patients in its early stages. An Australian population-based survey found the prevalence of COPD, defined by spirometric criteria, to be 7.5% for people aged 40 years and over, and 29.2% for people aged 75 and over (Toelle et al, 2013).

Asthma and COPD are largely diagnosed and managed within the primary care sector. According to 2014-15 data from the BEACH (Bettering the Evaluation and Care of Health) program,[1] asthma was managed by GPs at a rate of 21 per 1000 encounters and COPD was managed by GPs at a rate of 9 per 1000 encounters. Using the BEACH method of extrapolation,[2] this suggests that asthma was managed by GPs an estimated 2,883,000 times per year nationally, while COPD was managed by GPs about 1,236,000 times per year nationally.

1.3 Technology/Technique

Spirometry is an objective and reproducible test of lung function that measures the volume of exhaled air, after a maximal inhalation, during a specified period of time. It is preferable to the use of a peak flow meter to measure peak expiratory flow (PEF) because it allows clearer identification of

[1] The BEACH survey gathers information from a random sample of GPs in Australia. An 'encounter' relates to a consultation between a patient and a GP. Data need to be interpreted with some caution.
[2] Calculated using the method described in Section 2.9 of the BEACH publication by Britt et al, 2015. Medicare data for the 2014–15 year included data from the April 2014 to March 2015 quarters because the 2014–15 financial year data were not available at the time of preparation of the BEACH report.

airflow obstruction and the results are less dependent on effort (BTS/SIGN, 2014; GOLD, 2016; NAC, 2012).

The results of a spirometry test are expressed as the FEV_1/FVC ratio, where FEV_1 is the forced expiratory volume in one second and FVC is the forced vital capacity, or the total amount of air forcibly exhaled after full inspiration. Spirometry measurements are evaluated by comparison with reference values based on age, height, sex, and race, with airflow limitation diagnosed in those who fall below the lower limit of normal (LLN) (GOLD, 2016).

If there is evidence of airflow obstruction, spirometry may be performed before and after the administration of a short-acting bronchodilator to assess whether the airflow obstruction can be reversed – a hallmark of asthma. Reversibility testing involves pre-bronchodilator spirometry followed by the administration of the bronchodilator (e.g. 4 separate puffs of salbutamol via a spacer), then post-bronchodilator spirometry after a 10-15 minute wait (Johns et al, 2013). Reversibility may also be assessed by measuring spirometry before and several weeks after a trial of inhaled glucocorticosteroids or oral prednisone (Johns et al, 2013).

Although spirometry is a safe, non-invasive test with no absolute contraindications, it is physically demanding on the patient and there are some circumstances where it might be advisable to delay testing (Johns et al, 2015). Young children are unlikely to be able to produce reliable spirometry and interpretation of the results can be complex (Johns et al, 2015).

Poorly performed spirometry and misinterpretation of the results can lead to misdiagnosis (or missed diagnosis) and inappropriate management. Good quality spirometry relies on: the use of an accurate spirometer that meets the required international standards; active coaching to ensure the patient performs the test correctly; ongoing quality assurance; and adequately trained operators (Johns et al, 2013). Training and regular practice is considered to be vital. Likewise, the results of spirometry testing need to be properly interpreted in the light of the clinical history and presentation – ideally at the time of testing (Levy et al, 2009).

From a clinical perspective, an accurate diagnosis of asthma, COPD, or another obstructive lung condition, such as bronchiectasis, is important because of its therapeutic and prognostic implications for the patient. Patients who are misdiagnosed may be labelled as having a chronic disease when none exists, creating anxiety for them and their families (Walters et al, 2011). Misdiagnosed patients may then go on to receive inappropriate therapy (potentially lifelong), exposing them needlessly to possible side effects (albeit usually minor) and costs, while the true underlying pathology remains undiagnosed and untreated. The consequences of a missed diagnosis include untreated symptoms, and preventable recurrent exacerbations, emergency department visits and hospital admissions (Boulet et al, 2013).

In an Australian study of 341 patients in general practice with either a recorded diagnosis of COPD and/or a record of current treatment with COPD therapy, only 69% had spirometrically-confirmed COPD (Walters et al, 2011). Among the 31% of patients who did not meet the criteria for COPD, 56%

had normal lung function, 7% had mild airflow limitation but an FEV_1/FVC ratio just above 0.7, and 37% had restrictive lung function. Misclassification of COPD in practices was more likely in overweight or obese patients and in those with allergic rhinitis or hay fever.

Another Australian study in the primary care setting found that of 445 patients who had been prescribed medications for COPD, only 57.8% had post-bronchodilator spirometry showing COPD (with or without asthma), 3.6% had asthma only, 18.4% had normal spirometry, and 20.2% had other spirometric diagnoses such as restriction (Zwar et al, 2011).

Despite the importance of spirometry to detect and assess the extent of airway obstruction, studies from a number of countries indicate that it is frequently underused in primary care settings where a diagnosis is often made on the basis of symptoms and clinical history without objective confirmation (Aaron et al, 2008; Arne et al, 2010; Gershon et al, 2012; Salinas et al, 2011; Sokol et al, 2015).

In Australia, ownership of spirometers is reasonably high, estimated over a decade ago at between 64% and 76% of general practices (Barton et al, 2009; Johns et al, 2006); however, uptake of spirometry has been low (Holton et al, 2011; Matheson et al, 2006; Walters et al, 2005). In a retrospective review of the medical records of 270 Victorian patients who had been prescribed inhaled medication in the preceding six months and had a doctor diagnosis of asthma, COPD, or asthma/COPD, over 28% of diagnoses were made without spirometry at baseline (Abramson et al, 2012). Data from the BEACH program (2007 to 2010) showed that lung function tests[3] were performed in 5.7% of GP encounters for the management of asthma in adults, but less frequently in children (3.0%) (ACAM, 2011). Data from the BEACH program (April 2008 to March 2009) showed that respiratory function tests were performed in only 4.6 per 100 COPD problems managed (Charles et al, 2010).

There are a number of barriers to the performance of spirometry that have been identified in several Australian studies in the primary care setting (Abramson et al, 2012; Dennis et al, 2010; Johns et al, 2006; Goeman et al, 2005; Walters et al, 2005):

- low level of reimbursement for tests;
- high cost of spirometer;
- lack of access to a well maintained spirometer;
- patient reluctance to attend a referral centre for spirometry;
- difficulty in fitting testing into the normal workflow of consultations;
- practice nurse not available to perform the measurement;
- lack of confidence in ability to interpret the results;
- lack of time for adequate training and ongoing quality control;
- belief that a clinical diagnosis based on symptoms and history is sufficient;

[3] Lung function test includes any of the following: peak flow, pulmonary function, spirometry, lung function, physical function, FEV_1 and respiratory function.

- patient reluctance to engage in the diagnostic process.

Many of these barriers are not unique to Australia and have been reported in several other countries including Canada, the Netherlands, the United States and the United Kingdom (Boulet et al, 2013; Dirven et al, 2013; Joo et al, 2013; Roberts et al, 2011; Salinas et al, 2011).

1.4 MBS Context

Spirometry can be claimed on the MBS by general practitioners using item 11506, which specifically requires a permanently recorded tracing performed before and after inhalation of a bronchodilator. Spirometry may also be reimbursed though items 11500, 11503, 11509 and 11512, but these services are generally confined to specialist practice. Appendix 2 provides the full item descriptors and Schedule fees, together with item start dates.

The current Schedule fee for MBS item 11506 is $20.55. In the 2014-15 financial year, the total benefits paid for item 11506 was $5,372,888, and the total number of services was 270,258, across 231,878 patients. All services were provided out of hospital by a total of 18,358 providers. Further details, including a breakdown of the number of services by state/territory and by age, are provided in Appendix 3.

Usage of MBS item 11506 is relatively modest, given that: (i) asthma and COPD are highly prevalent in Australia (ACAM, 2011) and are largely diagnosed and managed within the primary care sector (Britt, 2015); and (ii) Australian and international CPGs regard spirometry as an essential clinical tool in the diagnosis and management of patients with asthma and COPD (see Sections 0 and 0 for a summary of recommendations relating to spirometry).

As a means to improve the diagnosis and management of asthma and COPD in primary care and to encourage best-practice use of spirometry, the MBS Review Taskforce's Thoracic Medicine Clinical Committee have proposed that consideration should be given to one or both of the following, pending the findings from a review of contemporary evidence and clinical guidance:

- Increasing the MBS rebate for MBS item 11506.
- Adding a new item to allow pre- *or* post- bronchodilator testing.

2 Rapid Review

2.1 Research Questions

Q1) Does the use of spirometry improve diagnostic accuracy and health outcomes in people presenting with respiratory symptoms?

Table 1 PICO criteria for research question 1

Population	Intervention	Comparator	Outcomes
Patients presenting with respiratory symptoms suggestive of asthma, COPD or other causes of airflow limitation Stratify by age: • paediatric • adult • geriatric	Spirometry • with reversibility testing (pre AND post) • without reversibility testing (pre OR post)	No spirometry (clinical diagnosis based on symptoms and history)	• Diagnostic accuracy (sensitivity, specificity, PPV, NPV) • Change in patient management • Change in health outcomes (e.g. mortality, frequency of exacerbations, quality of life)

Abbreviations: COPD, chronic obstructive pulmonary disease; NPV, negative predictive value; PICO, population, intervention, comparator, outcomes; PPV, positive predictive value.
Note 1: Spirometry may be used as a reference standard, which will impact on the interpretation of diagnostic accuracy.
Note 2: The review will include direct evidence for the impact of the diagnostic intervention on patient-relevant health outcomes. A linked evidence approach, which examines the impact of treatment for asthma or COPD on health outcomes, will not be used.

Q2a) In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for assessing acute exacerbations?

Q2b) In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for long-term monitoring?

Table 2 PICO criteria for research question 2

Population	Intervention	Comparator	Outcomes
Patients with a diagnosis of: • asthma • COPD Stratify by age: • paediatric • adult • geriatric	Spirometry • with reversibility testing (pre AND post) • without reversibility testing (pre OR post)	No spirometry (clinical assessment)	• Quality of life • Respiratory symptoms • Frequency and severity of exacerbations • Compliance • Healthcare service use

Abbreviations: COPD, chronic obstructive pulmonary disease; PICO, population, intervention, comparator, outcomes.

Q3) What is the published evidence for the cost-effectiveness of spirometry for the diagnosis of people presenting with respiratory symptoms?

Q4) What is the evidence that an increase in spirometry service fees (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

Q5) What is the evidence that financial incentives for performing spirometry over and above a fee for service (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

Q6) What is the evidence that introduction of an outcome based payment model that links provider payment to accurate diagnosis of asthma or COPD (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

2.2 Research Methods

2.2.1 Literature Search

A literature search was performed on 12th January 2016, using MEDLINE and the Cochrane Library, to identify studies published from 2005 onwards that address the research questions shown in Section 2.1. The search strategy is shown in Appendix 4. Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

In addition, the following databases were searched on 12th January 2016 to identify relevant clinical practice guidelines (CPGs): Guidelines International Network (G-I-N), Agency for Healthcare Research and Quality (AHRQ) National Guidelines Clearinghouse, and the Australian Clinical Practice Guidelines Portal.

A targeted search of the websites of health technology assessment (HTA) agencies and other relevant groups and societies was also undertaken on 12th January 2016. 0 lists the websites that were searched.

For the research questions that relate to financial incentives for spirometry, additional searches were conducted of government websites in an attempt to identify any relevant reports available in the public domain.

2.2.2 Inclusion Criteria

Systematic reviews, meta-analyses, HTAs and CPGs were included if they fulfilled the following criteria:

- English-language full publication;
- published between 1st January 2005 and 12th January 2016;
- focused on patients diagnosed with, or presenting with symptoms suggestive of, asthma, COPD or other causes of airflow limitation; and
- provided assessment of, or guidance relating to, the use of spirometry for diagnosis, assessment of acute exacerbations, or long-term monitoring.

2.2.3 Exclusion Criteria

The following exclusion criteria were applied:

- original (primary) studies, narrative reviews, editorials, conference abstracts;

- spirometry for screening rather than diagnosis or monitoring;
- studies reporting diagnostic yield only;
- studies reporting outcomes not relevant to the research questions.

2.2.4 Outcomes of Interest

The outcomes of interest related to diagnostic accuracy, patient health outcomes, and cost-effectiveness, as per the research questions and PICO criteria shown in Section 2.1.

2.3 Results of Literature Search

2.3.1 Systematic Reviews and Meta-analyses

The searches of MEDLINE and the Cochrane Library yielded 282 citations published between 1st January 2005 and 12th January 2016. After a review of titles and abstracts, 244 citations were excluded and 24 articles (10 of which were CPGs) were obtained for a review of the full text. An additional two systematic reviews were identified through a search of relevant websites and the 'grey' literature.

After full text review, no standalone systematic reviews, meta-analyses or HTAs were identified that fully addressed the research questions shown in Section 2.1. However, one HTA and four systematic reviews were identified that partially address the research questions, or attempted to address similar research questions. These studies are listed in Table 3, together with an overall AMSTAR quality assessment score (see Appendix 5).

Table 3 List of included systematic reviews and HTAs

Study ID	Commissioning body	Title	Overall AMSTAR score[a]
Cranston et al (2006)	APHCRI	Models of chronic disease management in primary care for patients with mild to moderate asthma or COPD.	6
José et al (2014)	Not applicable	Diagnostic accuracy of respiratory diseases in primary health units.	3
Langdown et al (2014)	Not applicable	The use of financial incentives to help improve health outcomes: is the quality and outcomes framework fit for purpose? A systematic review.	7
Wilt et al (2005)	AHRQ	Use of spirometry for case finding, diagnosis, and management of chronic obstructive pulmonary disease (COPD). Evidence Report/Technology Assessment No. 121.	8
Wilt et al (2007)	AHRQ	Management of stable chronic obstructive pulmonary disease: a systematic review for a clinical practice guideline.	10

Abbreviations: AHRQ, US Agency for Healthcare Research and Quality; APHCRI, Australian Primary Health Care Research Institute
a See Table A-5.1 in 0 for further details.

2.3.2 Clinical Practice Guidelines

The review of CPGs was undertaken to determine the appropriateness of MBS item 11506 relative to 'best practice' as recommended in evidence-based CPGs from Australia and comparable health systems overseas.

Guidelines specifically relating to best practice for the performance of spirometry (e.g. obtaining acceptable and repeatable spirometric data) and indications/contraindications for spirometry were considered out of scope for this MBS Review. Guidelines published prior to 2010 were also excluded on the basis that they may not reflect current practice.

After exclusion of superseded versions, a total of 24 relevant CPGs were identified. Of those, 11 evidence-based CPGs were selected for inclusion in the review because they provided guidance on best practice use of spirometry and were from peak bodies in Australia and overseas. The included CPGs, four of which are from Australia, are listed in Table 4. General information about each guideline, such as the primary aim and focus, and a brief summary of methodology is provided in Appendix 6.

For each CPG, relevant recommendations, evidence statements and practice tips/consensus statements are tabulated and other relevant guidance and general advice is reported in the text. Where applicable, the system used to grade recommendations and describe the level of evidence underpinning recommendations has been summarised; however, in several CPGs (GINA, 2015; GOLD 2016) the particular guidance relevant to this review was not developed into formal recommendations and was therefore not graded using the methods described. In these cases there was not necessarily a clear link between the general guidance provided in the CPG and the underlying evidence base.

In addition, while the *Australian Asthma Handbook* (NAC, 2015) stated that National Health and Medical Research Council (NHMRC) grades A to D were used to grade evidence-based recommendations, the recommendations relevant to this review were all consensus-based, with only occasional references to supporting evidence from the published literature.

Table 4 Summary of CPGs that address the use of spirometry in people with respiratory symptoms

Region	ID	Title	Affiliation
Australia	LFA/TSANZ (2015)	The COPD-X Plan: Australian and New Zealand guidelines for the management of chronic obstructive pulmonary disease 2015, Version 2.43[4]	Lung Foundation Australia (LFA); Thoracic Society of Australia and New Zealand (TSANZ)
	NAC (2015)	Australian Asthma Handbook, Version 1.1[5]	National Asthma Council Australia (NAC). Endorsed by: Royal

[4] An updated version of this guideline was released after the search date for this review. Version 2.44 included published evidence up to December 2015; however, it did not include any additional evidence relating to the use of spirometry.
[5] Version 1.1 of the Australian Asthma Handbook was sponsored by Mundipharma Australia and Novartis Australia.

Region	ID	Title	Affiliation
			Australian College of General Practitioners (RACGP); Australian Primary Health Care Nurses Association (APNA); and Thoracic Society of Australia and New Zealand (TSANZ)
	Abramson (2014)	COPD-X Concise guide for primary care	Lung Foundation Australia (LFA); Thoracic Society of Australia and New Zealand (TSANZ)
	NAC (2013)	Asthma and the over 65s – an information paper for health professionals	National Asthma Council Australia (NAC)
International	NCGC (2016) – UK	Asthma: diagnosis and monitoring of asthma in adults, children and young people *[Interim findings]*[6]	National Clinical Guideline Centre (NCGC). Commissioned by the National Institute of Health and Care Excellence (NICE)
	GOLD (2016) – International	Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease	Global Initiative for Chronic Obstructive Lung Disease (GOLD)
	GINA (2015) *International*	Global Strategy for Asthma Management and Prevention	Global Initiative for Asthma (GINA)
	BTS/SIGN (2014) – UK	British guideline on the management of asthma. SIGN 141	British Thoracic Society (BTS); Scottish Intercollegiate Guidelines Network (SIGN); Royal College of Physicians (RCP); Primary Care Respiratory Society (PCRS); Health Improvement Scotland; Asthma UK; Education for Health.
	VA/DoD (2014) – US	VA/DoD clinical practice guideline for the management of outpatient chronic obstructive pulmonary disease	Department of Veterans Affairs (VA); Department of Defense (DoD)
	Qaseem (2011) – US/Europe	Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society	American College of Physicians (ACP); American College of Chest Physicians (ACCP); American Thoracic Society (ATS); European Respiratory Society (ERS)
	NCGC (2010) – UK	Chronic obstructive pulmonary disease: Management of chronic obstructive pulmonary disease in adults in primary and secondary care	National Clinical Guideline Centre (NCGC). Commissioned by the National Institute of Health and Care Excellence (NICE)

Abbreviations: COPD, chronic obstructive pulmonary disease; CPG, clinical practice guideline; UK, United Kingdom; US, United States.

[6] On the guideline search date (12 January 2016) a draft version of the NCGC guideline was available on the NICE website. On 14 January, following a public consultation process, the guideline was finalised and on 20 January an updated version labelled 'Interim findings' was released. This is the version that has been summarised for this review and is referred to as NCGC (2016).

2.4 Does the use of spirometry improve diagnostic accuracy and health outcomes in people presenting with respiratory symptoms?

2.4.1 Systematic Reviews

The literature search identified three systematic reviews that address – to some extent – the research question. Two of the reviews (Cranston et al, 2006; Wilt et al, 2005) are quite old and the evidence may no longer be considered 'contemporary'. The third review (José et al, 2014) searched for articles assessing the concordance between the diagnosis by primary health care physicians and specialists (or spirometry) for common respiratory diseases.

Wilt et al (2005)[AHRQ]

Wilt and colleagues (2005) undertook an HTA for the AHRQ on the use of spirometry for case-finding, diagnosis and management of COPD. The evidence identified in the Wilt HTA will not be described in detail as the report has been officially archived for historical reference only. Of note, the authors concluded that spirometry, in addition to clinical examination, improves COPD diagnostic accuracy compared to clinical examination alone and it is a useful diagnostic tool in individuals with symptoms suggestive of possible COPD. They concluded that the primary benefit of spirometry is to identify individuals who might benefit from pharmacologic treatment in order to improve exacerbations.

Cranston et al (2006)[APHCRI]

A systematic review from the Australian Primary Health Care Research Institute (APHCRI) (Cranston et al, 2006) explored models of chronic disease management in primary care for patients with mild to moderate asthma or COPD. The clinical research questions relating to spirometry were: "What is the evidence base to support the use of spirometry in primary care?" and "What is the evidence that the performance of spirometry in primary care has been implemented and evaluated, and that it has influenced the clinical outcome of patients with mild to moderate asthma or COPD?"

A total of 17 studies were identified in relation to the two research questions above: two systematic reviews (one of which was the Wilt HTA for the AHRQ and the other focused on biomedical risk assessment as an aid for smoking cessation); two additional RCTs; and 13 surveys where spirometry was used to confirm airway obstruction, COPD or asthma. Each research question was addressed by a brief narrative summary of each included study. Not all of the included studies are relevant to the PICO criteria in the current MBS Review (many evaluated spirometry for screening or case-finding). For these reasons, plus the age of the evidence base, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria were not used in the current MBS Review to assess the quality of the body of evidence.

The relevant key findings from the APHCRI review were that "Spirometry is useful for the differential diagnosis of asthma and COPD, but using some defining criteria, could triple the number of adults being labelled as 'at-risk' or with COPD." and "Evidence suggests that spirometry results alone have not altered management of COPD in primary care. Only smoking cessation and influenza vaccination have been found to be effective in preventing symptom development in COPD" (Cranston et al, 2006).

José et al (2014)

The systematic review by José and colleagues (2014) aimed to evaluate the diagnostic ability of GPs working in primary health care in relation to common respiratory diseases, including asthma and COPD. Articles were included if they assessed concordance between the diagnosis from primary health care physicians with the diagnosis from respiratory specialists. Studies that compared a clinical diagnosis from a GP with a diagnosis using spirometry were also included, although it is not clear whether any of the studies specifically compared GP diagnoses with and without spirometry.

Of the 21 studies that related to diagnosis of asthma and COPD, 19 were cross-sectional and two were cohort studies. GRADE quality assessment was not undertaken on the body of evidence because not all of the studies specifically addressed the research questions of interest to this MBS Review. Many of the selected studies reported the proportion of spirometrically-confirmed cases that had not previously been diagnosed by their GP; however, it is not clear whether under-diagnosis was due to inappropriate interpretation of symptoms by the GP or the patients' failure to express their symptoms to the doctor (i.e. it is not known whether patients presented to primary care with respiratory symptoms suggestive of asthma, COPD or other causes of airflow limitation). Although the literature places the GP as the key player in the context of mistaken diagnosis, the authors of the José review acknowledge that the degree of liability for the mistakes cannot be determined.

Using spirometry as the reference standard, over-diagnosis of COPD varied across the eight COPD studies from 28% to 40% while under-diagnosis varied from 25.7% to 81.4%. The authors postulated that "This heterogeneity may have occurred, at least in part, because the studies were not randomised, due to diversification in sampling and definitions of each disease, and the variables considered in the populations analysed". Two of the COPD studies (Walters et al, 2011; Zwar et al, 2011) were conducted in Australia and have been described elsewhere in this report (see Section 1.3).

The eight studies that evaluated asthma and COPD in conjunction were also heterogeneous in relation to the methodologies employed and showed large variation in rates of over- and under-diagnosis of each condition. However, several of the studies compared GP diagnosis with specialist diagnosis rather than spirometry.

2.4.2 Clinical Practice Guidelines

Asthma

In general, the CPGs included in this review identified the same overarching clinical features that are required to diagnose asthma. Although there were differences in the exact wording, central to all definitions of asthma was the presence of clinical symptoms (dyspnoea, wheeze or cough), and variable airflow limitation. Spirometry allows for the measurement of airflow limitation and is therefore useful in confirming a diagnosis of asthma. Clinical guidance relating to the appropriate use of spirometry for the diagnosis of asthma is summarised in this section.

National Asthma Council Australia (2015)

According to the *Australian Asthma Handbook,* spirometry is the best lung function test for diagnosing asthma and for measuring lung function when assessing asthma control. It can be used to:

- detect airflow limitation;
- measure the degree of airflow limitation compared with predicted normal airflow (or with personal best); and
- demonstrate whether airflow limitation is reversible.

The algorithms for diagnosing asthma in adults and children in the NAC Handbook both mention the use of spirometry (see 0). The Handbook also includes a large number of recommendations relating to the diagnosis of asthma in adults and children. Those that are of relevance to this review are reproduced in Table 5 and Table 6, respectively.

Table 5 NAC (2015): Clinical guidance relating to spirometry and the diagnosis of asthma in adults

Clinical component	Recommendation	Type of recommendation
Taking a history	When respiratory symptoms are not typical, do not rule out the possibility of asthma without doing spirometry, because symptoms of asthma vary widely from person to person.	Consensus recommendation
Performing a physical examination	Do not rule out the possibility of asthma without doing spirometry, because physical examination may be normal when symptoms are absent and this does not exclude a diagnosis of asthma.	Consensus recommendation
Assessing lung function	Perform or arrange spirometry for every patient with suspected asthma. *Note: If reliable equipment and appropriately trained staff are available, spirometry can be performed in primary care. If not, refer to an appropriate provider such as an accredited respiratory function laboratory.*	Consensus recommendation
	Measure bronchodilator reversibility by performing spirometry before and after administration of a rapid-onset beta$_2$ agonist bronchodilator (e.g. 4 puffs of salbutamol 100 mcg/actuation via pressurised metered-dose inhaler and spacer). *Notes: Airflow limitation is defined as reversible (i.e. bronchodilator response is clinically important) if FEV_1 increases by ≥200 mL and ≥12%.* *Failure to demonstrate a reversible airflow limitation after bronchodilator ('bronchodilator reversibility') does not exclude asthma, and its presence does not prove asthma – the pattern of symptoms and other clinical features must also be considered.*	Consensus recommendation
	Record the ratio of FEV_1 to FVC (FEV_1/FVC). Before making the diagnosis of asthma, confirm that FEV_1/FVC is reduced (less than the LLN for age) at a time when FEV_1 is lower than predicted. *Note: If the spirometer does not provide LLN for age, use the following age-based cut-points to indicate expiratory airflow limitation in adults and older adolescents:* • *less than 0.85 (up to 19 years)* • *less than 0.80 (20-39 years)* • *less than 0.75 (40-59 years)*	Consensus recommendation with reference to named sources[a]

Clinical component	Recommendation	Type of recommendation
	• *less than 0.70 (60 years and older)*	
	If a patient shows some improvement in FEV_1 after bronchodilator, but does not meet criteria for reversible airflow limitation, consider other investigations. If necessary, repeat spirometry after a treatment trial of 4-6 weeks with regular low-dose inhaled corticosteroid plus short-acting $beta_2$ agonist as needed, to see if there is a significant improvement in symptoms and lung function. *Note: Airflow limitations can be transient (e.g. when recorded during a severe acute infection of the respiratory tract) and does not necessarily mean that the person has chronic asthma. Ideally, airflow limitation should be confirmed when the patient does not have a respiratory tract infection.*	Consensus recommendation
	Hand-held lung function-measuring devices (designed to measure FEV_1 and/or FEV_6, but not FVC) can be used in COPD case-finding and may also be useful in asthma case-finding, but must not be relied on either for ruling out asthma or when making a definitive diagnosis of asthma, because there is not enough evidence and validated protocols have not been developed.	Consensus recommendation
	Do not use peak flow meters in place of spirometry for diagnosing asthma.	Consensus recommendation
Considering alternative diagnoses in adults	Consider the possibility of upper airway dysfunction when FEV_1/FVC ratio on spirometry is normal or when symptoms of breathlessness or wheeze do not improve after taking short acting $beta_2$ agonist.	Consensus recommendation with reference to named sources[b]
	If airflow limitation is not completely reversible, consider the possibility of COPD (as an alternative diagnosis or a coexisting diagnosis), especially in smokers and ex-smokers over 35 years old and in people over 65 years old.	Consensus recommendation with reference to named sources[c]
Making a diagnosis of asthma in adults	Make a diagnosis of asthma if all of the following apply: • The person has a history of variable symptoms (especially cough, chest tightness, wheeze and shortness of breath). • Expiratory airflow limitation has been demonstrated (FEV_1/FVC less than LLN for age). • Expiratory airflow limitation has been shown to be variable. • There are no findings that suggest an alternative diagnosis. *Note: If the spirometer does not provide LLN for age, use the following age-based cut-points to indicate expiratory airflow limitation in adults and older adolescents:* • *less than 0.85 (up to 19 years)* • *less than 0.80 (20-39 years)* • *less than 0.75 (40-59 years)* • *less than 0.70 (60 years and older)*	Consensus recommendation
	If a patient's asthma has been diagnosed elsewhere (e.g. in a new patient reporting the diagnosis of asthma), try to confirm the diagnosis – whether or not the person has current symptoms, and whether or not the person is taking asthma medicines.	Consensus recommendation
Starting treatment and reviewing response in adults	Consider a treatment trial if asthma is strongly suspected but spirometry before and after bronchodilator does not demonstrate clinically important reversible airflow limitation	Consensus recommendation

Clinical component	Recommendation	Type of recommendation
	(change in FEV_1 of at least 200 mL and 12% from baseline) and other investigations have not confirmed variable airflow limitation.	
Considering further investigations in adults	Consider arranging further investigations and referral to appropriate specialists if the diagnosis cannot be made with confidence from clinical features, spirometry and response to treatment.	Consensus recommendation
	Consider investigation for conditions that may affect or mimic asthma symptoms (e.g. coronary heart disease, obstructive sleep apnoea, gastro-oesophageal reflux disease or aspirin-exacerbated respiratory disease).	Consensus recommendation
	Consider arranging bronchial provocation (challenge) tests for airway hyperresponsiveness if asthma is suspected but initial spirometry does not demonstrate reversible airflow limitation. *Notes: If challenge testing is needed, consider referring to a respiratory physician for investigation, or discussing with a respiratory physician before selecting which test to order.* *Don't test during a respiratory infection, or initiate inhaled corticosteroid treatment in the few weeks before challenge testing, because these could invalidate the result.*	Consensus recommendation

Note: Lower limit of normal (LLN) = less than the 5th percentile of normal population.
Abbreviations: COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; LLN, lower limit of normal.
a Johns and Pierce (2011); NHLBI (2007); Quanjer et al (2012)
b Benninger et al (2011); Deckert and Deckert (2010); Kenn and Balkissoon (2011); Morris and Christopher (2010); Weinberger and Abu-Hasan (2007).
c Abramson (2012).

The Handbook also included guidance for confirming asthma in patients already using preventer treatment. Similar advice is available in the GINA report (2015) and is summarised in Table 13.

Table 6 NAC (2015): Confirming the diagnosis of asthma in a person using preventer treatment

Clinical profile	Lung function	Interpretation or action
Typical variable respiratory symptoms-	Variable airflow limitation demonstrated	Consistent with asthma diagnosis. Note: In a patient with a confirmed diagnosis of asthma, these features are consistent with sub-optimal (poor or partial) asthma control and suggest treatment should be reviewed.
	Variable airflow limitation not demonstrated	Obtain historical documentation of variable airflow limitation if possible. If not available, test again (either of): • Repeat lung function test during and after symptoms • Withhold BD treatment (SABA 6 hours or LABA-containing preventer more than 12 hours) then repeat spirometry before and 10-15 minutes after salbutamol If diagnosis still not confirmed, consider bronchial provocation (challenge) test. Note: a negative challenge test would not rule out asthma in a person taking inhaled corticosteroids. Consider referral to a specialist respiratory physician to confirm the diagnosis.
Current respiratory symptoms	Fixed (irreversible or incompletely reversible) airflow limitation (post-bronchodilator FEV_1/FVC < LLN for age and FEV_1 <80% predicted)	• Obtain historical documentation of variable airflow limitation if possible. • Ask about age at onset of symptoms and whether there were typical asthma symptoms earlier in life. • Consider alternative (or additional) diagnosis (e.g. COPD in adults). • Consider referral to a specialist respiratory physician to confirm diagnosis, if lung function does not improve after 3-6 months of treatment with inhaled corticosteroids.
Few respiratory symptoms	Variable airflow limitation not demonstrated	Obtain historical documentation of variable airflow limitation if possible. If not available, consider back-titrating preventer by one step: • Reduced inhaled corticosteroid dose by 50%. • 2-3 weeks later reassess lung function by spirometry before and 10-15 minutes after salbutamol. • If still no evidence of variable airflow limitation, consider stopping preventer treatment (with close monitoring) and repeating spirometry another 2-3 weeks later. If preventer is ceased and symptoms do not return at 2-3 weeks, review within 6 months.

Source: NAC Australian Asthma Handbook, Version 1.1; p. 17.
Note: This information applies to patients taking maintenance inhaled corticosteroid or combination inhaled corticosteroid/long-acting $beta_2$ agonist.
Abbreviations: BD, bronchodilator; COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; LABA, long-acting $beta_2$-agonist; LLN, lower limit of normal; SABA, short-acting $beta_2$-agonist.

The recommendations in Table 7 relate to the use of spirometry in children 6 years and over. NAC Handbook (Section 1.2) also provides general advice about the use of spirometry in children, citing the 2012 version of the BTS/SIGN guideline. Although lung function testing is the preferred method to assess whether airflow limitation is excessively variable, children aged 5 years or younger are generally unable to perform reliable spirometry. Therefore, the diagnosis of asthma in children aged 0-5 years is generally provisional, based on clinical symptoms (e.g. episodic wheezing or cough) and/or a trial of treatment, until performance of objective lung function testing is possible.

Table 7 NAC (2015): Clinical guidance relating to spirometry and the diagnosis of asthma in children 6 years and over

Clinical component	Recommendations	Type of recommendation
Assessing lung function	In children able to perform spirometry, measure bronchodilator reversibility by performing spirometry before and after giving inhaled rapid-onset $beta_2$ agonist bronchodilator (e.g. 4 puffs of salbutamol 100 mcg/actuation) by metered-dose inhaler and spacer. *Notes: If reliable equipment and appropriately trained staff are available, spirometry can be performed in primary care. If not, refer to an appropriate provider such as an accredited respiratory function laboratory.* *Most children aged 6 and older can perform spirometry reliably.* *Airflow limitation is defined as reversible (i.e. bronchodilator response is clinically important) if FEV_1 increases by ≥12%.*	Consensus recommendation
	Operators who perform spirometry should receive comprehensive training to ensure good quality.	Consensus recommendation
Making a provisional diagnosis	A provisional diagnosis of asthma can be made if the child has (all of): • wheezing accompanied by breathing difficulty or cough • other features that increase the probability of asthma such as history of allergic rhinitis, atopic dermatitis or a strong family history of asthma and allergies • no signs or symptoms that suggest a serious alternative diagnosis • clinically important response to bronchodilator demonstrated on spirometry performed before and after short-acting $beta_2$ agonist (if child is able to perform spirometry). *Notes: If reliable equipment and appropriately trained staff are available, spirometry can be performed in primary care. If not, refer to an appropriate provider such as an accredited respiratory function laboratory.* *Most children aged 6 and older can perform spirometry reliably.* *Airflow limitation is defined as reversible (i.e. bronchodilator response is clinically important) if FEV_1 increases by ≥12%.* *If spirometry does not demonstrate a clinically important response to bronchodilator, the test can be repeated when the child has symptoms.*	Consensus recommendation

Note: In children, the definition of expiratory airflow limitation according to a specific cut-off for FEV_1/FVC ratio is of limited value, because normal values in children change considerably with age.
Abbreviations: FEV_1, forced expiratory volume in 1 second.

The Handbook also provides a list of typical asthma patterns in children 6 years and over who do not take regular preventer medication. Children with asthma symptoms can generally be categorised into three groups: infrequent intermittent asthma; frequent intermittent asthma; and persistent asthma (mild, moderate or severe). Determining the severity of persistent asthma relies, in part, on spirometry measurements (FEV_1 % predicted). Further details are available in Appendix 8.

National Asthma Council Australia (2013)

The information paper about asthma in people over 65 years provides extensive information about the diagnosis of asthma in older patients. It notes that asthma is commonly under-diagnosed or misdiagnosed in older people. While the clinical features of asthma (e.g. wheezing) are the same in older patients, those who have had the condition for a long period of time may not meet the usual diagnostic criteria for reversibility of airflow obstruction. Similarly, asthma that begins later in life is often associated with irreversible airflow limitation (also called 'fixed airway obstruction'). The information paper cited a publication by Reed (2010) that suggested that airway remodelling and stiffening of the chest wall occurs with age and may affect reversibility.

Several recommendations relating to the use of spirometry in patients over 65 are provided (see Table 8); however, the evidence base that underpins the recommendations was not clear.

Table 8 NAC (2013): The use of spirometry for investigating new asthma-like symptoms in older adults

Recommendations	Grade of recommendation
Consider the possibility of adult-onset asthma in people aged 65 and over with dyspnoea, wheeze or cough, even if they have no previous diagnosis of asthma.	Not reported
New-onset respiratory symptoms that suggest asthma should be investigated fully, including use of pre- and post-bronchodilator spirometry	Not reported
If spirometry before and after bronchodilator demonstrates airflow obstruction that is not completely reversible, consider the possibility of COPD, even if the person has never smoked. Start a treatment trial with an inhaled corticosteroid and repeat spirometry 6–8 weeks later.	Not reported

Note: More than 90% of patients with obstructive airway disease aged 65 years and over can perform an acceptable spirometry test (when staff are appropriately trained and rigorous quality control protocols are followed).
Abbreviations: COPD, chronic obstructive pulmonary disease.

According to the information paper, acute response to bronchodilator is defined as positive (i.e. airflow obstruction is reversible) if both of the following apply:

- Post-bronchodilator FEV_1 is at least 200 mL higher than pre-bronchodilator FEV_1; and
- Increase in FEV_1 is at least 12%.

Airflow limitation was deemed as 'not fully reversible' if both the following apply:

- Post-bronchodilator FEV_1/FVC is less than 70% or less than LLN;[7] and
- Post-bronchodilator FEV_1 is less than 80% of the predicted value.

The information paper also addressed the issue of coexisting asthma and COPD, stating that the co-existence of incompletely reversible airflow limitation (characteristic of COPD) and increased airflow variability (characteristic of asthma) is relatively common among older people with respiratory symptoms.

[7] LLN is the bottom 5% of the normal population distribution for FEV_1/FVC ratio by age category. Most spirometers give an age-adjusted cut-point for this parameter.

National Clinical Guideline Centre (2016)

The NCGC guideline (2016) was based on a systematic literature search underpinned by a number of key questions. One of the diagnostic key questions was:

> *In people under investigation for asthma, what is the diagnostic test accuracy and cost-effectiveness of spirometry/flow volume loop measures?*

The CPG identified six cross-sectional studies that assessed the diagnostic accuracy of spirometry in patients with signs and symptoms of asthma (Fortuna et al, 2007; Pino et al, 1996; Popovic-Grle et al, 2002; Schneider et al, 2009; Sivan et al, 2009; Smith et al, 2004). Only one study used the 'ideal' index test measure of FEV_1/FVC ratio <70%. In all cases, the reference standard was physician's diagnosis of asthma with an objective test.[8]

Only one study (Sivan et al, 2009; N=133) provided evidence about the use of spirometry in children and young people. The index test in that study was FEV_1 <80%. Based on evidence from the six included studies, the following evidence statements were developed.

Table 9 NCGC (2016): Evidence statements relating to the use of spirometry for the diagnosis of asthma

Population	Evidence statements	Quality of evidence
Adults	One study with 47 adults showed that spirometry (FEV_1/FVC <70%) has a sensitivity of 35.3% and a corresponding specificity of 100% for diagnosing asthma in people presenting with respiratory signs and symptoms.	Moderate quality
	Two studies with 303 adults showed that spirometry (FEV_1/FVC <70% and/or FEV_1 <80%) has a sensitivity range of 29-47% and a corresponding specificity range of 41-59% for diagnosing asthma in people presenting with respiratory signs and symptoms.	Very low quality
	Three studies with 292 adults showed that spirometry (FEV_1 <80%) has a median sensitivity of 29.4% and a corresponding specificity of 100% for diagnosing asthma in people presenting with respiratory signs and symptoms.	Very low quality
	No evidence was available for flow volume loop.	Not applicable
Children	No evidence was available for FEV_1/FVC <70% in children.	Not applicable
	No evidence was available for flow volume loop.	Not applicable
	One study with 133 children showed that spirometry (FEV_1 <80%) has a sensitivity of 52% and a corresponding specificity of 72% for diagnosing asthma in people presenting with respiratory signs and symptoms.	Low quality

Abbreviations: FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity.

[8] Objective tests conducted as part of the reference standard varied between studies. The tests included methacholine challenge test, bronchodilator response, plethysmography, methacholine challenge test, positive hypertonic saline challenge test. In the study of children, the reference standard was diagnosis by a paediatric pulmonologist after 18 months follow-up based on history of symptoms, treatment trials, documented variability in FEV_1 with or without controller medications (Sivan et al, 2009).

In children younger than 5 years, the guideline recommends treating symptoms based on observation and clinical judgment. If the child still has symptoms when they reach age 5, objective tests should be performed while on current treatment. In children without symptoms at 5 years of age, treatment should be stepped down (or stopped) before performing objective tests.

Another key question of relevance to this review that was addressed in the NGCG guideline was:

> *In people under investigation for asthma, what is the diagnostic test accuracy and cost-effectiveness of bronchodilator response (using PEF or FEV_1)?*

A determination of airflow-limitation reversibility with drug administration is commonly undertaken as part of lung function testing in patients in whom obstruction is observed. There is no clear consensus about what constitutes reversibility in subjects with airflow obstruction, although, according to NCGC (2016), the *ATS/ERS Task Force Standardisation of Lung Function Testing: Standardisation of spirometry* (2005) provides the clearest guidance and is most widely used.

The NCGC guideline recommended the following procedure for assessing bronchodilator response, citing the ATS/ERS Task Force (Miller et al, 2005).

- Assess lung function at baseline. If obstruction is present (FEV_1/FVC ratio <70%) administer four separate doses of 100 mcg salbutamol through a spacer and reassess lung function after 15 minutes.
- An increase in FEV_1 ≥ 12% and ≥ 200 mL above baseline FEV_1 after short-acting β2 agonist constitutes a positive bronchodilator response.
- The lack of a spirometric bronchodilator response in the laboratory does not preclude a clinical response to bronchodilator therapy.

The guideline identified four studies that aimed to assess the diagnostic accuracy of bronchodilator reversibility in distinguishing between asthma and COPD (Brand et al, 1992; Chhabra, 2005; Kim et al, 2012; Quadrelli et al, 1999). All of the studies included adults with asthma or COPD, rather than suspected asthma.

Only two of the studies used a reference standard that included an objective test for asthma and in one of those studies (Quadrelli et al, 1999) it was unclear whether all patients received the objective test.

Table 10 NCGC (2016): Evidence statements relating to the use of bronchodilator reversibility for the diagnosis of asthma

Population	Evidence statements	Quality of evidence
Adults	Two studies with 868 adults showed that bronchodilator reversibility (ΔFEV_1%init ≥12% and ΔFEV_1[L] ≥0.2 L) has a sensitivity range of 0.17 to 0.65 and a corresponding specificity range of 0.61 to 0.81 for diagnosing asthma in people presenting with respiratory signs and symptoms and obstructive airways disease.	Very low quality
	Two studies with 269 adults showed that bronchodilator reversibility (ΔFEV_1%init >15% and ΔFEV_1[L] >0.2 L) has a sensitivity range of 0.69 to 0.69 and a corresponding specificity range of 0.55 to 0.71 for diagnosing asthma in people presenting with respiratory signs and symptoms and obstructive airways disease.	Low quality
Children	No evidence was identified in children aged 5-16 years.	Not applicable

Abbreviations: FEV_1, forced expiratory volumes in 1 second.

Based on the available evidence, the Guideline Development Group (GDG) agreed spirometry should not be used in isolation for the diagnosis of asthma due to the low sensitivity of the test, and due to the fact that obstruction also occurs in other conditions that have symptoms in common with asthma (such as COPD). When considering the placement of spirometry in a diagnostic pathway, the GDG noted the importance of spirometry as a first line investigation in all patients, to detect the presence or absence of obstruction, which then determines whether other tests are appropriate. The GDG agreed that a bronchodilator reversibility test should be used on all patients with an obstructive spirometry because it can be performed at a low cost immediately after initial spirometry, and a positive result is recognised as strong indication that the individual has asthma. However the GDG noted that the clinical evidence showed it did not have a high specificity and that there were other obstructive airway diseases, such as COPD, that could produce a positive result.

Although there was no diagnostic accuracy evidence in children, the general consensus of the GDG suggests that a positive bronchodilator reversibility test is enough to confirm the diagnosis of asthma in children. Therefore, in children a bronchodilator reversibility test has high value relative to its low cost. The GDG noted that a negative bronchodilator reversibility test would not rule out the diagnosis of asthma and there was value in further testing to prevent false-negative diagnoses.

NCGC (2016) developed four recommendations of relevance to this review (see Table 11).

Table 11 NCGC (2016): Recommendations on the use of spirometry for the diagnosis of asthma

Recommendations	Grading of recommendations
R12: Use spirometry as the first investigation for asthma in adults and young people older than 16 and children aged 5-16 years. Regard a forced expiratory volume in 1 second/forced vital capacity (FEV_1/FVC) ratio of less than 70%[a] as a positive test for obstructive airway disease (obstructive spirometry). See also R28.	Not reported
R13: Offer a bronchodilator reversibility test to adults and young people older than 16 with obstructive spirometry (FEV_1/FVC ratio less than 70%). Regard an improvement in FEV_1 of 12% or more, together with an increase in volume of 200 mL or more, as a positive test.	Not reported
R14: Consider a bronchodilator reversibility test in children aged 5-16 years with obstructive spirometry (FEV_1/FVC ratio less than 70%). Regard an improvement in FEV_1 of 12% or more as a positive test.	Not reported
R28: Do not diagnose asthma based on any single test alone in adults and children aged 5 years and over.	Not reported

Abbreviations: FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; LLN, lower limit of normal.
a Or the LLN if the calculation is available for children aged 5-16 years.

Global Initiative for Asthma (2015)

While the GINA report adopted a method of rating the level of evidence from A to D, guidance relating to diagnosis and assessment of asthma was not rated in this way. It was often unclear what the evidence base was that underpinned guidance relating to lung function testing, including spirometry. Nonetheless, the diagnostic guidance provided by GINA is summarised below.

GINA (2015) states that the diagnosis of asthma relies on two essential components: (i) identification of clinical symptoms such as wheezing, dyspnoea, chest tightness or cough; and (ii) the demonstration of excessive variability in expiratory airflow limitation. While many respiratory conditions may cause a reduction in FEV_1, a reduced FEV_1/FVC ratio indicates airflow limitation.[9] The concept of 'variability' in lung function refers to improvement and/or deterioration in lung function that may be observed over the course of one day or over a longer period of time (e.g. seasonally).

Asthma is most likely to be present in patients who experience large variations in lung function. According to GINA (2015), an increase or decrease in FEV_1 of >12% and >200 mL from baseline, or (if spirometry is not available) a change in PEF of at least 20%, is accepted as being consistent with asthma.[10] Some specific examples of variability in airflow limitation and the corresponding criteria required for making a diagnosis of asthma are shown in Table 12.

[9] A population study by Quanjer et al (2012) is cited as a source of reference values for the FEV_1/FVC ratio. Based on this (and possibly other) evidence, the 2015 GINA report suggests that the FEV_1/FVC ratio is normally greater than 0.75 to 0.80, and usually greater than 0.90 in children. Any values less than these suggest airflow limitation.
[10] The report stated the FEV_1 is more reliable than PEF.

Table 12 GINA (2015): Diagnostic criteria for demonstrating variable expiratory airflow limitation

Indicator of variable expiratory airflow limitation	Criteria for making the diagnosis of asthma
Positive BD reversibility test[a]	Adults: increase in FEV_1 of >12% and >200 mL from baseline, 10–15 minutes after 200–400 mcg albuterol or equivalent[c] Children: increase in FEV_1 of >12% predicted
Excessive variability in twice-daily PEF over 2 weeks	Adults: average daily diurnal PEF variability >10% Children: average daily diurnal PEF variability >13% *Note: daily diurnal PEF variability is calculated from twice daily PEF as ([day's highest minus day's lowest] / mean of day's highest and lowest), and averaged over one week.*
Significant increase in lung function after 4 weeks of anti-inflammatory treatment	Adults: increase in FEV_1 by >12% and >200 mL (or PEF[d] by >20%) from baseline after 4 weeks of treatment, outside respiratory infections
Positive exercise challenge test	Adults: fall in FEV_1 of >10% and >200 mL from baseline Children: fall in FEV_1 of >12% predicted, or PEF >15%
Positive bronchial challenge test[b]	Fall in FEV_1 from baseline of ≥20% with standard doses of methacholine or histamine, or ≥15% with standardised hyperventilation, hypertonic saline or mannitol challenge
Excessive variation in lung function between visits (less reliable)	Adults: variation in FEV_1 of >12% and >200 mL between visits, outside of respiratory infections Children: variation in FEV_1 of >12% in FEV_1 or >15% in PEF[d] between visits (may include respiratory infections)

Source: GINA (2015); Box 1-2, p. 5.
Abbreviations: BD, bronchodilator; FEV_1, forced expiratory volume in 1 second; GINA, Global Initiative for Asthma; LABA, long-acting $beta_2$-agonist; PEF, peak expiratory flow (highest of three readings); SABA, short-acting $beta_2$-agonist.
a More likely to be positive if bronchodilator medication is withheld before test: SABA ≥4 hours, LABA ≥15 hours.
b Usually only performed in adults.
c Greater confidence if increase is >15% and >400 mL.
d For PEF, use the same meter each time, as PEF may vary by up to 20% between different meters.

The GINA (2015) diagnostic algorithm suggests that reversibility testing with spirometry/PEF should be undertaken where the patient history and clinical examination support a diagnosis of asthma. This indicates that reversibility testing may be the preferred method of demonstrating airflow variability compared with the other tests listed in Table 12.

The report also includes advice about the diagnosis of asthma in special populations including: patients presenting with cough as the only respiratory symptom; possible occupational asthma; athletes; pregnant women; the elderly; smokers and ex-smokers; obese patients; low resource settings; and patients already taking controller treatment.

The latter is most relevant to this review because the use of spirometry is encouraged in some of these patients to confirm the diagnosis of asthma, as per the guidance provided in Table 12.

Table 13 GINA (2015): Confirming the diagnosis of asthma patients already taking controller treatment

Current status	Steps to confirm the diagnosis of asthma
Variable respiratory symptoms and variable airflow limitation	Diagnosis of asthma is confirmed. Assess the level of asthma control and review controller treatment.
Variable respiratory symptoms but no variable airflow limitation	Repeat BD reversibility test again after withholding BD (SABA: 4 hours; LABA: 12+ hours) or during symptoms. If normal, consider alternative diagnoses. *If FEV_1 is >70% predicted*: consider a bronchial provocation test. If negative, consider stepping down controller treatment and reassess in 2–4 weeks. *If FEV_1 is <70% predicted*: consider stepping up controller treatment for 3 months, then *reassess symptoms and lung function. If no response, resume previous treatment and refer patient for diagnosis and investigation.*
Few respiratory symptoms, normal lung function, and no variable airflow limitation	Repeat BD reversibility test again after withholding BD (SABA: 4 hours; LABA: 12+ hours) or during symptoms. If normal, consider alternative diagnoses. Consider stepping down controller treatment: • If symptoms emerge and lung function falls: asthma is confirmed. Step up controller treatment to lowest previous effective dose. • If no change in symptoms or lung function at lowest controller step: consider ceasing controller, and monitor patient closely for at least 12 months.
Persistent shortness of breath and fixed airflow limitation	Consider stepping up controller treatment for 3 months, then reassess symptoms and lung function. If no response, resume previous treatment and refer patient for diagnosis and investigation. Consider asthma–COPD overlap syndrome.

Source: GINA (2015); Box 1-4, p. 10.
Note: Refer to GINA report for further information about stepping down controller treatment and assessing level of asthma control.
Abbreviations: BD, bronchodilator; COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; LABA, long-acting $beta_2$-agonist; SABA, short-acting $beta_2$-agonist.

According to GINA (2015), asthma severity should be assessed retrospectively from the level of treatment required to control symptoms and exacerbations (Chung et al, 2014; Reddel et al, 2009; Taylor et al, 2008). It can be assessed once the patient has been on controller treatment for several months and, if appropriate, treatment step down has been attempted to find the patient's minimum effective level of treatment. The assessment of asthma severity does not require spirometry and is of limited relevance to this review.

British Thoracic Society / Scottish Intercollegiate Guidelines Network (2014)

This guideline and the related systemic literature search was based on a series of structured key questions about the diagnosis and management of asthma, patient education and delivery of care. The key questions that underpinned recommendations relating to spirometry and diagnosis are presented in Appendix 9.[11]

The guideline included recommendations and practice points about the use of spirometry in adults and children who can perform spirometry, acknowledging that the use of this test in children (≤5 years) is generally not feasible (see Table 14).

[11] The full list of key questions is available on the SIGN website.

Table 14 BTS/SIGN (2014): Clinical guidance relating to spirometry and the diagnosis of asthma in adults and children

Population	Recommendations	Grade of recommendation
Adults	In adults, initial diagnosis should be based on a careful assessment of symptoms and a measure of airflow obstruction. • In patients with a high probability of asthma move straight to a trial of treatment. Reserve further testing for those whose response to a trial of treatment is poor. • In patients with a low probability of asthma, whose symptoms are thought to be due to an alternative diagnosis, investigate and manage accordingly. Reconsider the diagnosis of asthma in those who do not respond. • In patients with an intermediate probability of asthma the preferred approach is to carry out further investigations, including an explicit trial of treatments for a specified period, before confirming a diagnosis and establishing maintenance treatment.	GPP
	Spirometry is the preferred initial test to assess the presence and severity of airflow obstruction in adults.	D
	Offer patients with airways obstruction and intermediate probability of asthma a reversibility test and/or a trial of treatment for a specified period: • if there is significant reversibility, or if a treatment trial is clearly beneficial treat as asthma • if there is insignificant reversibility and a treatment trial is not beneficial, consider tests for alternative conditions.	GPP
	Assess FEV_1 (or PEF) and/or symptoms: • before and after 400 mcg inhaled salbutamol in patients with diagnostic uncertainty and airflow obstruction present at the time of assessment • in other patients, or if there is an incomplete response to inhaled salbutamol, after either inhaled corticosteroids (200 mcg twice daily beclomethasone equivalent for 6–8 weeks) or oral prednisolone (30 mg once daily for 14 days).	C
Children	In children with an intermediate probability of asthma who can perform spirometry and have evidence of airways obstruction, assess the change in FEV_1 or PEF in response to an inhaled bronchodilator (reversibility) and/or the response to a trial of treatment for a specified period: • If there is significant reversibility, or if a treatment trial is beneficial, a diagnosis of asthma is probable. Continue to treat as asthma, but aim to find the minimum effective dose of therapy. At a later point, consider a trial of reduction, or withdrawal, of treatment. • If there is no significant reversibility, and treatment trial is not beneficial, consider tests for alternative conditions.	GPP
	In children with an intermediate probability of asthma who can perform spirometry and have no evidence of airways obstruction: • consider testing for atopic status, bronchodilator reversibility and if possible, bronchial hyper-responsiveness using methacholine, exercise or mannitol • consider specialist referral.	C
	In children with an intermediate probability of asthma who cannot perform spirometry, offer a trial of treatment for a specified period: • if treatment is beneficial, treat as asthma and arrange a review • if treatment is not beneficial, stop asthma treatment, and consider tests for alternative conditions and specialist referral.	GPP

Notes: Grade C = A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++; Grade D = Evidence level 3 or 4; or extrapolated evidence from

studies rated as 2+; GPP = Recommended best practice based on the clinical experience of the Guideline Development Group. See 0 for a guide to the levels of evidence.
Abbreviations: FEV_1, forced expiratory volume in 1 second; GPP, Good Practice Point; PEF, peak expiratory flow.

Chronic Obstructive Pulmonary Disease (COPD)

Lung Foundation Australia /Thoracic Society of Australia and New Zealand (2015)

The LFA/TSANZ (2015) guideline reiterates the finding of a systematic review (Wilt et al, 2005), stating that spirometry, in additional to clinical examination, improves the diagnostic accuracy of COPD compared to clinical examination alone (refer to Section 2.4.1 for further discussion of the Wilt review).

The guideline also highlights the fact that airflow limitation identified through spirometry can be classified according to several criteria. Spirometric airflow limitation is most commonly defined using an FEV_1/FVC ratio cut-off (usually 0.7) or a comparison with the LLN. The guideline emphasises that the former may lead to over-diagnosis of COPD in older populations, under-diagnosis in younger population, and may lead to gender imbalances (women have higher FEV_1/FVC than males).

A systematic review was identified that examined the relationship between FEV_1/FVC ratio and LLN with clinical outcomes. The systematic review, which included 11 studies, found that both measures were related to clinical outcomes and concluded that neither approach could be preferred over the other (van Dijk et al, 2014).

Two evidence statements relevant to spirometry and the diagnosis of COPD were included in the guideline and are shown in Table 15.

Table 15 LFA/TSANZ (2015): Evidence statements relating to spirometry and the diagnosis of COPD

Evidence statements	Evidence level
The diagnosis of COPD rests on the demonstration of airflow limitation which is not fully reversible *(NHLBI/WHO Workshop Report, April 2001)*	II
It is important in general practice settings to obtain accurate spirometric assessment *(Walters, 2011)*	III-3

Note: II = Evidence obtained from at least one properly designed randomised controlled trial; III-3 = Evidence obtained from comparative studies with historical controls, two or more single-arm studies, or interrupted time series without a parallel group.
Abbreviations: COPD, chronic obstructive pulmonary disease; NHLBI, National Heart, Lung and Blood Institute; WHO, World Health Organization.

According to the LFA/TSANZ guideline, response to bronchodilators is determined in order to: (i) assign a level of severity of airflow obstruction (post-bronchodilator); and (ii) help confirm asthma. In relation to reversibility testing, the LFA/TSANZ guideline provided the following advice: *if airflow limitation is fully or substantially reversible, (FEV_1 response to bronchodilator >400 mL), the patient should be treated as for asthma.*[12] Furthermore, the guideline stated that an increase in FEV_1 of more than 12% and 200 mL is greater than average day-to-day variability and is unlikely to occur by chance.[13]

[12] Based on evidence available in Hunter et al (2002) and British Thoracic Society (2008).
[13] Sourk and Nugent (1983) and Pellegrino et al (2005).

Abramson (2014) – Lung Foundation Australia /Thoracic Society of Australia and New Zealand

The Concise Guide by Abramson et al (2014) recommends the measurement of pre- and post-bronchodilator spirometry to confirm COPD, with the basis of diagnosis being post-bronchodilator levels and persistent airflow limitation. The evidence statements, relating to spirometry and reversibility testing are shown in Table 16.

Table 16 Abramson (2014): Evidence statements relating to spirometry and the diagnosis of COPD

Evidence statements	Evidence level
COPD is confirmed by the presence of persistent airflow limitation [post-bronchodilator FEV_1/FVC < 0.7] *(NHLBI/WHO Workshop Report, April 2001).*	III-2
If FEV_1 increases >400 mL following bronchodilator, consider asthma or asthma / COPD overlap *(British Thoracic Society, 2008).*	III-2
An FEV_1 increase ≥ 12% and ≥ 200 mL constitutes a positive bronchodilator response. An FEV_1 increase > 400 mL strongly suggests underlying asthma or asthma / COPD overlap *(Pellegrino, 2005).*	III-2

Note: III-2 = Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies, or interrupted time series with a control group.
Abbreviations: COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; NA, not applicable.

Abramson et al (2014) emphasise the importance of spirometry for diagnosis, stating that COPD cannot be diagnosed reliably on clinical features and/or chest x-ray findings alone. However, the guideline also acknowledges some limitations of complete reliance on spirometry, including the fact that many patients with COPD have some reversibility of airflow limitation with bronchodilators and that asthma and COPD can coexist in some patients. Clinical guidance relating to reversibility testing is shown in Table 17, with related practice tips in Table 18.

Table 17 Abramson (2014): Recommendations relating to spirometry and the diagnosis of COPD

Recommendations	Grading of recommendation
Spirometry should be performed using techniques that meet published standards.	Strong recommendation; low-quality evidence
Perform pre- and post-bronchodilator spirometry to confirm COPD, which is characterised by airflow limitation that is not fully reversible (post-bronchodilator FEV1/FVC ratio < 0.7 and FEV1 < 80% predicted).	Strong recommendation; high-quality evidence
Interpret borderline spirometry results with caution, particularly in older (> 65 years of age) and younger patients (< 45 years of age), or those without a history of smoking or exposure to occupational / environmental pollutants or dust.	Strong recommendation; moderate-quality evidence
In patients with borderline spirometry, consider alternative diagnoses and investigate appropriately.	Strong recommendation; moderate-quality evidence
If the FEV1 response to bronchodilator is >400 mL, strongly consider asthma or asthma / COPD overlap.	Strong recommendation; moderate-quality evidence

Recommendations	Grading of recommendation
If the FEV1 response to bronchodilator is <400 mL (but ≥200 mL and ≥12%), consider asthma / COPD overlap or an asthma component depending on history and pattern of symptoms.	Weak recommendation; low-quality evidence

Abbreviations: COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity.

Table 18 Abramson (2014): Practice tips relating to spirometry and the diagnosis of COPD

Practice tips
Conduct risk assessment and screening (using Lung Foundation Australia's Lung Health Checklist and a COPD screening device such as the PiKo-6 or COPD-6) to target those patients who should have further spirometry testing.
A practice nurse could assist the GP by undertaking screening activities and establishing a register of COPD patients.
All patients with a diagnosis of COPD should have a post-bronchodilator spirometry test documented in their clinical record.
There is some risk with spirometry of over diagnosis in older people or under diagnosis in younger people, especially when the FEV_1/ FVC is close to 0.7. Consider referral for lung function testing at an accredited lung function testing laboratory if there is uncertainty, or the patient has difficulty performing the test.

Abbreviations: COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; GP, general practitioner.

Global Initiative for Chronic Obstructive Lung Disease (2016)

As discussed earlier, clinical practice recommendations that are included in the GOLD guideline focus on asthma management rather than diagnosis. Nonetheless, the guideline includes some statements relevant to diagnosis, although the evidence base underpinning this guidance is not clear. According to GOLD (2016), a post-bronchodilator $FEV_1/FVC < 0.70$ confirms the presence of persistent airflow limitation and is required to make a confident diagnosis of COPD. The guideline emphasises that the advantage of this criterion is that it is independent of reference values and has been adopted in many clinical trials that form the evidence base for most of the treatment recommendations.

The guideline advises against the use of reversibility testing for the diagnosis of COPD, citing Albert et al (2012), and noted that "the degree of reversibility has never been shown to add to the diagnosis, differential diagnosis with asthma, or to predicting the response to long-term treatment with bronchodilators or corticosteroids" (GOLD, 2016).

Like the LFA/TSANZ (2015) guideline, GOLD (2016) discusses the risk of over-diagnosis in elderly patients using a fixed FEV_1/FVC ratio to define airflow limitation and potential under-diagnosis in adults younger than 45 years, particularly those with mild disease, compared with using a cut-off based on the LLN.

Table 19 shows the GOLD classification system in which airflow limitation is divided into four grades from mild to very severe. COPD grade is based on post-bronchodilator impairment of lung function as measured by spirometry. It should be noted that spirometry cut-points are used for purposes of simplicity; however, there is only a weak correlation between FEV_1, symptoms and impairment of a patient's health-related quality of life (Jones, 2009).

Of interest, the GOLD report provides the most widely accepted classification system of the severity of COPD, which is based on the degree of impairment of lung function as measured by spirometry. This grading system has been adopted by many other CPGs and regulatory bodies; for example, the European Medicines Agency (EMA) advocates the use of the GOLD grading system for defining target COPD populations in clinical trials (EMA, 2012).

Table 19 GOLD (2016): Classification of severity of airflow limitation in COPD (based on post-bronchodilator FEV_1)

In patients with FEV_1/FVC <0.70	**Predicted airflow**
GOLD 1: Mild	$FEV_1 \geq 80\%$
GOLD 2: Moderate	$50\% \leq FEV_1 < 80\%$
GOLD 3: Severe	$30\% \leq FEV_1 < 50\%$
GOLD 4: Very severe	$FEV_1 < 30\%$

Abbreviations: COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease.

Department of Veterans Affairs / Department of Defense (2014)

The main key question addressed in this guideline and of relevance to this Rapid Review was:

> *In patients with COPD, what is the evidence that using spirometry (including the value of bronchodilator responsiveness), symptom severity, risk of exacerbations (e.g. annual exacerbation rate, time to first exacerbation), and comorbidities, alone or in combination, improves diagnosis, clinical classification (including pre-operative assessments), treatment planning, and clinician adherence to treatment protocols?*

The recommendation relevant to spirometry is shown in Table 20. While the recommendation makes reference to a particular FEV_1/FVC ratio, the guideline emphasises that clinicians should use caution when applying this criterion, particularly in elderly patients, where a reduced FEV_1/FVC ratio may simply be a normal part of aging. To this end, the guideline suggests that in elderly patients, a reliance on history of risk factors, history of asthma and symptoms as well as the LLN of FEV_1/FVC to confirm the diagnosis, may be more appropriate.

Table 20 VA/DoD (2014): Recommendation relating to the use of spirometry for the diagnosis of COPD

Recommendation	**Grading of recommendation**
We recommend that spirometry, demonstrating airflow obstruction (post-bronchodilator FEV1/FVC <70%, with age adjustment for more elderly individuals), be used to confirm all initial diagnoses of COPD (Walker et al, 2006).	Strong for

Abbreviations: COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity.

Of particular importance to this MBS Review, the guideline notes that clinics with spirometry equipment and the necessary training may still lack the resources to undertake post-bronchodilator spirometry. Therefore, the Working Group emphasised that the post-bronchodilator measurement can form a significant barrier to care and, while eliminating the post-bronchodilator requirement is more convenient, it has the potential to misdiagnose asthmatic patients as having COPD.

Qaseem (2011) – American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society

This CPG focuses on three main research questions, one of which is relevant to this review:

> *What is the value of spirometry for screening and diagnosis of adults who are asymptomatic and have risk factors for developing airflow obstruction, or who are COPD treatment candidates?*

Based on evidence obtained in the published literature, the CPG contains one recommendation regarding the use of spirometry for the diagnosis of COPD (see Table 21).

Table 21 Qaseem (2011): Recommendations on the use of spirometry for diagnosis of COPD

Recommendations	Grading of recommendation
ACP, ACCP, ATS and ERS recommend that spirometry should be obtained to diagnose airflow obstruction in patients with respiratory symptoms.	Strong recommendation; moderate-quality evidence.

Abbreviations: ACCP, American College of Chest Physicians; ACP, American College of Physicians; ATS, American Thoracic Society; ERS, European Respiratory Society.

Qaseem (2011) also include several recommendations for initiating therapy on the basis of FEV_1 thresholds measured using spirometry. They note that the evidence of benefit of the initiation of inhaled bronchodilators in symptomatic patients with FEV_1 between 60% and 80% is limited and conflicting. Patients with FEV_1 <60% predicted seem to benefit the most from inhaled bronchodilators.

National Clinical Guideline Centre (2010)

The GDG formulated nine consensus statements relating to the use of spirometry for the diagnosis of COPD (see Table 22). Importantly the consensus statements advise that a confident diagnosis of COPD can only be made with spirometry, but that spirometry alone cannot separate asthma from COPD.

Table 22 NCGC (2010): GDG consensus statements on the performance of spirometry

Consensus statements	Hierarchy of evidence
Spirometry is fundamental to making a diagnosis of COPD and a confident diagnosis of COPD can only be made with spirometry.	IV
A diagnosis of airflow obstruction can be made if the $FEV_1/FVC < 0.7$ (i.e. 70%) and $FEV_1 < 80\%$ predicted.	IV
In individual patients PEF rates have not been validated for the diagnosis of COPD and a normal PEF rate does not exclude significant airflow obstruction *(Nolan, 1999)*.	IV
Spirometry is a poor predictor of disability and quality of life in COPD *(Jones, 2001)*.	IV
Spirometry predicts prognosis in COPD *(Anthonisen, 1986; Burrows, 1989)*.	IV
Spirometry contributes to the assessment of the severity of COPD.	IV
Spirometry alone cannot separate asthma from COPD.	IV
Changes in the flow volume loop may give additional information about mild airflow obstruction.	IV
Measurement of the slow vital capacity may allow the assessment of airflow obstruction in patients who are unable to perform a forced manoeuvre to full exhalation.	IV

Note: IV = Evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
Abbreviations: COPD, chronic obstructive pulmonary disease; FEV, forced expiratory volume; FVC, forced vital capacity; GDG, Guideline Development Group; PEF, peak expiratory flow.

Two diagnostic research questions were addressed in the NCGC guideline; they are both of relevance to this MBS Review.

> *How does post bronchodilator FEV_1 (forced expiratory volume in one second) compare with pre bronchodilator FEV_1 in terms of: a) sensitivity / specificity of FEV_1 for diagnosis; b) classification of severity of disease?*
>
> *In individuals where the diagnosis of COPD is considered and spirometry is conducted, what are the sensitivity and specificity of a fixed ratio FEV_1/FVC compared with the lower limit of normal FEV_1/FVC ratio to diagnose COPD?*

The systematic literature review (search date August 2009) identified two studies that compared pre- and post-bronchodilator FEV_1 measures to a clinical diagnosis of COPD (based on symptoms) and were relevant to the first question. Importantly, the purpose of this question was to examine pre- and post-bronchodilator spirometry as independent tests of airway obstruction/COPD and not to assess reversibility testing. The guideline stated that reversibility testing is not deemed to be a necessary routine diagnostic procedure; this is discussed in more detail later in this section.

Neither of the studies allowed for assessment of sensitivity and specificity and no evidence was found to compare the impact of pre- versus post-bronchodilator spirometry on mortality over time.

Despite a paucity of robust evidence, the NGCG guideline recommended that post-bronchodilator spirometry is assessed to confirm the diagnosis of COPD. This resulted in an update to Recommendation 4 (see Table 23). The GDG noted that this update makes the recommendation

concordant with international guidelines, the Quality Outcome Framework, and the National Strategy for COPD.

Four cross-sectional studies were identified that compared FEV_1/FVC ratio – fixed versus LLN – with a physician's diagnosis of COPD.[14] These studies were relevant to the second diagnostic question.[15]

The two larger studies showed that fixed ratio FEV_1/FVC was most similar to the physician's diagnosis, whereas the two smaller studies showed that the LLN FEV_1/FVC was most similar to the physician's diagnosis. Nonetheless, the guideline stated that ultimately the lack of predictive equations and reference values for post-bronchodilator FEV_1 and FVC values render the use of LLN impractical.

The NCGC recommendations relating to the use of spirometry for the diagnosis of COPD are listed in Table 23. The recommendations are graded to indicate the strength of evidence underpinning the recommendations. In light of the limited evidence base, the majority of recommendations relevant to this MBS Review were Grade D recommendations, indicating that they are based on low-level evidence or extrapolated from higher-level evidence.

Table 23 NCGC (2010): Recommendations on the use of spirometry for diagnosis of COPD

Recommendations	**Grading of recommendations**
R4: Spirometry should be performed: • at the time of diagnosis • to reconsider the diagnosis, if patients show an exceptionally good response to treatment. U1: Measure post-bronchodilator spirometry to confirm the diagnosis of COPD. U2: Consider alternative diagnoses or investigations in: • older people without typical symptoms of COPD where the FEV1/FVC ratio is < 0.7 • younger people with symptoms of COPD where the FEV_1/FVC ratio is ≥ 0.7.	D
R5: All health professionals involved in the care of people with COPD should have access to spirometry and be competent in the interpretation of the results.	D
R6: Spirometry can be performed by any health care worker who has undergone appropriate training and who keeps his or her skills up to date.	D
R7: Spirometry services should be supported by quality control processes.	D
R8: It is recommended that ERS 1993 reference values are used[16] but it is recognised that these values may lead to under-diagnosis in older people and are not applicable in black and Asian populations. *Note: Definitive spirometry reference values are not currently available for all ethnic populations The GDG was aware of on-going research in this area.*	D
R9: At the time of their initial diagnostic evaluation, in addition to spirometry all patients should have: • a chest radiograph to exclude other pathologies • a full blood count to identify anaemia or polycythaemia • BMI calculated.	D

[14] All measurements were post-bronchodilator except for one study (Celli et al, 2003).
[15] No relevant economic analyses were identified that compared COPD diagnosis using a fixed ratio FEV_1/FVC compared with the LLN FEV_1/FVC ratio.
[16] Quanjer et al (1993)

Note: Grade D = Directly based on hierarchy IV evidence or extrapolated from hierarchy I, II or III evidence.
Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; ERS, European Respiratory Society; FEV, forced expiratory volume; FVC, forced vital capacity; GDG, Guideline Development Group; NGCG, National Clinical Guideline Centre; R, recommendation; U, updated recommendation.

As mentioned earlier, the NCGC guideline emphasises that, while post-bronchodilator spirometry is recommended in the 2010 update for the assessment of COPD, this measurement should not be confused with reversibility testing. The NCGC guideline (2010) highlights some major limitations with the traditional diagnostic approaches that often adopted reversibility testing to distinguish between COPD and asthma patients. Those limitations are addressed in a number of evidence statements, shown in Table 24.

Table 24 NCGC (2010): Evidence statements relating to reversibility testing and COPD

Evidence statements	Hierarchy of evidence
There is considerable variation in the magnitude of change in FEV_1 following inhalation of a bronchodilator between individuals and within individuals tested on different days *(Calverley 2003; Anthonisen 1986).*	IIb
A number of different methods for assessing the response to bronchodilators have been proposed *(Nisar 1990; Nisar 1992; Hadcroft 2001; Brand 1992)*.	IIb, IIb, Ib, IIb
A change in FEV_1 of at least 160 mL is required to exclude changes within the natural variability in of FEV_1 in people with obstructive ventilatory defects *(Tweeddale 1987)*.	IIb
A study of patients with fixed airflow obstruction diagnosed as having COPD or asthma on the basis of the clinical history *(Fabbri 2003)* has shown that the clinical diagnosis was correct as assessed by the basis of the pattern of inflammation seen on bronchial biopsies and the differential cell counts in induced sputum findings. Reversibility testing was unable to differentiate the two groups.	III
Bronchodilator tests performed with different inspiratory manoeuvres before and after bronchodilator administration provide differing results *(Santus 2003)*.	IIb
The response to a short course of oral steroids does not predict the response to long-term therapy *(Burge 2003)*.	Ib

Note: Ib = Evidence from at least one randomised controlled trial; IIb = Evidence from at least one other study type of quasi experimental study; III = Evidence from non experimental descriptive studies, such as comparative studies, such as comparative studies, correlation studies and case control studies.
Abbreviations: COPD, chronic obstructive pulmonary disease; FEV, forced expiratory volume; NGCG, National Clinical Guideline Centre.

In addition to evidence statements, the NCGC guideline (2010) also included six recommendations relating to reversibility testing (see Table 25). Importantly, Recommendation 12 highlights several factors that may cause misleading results on reversibility testing.

The guideline points out that while several earlier guidelines (BTS and GOLD) promoted reversibility testing, it is not recommended in the latest joint guidance from the American Thoracic Society (ATS) and the European Respiratory Society (ERS)[17]. Similarly, reversibility testing is not recommended in recent updates from GOLD.

[17] Presumably this refers to the CPG from Qaseem et al (2007).

Table 25 NCGC (2010): Recommendations and updated recommendations about reversibility testing and COPD

	Recommendations	Grading of recommendations
R12	In most patients routine spirometric reversibility testing is not necessary as a part of the diagnostic process or to plan initial therapy with bronchodilators or corticosteroids. It may be unhelpful or misleading because:	D
	• repeated FEV_1 measurements can show small spontaneous fluctuations	B
	• the results of a reversibility test performed on different occasions can be inconsistent and not reproducible	B
	• over-reliance on a single reversibility test may be misleading unless the change in FEV1 is greater than 400 ml	B
	• the definition of the magnitude of a significant change is purely arbitrary	B
	• response to long-term therapy is not predicted by acute reversibility testing.	A
R13	COPD and asthma are frequently distinguishable on the basis of history (and examination) in untreated patients presenting for the first time. Features from the history and examination should be used to differentiate COPD from asthma whenever possible.	D
R14	Longitudinal observation of patients (whether using spirometry, peak flow or symptoms) should also be used to help differentiate COPD from asthma.	D
R15	To help resolve cases where diagnostic doubt remains, or both COPD and asthma are present, the following findings should be used to help identify asthma: • a large (>400 ml) response to bronchodilators • a large (>400 ml) response to 30 mg oral prednisolone daily for 2 weeks • serial peak flow measurements showing 20% or greater diurnal or day-to-day variability. Clinically significant COPD is not present if the FEV_1 and FEV_1/FVC ratio return to normal with drug therapy.	D
R16	If diagnostic uncertainty remains, referral for more detailed investigations, including imaging and measurement of T_LCO, should be considered.	D
R17	If patients report a marked improvement in symptoms in response to inhaled therapy, the diagnosis of COPD should be reconsidered.	D

Note: Grade A = Based on hierarchy I evidence (systematic review or meta-analysis of RCTs or evidence from at least one RCT); Grade B = Based on hierarchy II evidence (at least one controlled study without randomisation or at least one other type of quasi experimental study) or extrapolated from hierarchy I evidence. Grade D = Directly based on hierarchy IV evidence (evidence from expert committee reports or opinions) or extrapolated from hierarchy I, II or III evidence.
Abbreviations: COPD, chronic obstructive pulmonary disease; FEV, forced expiratory volume; FVC, forced vital capacity; NGCG, National Clinical Guideline Centre; R, recommendation; T_LCO, transfer factor for carbon monoxide.

Asthma-COPD Overlap Syndrome (ACOS)

Several of the guidelines summarised in Section 2.4.2 note that asthma and COPD frequently coexist, particularly in patients aged 55 years and over with a history of smoking (NAC 2015).

National Asthma Council Australia (2015)

The *Australian Asthma Handbook* emphasises the fact that coexisting COPD and asthma should be considered a possibility in patients with respiratory symptoms and any of the following risk factors:

- current smoking or history of smoking and age 35 years and over;
- exposure to environmental tobacco smoke or other smoke;

- age 55 years and over; or
- longstanding asthma.

Table 26 NAC (2015): Diagnostic considerations when COPD is a possibility

Recommendations	Type of recommendation
If spirometry before and after bronchodilator demonstrates airflow limitation that is not completely reversible in an adult with risk factors for COPD, consider the possibility of COPD, even if the person has never smoked.	Consensus recommendation with reference to named sources[a]
If an adult has risk factors for COPD, spirometry before and after bronchodilator demonstrates airflow limitation that is not completely reversible, and other diagnostic tests do not confirm asthma, start a treatment trial with an inhaled corticosteroid and repeat spirometry 6–8 weeks later. After the trial of inhaled corticosteroid treatment, the diagnosis of asthma is supported if pre-bronchodilator spirometry shows that airflow limitation has resolved, or if spirometry before and after bronchodilator demonstrates airflow limitation that is fully reversible.	Consensus recommendation

Source: NAC (2015). Available at: http://www.asthmahandbook.org.au/clinical-issues/copd/diagnostic-considerations.
Abbreviations: COPD, chronic obstructive pulmonary disease.
a Abramson et al (2012).

Global Initiative for Chronic Obstructive Lung Disease (2016) / Global Initiative for Asthma (2015)

Recent versions of the GINA and GOLD reports have incorporated joint guidance on the diagnosis of ACOS. According to this guidance, the presence of a chronic airways disease should be confirmed through a detailed medical history and physical examination. A comparison of features favouring asthma or COPD should be undertaken based on age, symptoms and exposure to risk factors. If those factors do not clearly favour asthma or COPD, ACOS should be considered.

According to GINA/GOLD guidance, spirometry is essential for the confirmation of chronic airflow limitation; however, its value in distinguishing between asthma with fixed airflow obstruction, COPD and ACOS is limited. Table 27 shows a range of spirometric results with the corresponding interpretations of those results in the context of asthma, COPD and ACOS.

Table 27 GOLD (2016): Spirometric measures in asthma, COPD and ACOS

Spirometric variable	Asthma	COPD	ACOS
Normal FEV_1/FVC pre- or post-BD	Compatible with diagnosis	Not compatible with diagnosis	Not compatible unless other evidence of chronic airflow limitation
Post-BD FEV_1/FVC <0.7	Indicates airflow limitation but may improve spontaneously or on treatment	Required for diagnosis (GOLD)	Usually present
FEV_1 ≥80% predicted	Compatible with diagnosis (good asthma control or interval between symptoms)	Compatible with GOLD classification of mild airflow limitation (categories A or B) if post-BD FEV_1/FVC <0.7	Compatible with diagnosis of mild ACOS
FEV_1 <80% predicted	Compatible with diagnosis. Risk factor for asthma exacerbations	An indicator of severity of airflow limitation and risk of future events (e.g. mortality and COPD exacerbations)	An indicator of severity of airflow limitation and risk of future events (e.g. mortality and exacerbations)
Post-BD increase in FEV_1 >12% and 200 ml from baseline (reversible airflow limitation)	Usual at some time in course of asthma, but may not be present when well-controlled or on controllers	Common and is more likely when FEV_1 is low, but ACOS should also be considered	Common and more likely when FEV_1 is low, but ACOS should also be considered
Post-BD increase in FEV_1 >12% and 400 ml from baseline (marked reversibility)	High probability of asthma	Unusual in COPD. Consider ACOS	Compatible with diagnosis of ACOS

Source: GOLD 2016; Appendix p.A6.
Abbreviations: ACOS, asthma-COPD overlap syndrome; BD, bronchodilator; COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease.

Summary

All of the included guidelines indicate that spirometry plays a vital role in the diagnosis of asthma, COPD and ACOS in adults and children aged approximately 6 years and older.

Table 28 provides collated guidance from the 11 CPGs that were summarised in Section 2.4.2. For the diagnosis of asthma, there is complete consensus among the guidelines that bronchodilator reversibility testing should be undertaken. Of particular importance, several key asthma guidelines (BTS/SIGN 2014; NCGC 2016) advise that spirometry should first be undertaken to measure airflow limitation; a subsequent (consensus-based) recommendation advocates the measurement of bronchodilator reversibility in patients with evidence of airflow limitation/obstruction.

Consistent with international guidance, the NAC (2015) advocates the use of bronchodilator reversibility testing; however, the Australian guidance does not explicitly mention that bronchodilator reversibility should only be measured in those patients who have demonstrated airflow limitation on pre-bronchodilator spirometry.

The advice from current COPD guidelines is more varied about the use of spirometry for diagnosis. Three CPGs advise that COPD should be diagnosed based on post-bronchodilator spirometry alone; two (both from Australia) advocated the use of reversibility testing; and one, while recommending the use of spirometry, was not explicit about the necessity of pre-bronchodilator measurements.

Table 28 Summary of guidance from current CPGs relating to the diagnosis of asthma, COPD and ACOS

Condition	Guideline	Population	Pre -BD spirometry	Post -BD spirometry	Pre- and post-BD spirometry (reversibility)	Spirometry recommended, but timing not specified	Source of guidance
Asthma	NAC (2015)	Adults	NA	NA	Yes	NA	Consensus
		Children ≥6 yrs	NA	NA	Yes	NA	Consensus
	NAC (2013)	Adults >65 yrs	NA	NA	Yes	NA	Unclear
	NCGC (2016)	Adults	NA	NA	Yes	NA	Evidence
		Children ≥5 yrs	NA	NA	Yes	NA	Evidence
	GINA (2015)	Adults	NA	NA	Yes	NA	Unclear
		Children ≥6 yrs	NA	NA	Yes	NA	Unclear
	BTS/SIGN (2014)	Adults	NA	NA	Yes	NA	Consensus
		Children[a]	NA	NA	Yes	NA	Consensus
COPD	LFA/TSANZ (2015)	Adults	NA	NA	Yes	NA	Unclear
	Abramson (2014)	Adults	NA	NA	Yes[b]	NA	Evidence[c]
	GOLD (2016)	Adults	NA	Yes	NA	NA	Unclear
	VA/DoD (2014)	Adults	NA	Yes	NA	NA	Evidence
	Qaseem (2011)	Adults	NA	NA	NA	Yes	Evidence
	NCGC (2010)	Adults	NA	Yes[d]	NA	NA	Evidence
ACOS	NAC (2015)	Adults	NA	NA	Yes	NA	Consensus
	GINA (2015) / GOLD (2016)	Adults	NA	NA	Yes	NA	Unclear

Note: Australian guidance is shaded white; international guidance is shaded blue. NA indicates not applicable
Abbreviations: ACOS, Asthma-COPD Overlap Syndrome; BD, bronchodilator; BTS, British Thoracic Society; COPD, chronic obstructive pulmonary disease;GINA, Global Initiative for Asthma; GOLD, Global Initiative for Chronic Obstructive Lung Disease; LFA, Lung Foundation Australia; NAC, National Asthma Council Australia, NCGC, National Clinical Guidelines Centre; SIGN, Scottish Intercollegiate Guidelines Network; TSANZ, The Thoracic Society of Australia and New Zealand; VA / DoD, Department of Veterans' Affairs / Department of Defence.
a Children who can perform spirometry (age not specified).
b Although Abramson et al (2014) advocate undertaking both pre- and post-BD spirometry, the definition of airflow limitation that is not fully reversible was said to be post-BD FEV_1/FVC ratio <0.7 and FEV_1 <80% predicted (rather than a change from baseline). In practice, only post-BD spirometry would be required to meet this criteria.
c Evidence to support the consideration of asthma or ACOS if airflow limitation is reversible, not that reversibility testing is more accurate for the diagnosis of COPD.
d The guideline recommends against the use of routine reversibility testing; however, it suggests that reversibility testing may have a place where diagnostic doubt remains, or both COPD and asthma are present.

2.5 In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for assessing acute exacerbations?

2.5.1 Systematic Reviews

No systematic reviews or HTAs were identified that address this research question.

2.5.2 Clinical Practice Guidelines

Exacerbations are defined as a change in symptoms and lung function from the patient's usual status (GINA, 2015). Not all of the included CPGs provide guidance relating to the use of spirometry for the management of acute exacerbations.

Asthma

National Asthma Council Australia (2015)

The *Australian Asthma Handbook* does not refer to spirometry for the assessment of acute asthma exacerbations. During these episodes (moderate, severe or life-threatening), severity should be assessed through clinical observations and pulse oximetry.[18]

However, for patients who have initiated treatment for acute asthma, the clinical management algorithms for adults and children indicate that spirometry should be performed (if the patient is capable) to reassess response to treatment, one hour after starting bronchodilator. Pulse oximetry is also repeated at this time point.[19]

National Asthma Council Australia (2013)

The NAC information paper about asthma in older patients notes that in acute asthma, spirometry and pulse oximetry should be performed at baseline and at intervals throughout recovery.

Global Initiative for Asthma (2015)

The GINA report suggests that spirometry may be used in the assessment of acute exacerbations. It advises that in patients presenting to a primary care or an acute care facility, the assessment of exacerbation severity should be based on the degree of dyspnoea, respiratory rate, pulse rate, oxygen saturation and lung function, while starting a short-acting beta$_2$-agonist (SABA) and oxygen therapy.

[18] NAC (2015). Completing a rapid primary assessment and starting initial treatment. In: *Australian Asthma Handbook*,
[19] NAC (2015). Managing acute asthma in adults and Managing acute asthma in children. In: *Australian Asthma Handbook*,

In addition, lung function tests, along with clinical status, response to treatment, recent and past history of exacerbations, and ability to manage at home should all be considered during decisions about hospitalisation.

Chronic Obstructive Pulmonary Disease (COPD)

An exacerbation is an acute event in the natural course of COPD characterised by a change in the patient's baseline dyspnoea, cough and/or sputum that is beyond normal day-to-day variations. Exacerbations may warrant a change in regular medication and/or hospitalisation (LFA/TSANZ 2015).

Lung Foundation Australia /Thoracic Society of Australia and New Zealand (2015)

This CPG advocates the use of spirometry for confirming and categorising the severity of acute exacerbations, along with medical history, examination, blood gas measurements, chest x-rays and electrocardiography.

The guideline advises that an FEV_1 less than 1.0 L (or < 40% predicted) is usually indicative of a severe exacerbation in patients with moderate COPD. In patients with severe COPD, the most important signs of a severe exacerbation are worsening hypoxaemia, acute respiratory acidosis (carbon dioxide retention) or both.

In terms of discharge and follow-up from an acute exacerbation, it is suggested that clinical symptoms and gas exchange levels should be monitored and respiratory function testing (FEV_1) should be recorded after recovery.

Abramson (2014) – Lung Foundation Australia / Thoracic Society of Australia and New Zealand

As in the full LFA/TSANZ guideline, the Concise Guide does not include any formal recommendations regarding the use of spirometry in acute exacerbations. Like the full guideline, Abramson et al (2014) indicates that spirometry has a place in the follow-up of acute exacerbations, stating that when patients with COPD are discharged from hospital following an exacerbation, they should receive comprehensive follow-up led by the primary health care team, including measurement of FEV_1 and performance status.

Global Initiative for Chronic Obstructive Lung Disease (2016)

The GOLD report suggests a range of tests that may help to assess the severity of acute COPD exacerbations and rule out other causes, including pulse oximetry, chest radiographs, electrocardiography, whole blood count, the presence of purulent sputum, biochemical test abnormalities.

The guideline indicates that spirometry is of insufficient accuracy during exacerbations due to the difficulty of performing the test and therefore recommends against its use in this context.

Summary

Guidance around the use of spirometry for assessing acute exacerbations was more varied and less prescriptive than the diagnostic guidance (see Table 29). For asthma, there was a suggestion that lung function testing could be of value; however, clinical observations and other tests such as pulse oximetry (oxygen saturation), respiratory rate and pulse rate may also be useful in this situation. Lung function may also be tested to inform decisions about hospitalisation and to assess patients during recovery.

In COPD, the Australian guidelines do not rule out the use of spirometry to grade the severity of exacerbations. Conversely, one international guideline (GOLD, 2016) indicates that spirometry is of little value and that other tests such as pulse oximetry are preferred in acute exacerbations.

Table 29 Summary of guidance from current CPGs relating to the use of spirometry to assess acute exacerbations in asthma and COPD

Condition	Guideline	Spirometry to assess acute exacerbations	Notes
Asthma	NAC (2015)	No	Assess clinical signs and pulse oximetry
	NAC (2013)	Yes	Assess spirometry and pulse oximetry [patients >65 years]
	GINA (2015)	Yes	Assess dyspnoea, respiratory rate, pulse rate, oxygen saturation and lung function
COPD	LFA/TSANZ (2015)	Yes	Assess history, clinical signs, blood gas measurements, chest x-ray, ECG and spirometry
	Abramson (2014)	Not applicable	FEV_1 and performance status should be measured following discharge after an acute exacerbation
	GOLD (2016)	No	Assess severity and exclude other causes using pulse oximetry, chest radiographs, ECG, whole blood count, presence of purulent sputum, biochemical test abnormalities

Note: Australian guidance is shaded white; international guidance is shaded blue.
Abbreviations: COPD, chronic obstructive pulmonary disease; ECG, electrocardiogram; GINA, Global Initiative for Asthma; GOLD, Global Initiative for Chronic Obstructive Lung Disease; LFA, Lung Foundation Australia; NAC, National Asthma Council Australia; TSANZ, The Thoracic Society of Australia and New Zealand.

2.6 In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for long-term monitoring?

2.6.1 Systematic Reviews

Two systematic reviews were identified that partially address this research question: Wilt et al, 2005; Wilt et al, 2007.

Wilt et al (2005) [AHRQ]

The archived HTA prepared by Wilt and colleagues (2005) concluded that spirometry for monitoring individuals or adjusting treatment is unlikely to be beneficial unless future studies establish that spirometry improves smoking cessation rates, treatments other than smoking cessation benefit

individuals with airflow obstruction who do not report respiratory symptoms, or that relative effectiveness between therapies varies according to an individual's baseline or follow-up spirometry.

Wilt et al (2007) [AHRQ]

A subsequent systematic review by Wilt and colleagues (2007)20 evaluated the effectiveness of COPD management strategies and sought to determine whether clinicians should base treatment decisions on spirometric results, symptoms, or both. No controlled clinical trials were identified that evaluated the use of spirometric results to modify therapy, institute combination inhaled therapy, or monitor disease status. However, based on "fair evidence" from their earlier HTA (Wilt et al, 2005), the authors concluded that modifying therapy according to spirometric results is unlikely to be beneficial because:

- clinical improvement is not closely associated with an individual's spirometric response to therapy;
- pharmacologic treatments provide only a small change in long-term decline in lung function;
- wide intra-individual variation exists in spirometric decline;
- higher doses (compared with lower doses) or combination inhaled therapies (compared with monotherapy) have not been shown to provide clinically significant benefits;
- limited evidence suggests that interventions are not effective in asymptomatic individuals.

2.6.2 Clinical Practice Guidelines

Asthma

National Asthma Council Australia (2015)

Consensus-based recommendations about the use of lung function testing as part of long-term asthma monitoring in adults are listed in Table 30.

[20] The systematic review by Wilt et al (2007) also served as the background paper for the 2007 American College of Physician's clinical practice guideline on the diagnosis and management of stable COPD.

Table 30 NAC (2015): Guidance relating to the use of spirometry for ongoing monitoring of asthma in adults

Clinical component	Recommendations	Type of recommendation
Assessing recent asthma symptom control and risk of adverse asthma outcomes in adults	Measure lung function by spirometry to establish the patient's baseline values. *Note: If reliable equipment and appropriately trained staff are available, spirometry can be performed in primary care. If not, refer to an appropriate provider such as an accredited respiratory function laboratory.* *Document if spirometry is pre- or post-bronchodilator.*	Consensus recommendation
Conducting asthma review at scheduled asthma visits[21]	At scheduled asthma visits, assess (all of): • any problems or issues the person is having with their asthma • current level of control based on symptoms and reliever use during the previous 4 weeks • flare-ups during the previous 12 months • lung function (every 1–2 years for most people; more often when good asthma control has been lost or not achieved, or when the person has a known risk factor for accelerated loss of lung function) • other risk factors (e.g. smoking, exposure to other triggers) or comorbid conditions • current treatment, including adherence to preventer if prescribed. Do not assume the person is taking the dose most recently prescribed. Ask which asthma medicines the person is using, in a non-judgmental, empathic manner • inhaler technique • whether the person has a written asthma action plan and knows how to use it, and whether it is up to date	Consensus recommendation
Performing spirometry in asthma review in adults	Perform or arrange spirometry at baseline and after symptoms stabilise (3–6 months) to establish the person's personal best as the basis for future comparison. *Note: If reliable equipment and appropriately trained staff are available, spirometry can be performed in primary care. If not, refer to an appropriate provider such as an accredited respiratory function laboratory.*	Consensus recommendation
	Perform spirometry before and after bronchodilator. Ask patients to use their own reliever inhaler and take the opportunity to check inhaler technique. ***Note: Spirometry is reimbursed by MBS only if pre- and post-bronchodilator readings are taken and a permanently recorded tracing is retained.***	Consensus recommendation

[21] The Handbook includes a guide for asthma check-ups (which may include spirometry) based on various clinical criteria (see Appendix 8).

Clinical component	Recommendations	Type of recommendation
	Do not advise patients to skip their preventer before a spirometry visit, but document whether the person has taken a combination preventer that contains a long-acting $beta_2$ agonist on the day of spirometry. *Note: Patients referred to a respiratory function laboratory may be asked to skip certain medicines before a spirometry visit.*	Consensus recommendation
	Measure lung function using spirometry when: • making or confirming the diagnosis • assessing future risk • person has been experiencing worsening asthma control or a flare-up • monitoring response after dose adjustment • periodically reviewing asthma (every 1–2 years for most patients).	Consensus recommendation
	Record spirometry at **every** asthma visit for: • patients with severe asthma • patients who are known to have poor perception of airflow limitation (e.g. those who do not feel any different with a 15% decrease or increase in FEV_1).	Consensus recommendation
	When spirometry findings are markedly discordant with symptoms (e.g. normal spirometry in a patient with frequent symptoms, or FEV_1 <70% predicted in a patient with no symptoms), consider the possibility of an alternative diagnosis and consider referral for specialist assessment.	Consensus recommendation
Reviewing asthma during visits for respiratory symptoms	If current symptoms are probably due to asthma, assess: • level of recent asthma symptom control including symptoms and reliever use • flare-ups during the previous 12 months • lung function (if possible) • other risk factors (e.g. smoking, exposure to other triggers) or comorbid conditions • current treatment, including adherence to preventer if prescribed. Do not assume the person is taking the dose most recently prescribed. Ask which asthma medicines the person is using, in a non-judgmental, empathic manner • inhaler technique. Watch the person use their inhaler • whether the person has a written asthma action plan. If so, ask if they have followed it and whether it has helped	Consensus recommendation

Abbreviations: FEV_1, forced expiratory volume in 1 second; MBS, Medicare Benefits Schedule.

Importantly, spirometry has poor reproducibility between visits, so the Handbook advises that only a change in FEV_1 of greater than 0.2 L and 12% from baseline should be considered clinically meaningful in adults.[22] Other limitations of spirometry for long-term monitoring are noted, including the fact that patients with longstanding asthma often develop fixed (irreversible or incompletely reversible) airflow limitation.

Assessment of asthma control in children is largely informed by recent asthma symptom control and the frequency of flare-ups, particularly in young children who cannot perform spirometry. In older children, lung function testing should be conducted at follow-up visits as per the recommendations in Table 31.

Table 31 NAC (2015): Guidance relating to the use of spirometry for ongoing monitoring of asthma in children

Clinical component	Recommendations	Type of recommendation
Planning routine asthma review for children	As a general guide, review the child's asthma: • every 3–6 months when asthma is stable and well controlled • 4 weeks after increasing the dose or number of medicines to regain control of partially or poorly controlled asthma • 2–4 weeks after a visit to the emergency department or a hospital stay due to acute asthma.	Consensus recommendation
	At each asthma review, assess recent asthma symptom control and future risk: • recent asthma symptom control based on reported symptoms, limitation of daily activity and need for reliever medicine • lung function using spirometry (for children old enough to perform the test) • adherence to treatment • inhaler technique • whether the written asthma action plan is up to date • modifiable environmental factors • whether the child has any risk factors for poor asthma outcomes in future (e.g. persistent symptoms, difficult-to-control asthma due to severe disease or poor adherence, severe allergies such as food allergies or history of anaphylaxis, previous severe life-threatening acute asthma, history of sudden severe unpredictable asthma flare-ups, or significant psychosocial factors). *Note: Assessments can be made by asking the same questions at each visit, or using validated questionnaires.*	Consensus recommendation
Assessing symptoms and control in children 6 years and over	Assess level of asthma control based on: • symptoms • spirometry (for children able to perform spirometry reliably) *Notes: If reliable equipment and appropriately trained staff are available, spirometry can be performed in primary care. If not, refer*	Consensus recommendation

[22] The Handbook cited Pelligrino et al (2005).

Clinical component	Recommendations	Type of recommendation
	to an appropriate provider such as an accredited respiratory function laboratory. *Most children aged 6 and older can perform spirometry reliably.*	
	If the diagnosis of asthma was made in the past or elsewhere, confirm the diagnosis, if possible.	Consensus recommendation

National Asthma Council Australia (2013)

The information paper *Asthma & the Over 65s* included one recommendation relating to the use of spirometry for monitoring in older patients (see Table 32).

Table 32 NAC (2013): Assessing and monitoring asthma in older patients

Recommendations	Type/Grade of recommendation
Measure lung function objectively at each asthma review using spirometry.	Not reported

National Clinical Guideline Centre (2016)

The NCGC guideline assessed the evidence for the use of lung function testing to monitor asthma. The guideline noted that although the role of spirometry in the diagnosis and initial assessment of asthma is well established, its optimal role in the ongoing monitoring of asthma is still an area of uncertainty. The following key question was developed to underpin the systematic literature review and address this uncertainty.

> *In people with asthma, what is the clinical and cost-effectiveness of using measures of pulmonary function assessing asthma control (for example, spirometry and peak expiratory flow) to monitor asthma?*

No studies were identified that assessed the clinical or cost-effectiveness of monitoring spirometry to measure asthma control (the guideline limited the search to RCTs). All studies were of self-management, with the action plans based on PEF readings versus action plans based on symptoms.

The GDG considered that the cost of providing the equipment, such as peak flow meters, to monitor asthma is likely to be negligible. The main cost-consequence of monitoring using lung function tests is the impact it has on medication usage. If monitoring using lung function tests produce false results that increase medication usage then this will increase costs with no added health benefits. On the other hand, if accurate, monitoring using lung function tests could reduce medication usage and provide cost savings.

The GDG debated the importance of monitoring spirometry and the additional information that it provided over and above PEF. Given the relative ease of monitoring spirometry and the additional information that it provides, the GDG felt that spirometry should be measured at every review. Spirometry provides additional information on the level of airways obstruction and can be compared

to the previous best measurement or predicted measurement based on age and height of the individual.

Table 33 NCGC (2016): Recommendations on the use of lung function tests for monitoring asthma

Recommendations	Grading of recommendation
R42: Monitor asthma control at each review in adults and children aged 5 years and over by measuring either spirometry (FEV1) or peak flow.	Not reported

Note: The guideline advised that a low FEV_1 identifies patients at risk of asthma exacerbations, independent of symptom levels, especially if FEV_1 is <60% predicted.

Global Initiative for Asthma (2015)

The GINA report states that ongoing monitoring of asthma should include assessments of:

- asthma control (both symptom control and future risk of adverse outcomes);
- treatment issues (particularly inhaler technique and adherence); and
- any comorbidities that could contribute to symptom burden and poor quality of life.

The report advises that lung function should be measured at the start of treatment, after 3-6 months of treatment (to identify the patient's personal best), and periodically thereafter for ongoing risk assessment. The advice in Table 34 is provided to aid the interpretation of lung function results at asthma follow-up visits.

Table 34 GINA (2015): Interpreting interval lung function in asthma

Lung function status	Interpretation
A low FEV_1 percent predicted[23]	• Identifies patients at risk of asthma exacerbations, independent of symptom levels, especially if FEV_1 is <60% predicted (Fuhlbrigge et al, 2001; Li et al, 1995; Kitch et al, 2004; Osborne et al, 2007). • Is a risk factor for lung function decline, independent of symptom levels (Ulrik, 1999). • If symptoms are few, suggests limitation of lifestyle, or poor perception of airflow limitation (Killian et al, 2000), which may be due to untreated airway inflammation (Rosi et al, 2006).
A 'normal' or high FEV_1 in a patient with frequent respiratory symptoms (especially when symptomatic)	Prompts consideration of alternative causes for the symptoms; e.g. cardiac disease, or cough due to post-nasal drip or gastroesophageal reflux disease.
Persistent bronchodilator reversibility	Finding significant bronchodilator reversibility (increase in FEV1 >12% and >200 mL from baseline [Pellegrino et al, 2005]) in a patient taking controller treatment, or who has taken a short-acting beta2-agonist within 4 hours, or a LABA within 12 hours, suggests uncontrolled asthma.

[23] With regular inhaled corticosteroid treatment, FEV_1 starts to improve within days, and reaches a plateau after around 2 months. The patient's highest FEV_1 reading (personal best) should be documented, as this provides a more useful comparison for clinical practice than FEV_1 percent predicted. If predicted values are used in children, measure their height at each visit (GINA, 2015).

Note: GINA (2015) advised that once the diagnosis of asthma has been confirmed patient will generally not be required to withhold medications before lung function tests (Reddel et al, 2009); however preferable the same conditions should apply at each visit.

The guidance outlined above pertains to adults, adolescents, and children 6-11 years. In children less than 5 years of age spirometry cannot be reliably obtained; however, the report notes that many children with uncontrolled asthma have normal lung function between exacerbations.

British Thoracic Society / Scottish Intercollegiate Guidelines Network (2014)

The BTS/SIGN guideline advocates regular asthma monitoring in primary care on (at least) an annual basis. The relevant guidance is shown in Table 35. The guideline notes that reduced lung function compared to previously recorded values may indicate current bronchoconstriction or a long-term decline in lung function and should prompt detailed assessment.

Table 35 BTS/SIGN (2014): Guidance relating to the use of spirometry for monitoring asthma in primary care

Good Practice Point
In adults, the following factors should be monitored and recorded in primary care: • symptomatic asthma control • lung function, assessed by spirometry or by PEF • asthma attacks, oral corticosteroid use and time off work or school since last assessment • inhaler technique • adherence • bronchodilator reliance • possession of and use of a self-management plan/personal action plan.

Abbreviations: PEF, peak expiratory flow.

Chronic Obstructive Pulmonary Disease (COPD)

Lung Foundation Australia / Thoracic Society of Australia and New Zealand (2015)

Citing evidence from the NHLBI/WHO Workshop Report (2001), the LFA/TSANZ advocates regular review, with objective measures of function and medication review, in the hope that this may reduce complications and the frequency or the severity (or both) of exacerbations and admissions to hospital.

The guideline identified a cluster randomised controlled trial that was undertaken across 31 general practices in Melbourne (Abramson et al, 2010). Patients with COPD and/or asthma on inhaled medication (N=305; median age: 58 years) were randomised to a) three-monthly spirometry by a respiratory scientist with results returned to the practice and regular medical review, b) usual care and spirometry before and after the trial and c) usual care. This study did not show any significant changes in quality of life (assessed with the 36-item Short Form Health Survey (SF-36)) or other health outcomes (assessed with the European Community Respiratory Health Survey) from baseline to 12 months, or any significant differences between groups. Abramson et al (2010) also reported that there were no significant differences in respiratory symptoms, asthma attacks, written asthma action plans, days lost from usual activities or health care utilisation.

The LFA/TSANZ (2015) lists several possible explanations for the negative results, including limited power, few events and inclusion of doctor-diagnosed as opposed to spirometry-defined patients.

Abramson (2014)

The Concise Guide by Abramson et al (2014) suggests that severity of COPD should be monitored on a regular basis after initial diagnosis. The relevant recommendation is shown in Table 36.

Table 36 Abramson (2014): Recommendation relating to lung function and long-term monitoring

Recommendation	Grading of recommendation
To guide ongoing management, assess COPD severity based on lung function and a careful assessment of symptoms and signs, and review the history of exacerbations at least annually.	Strong recommendation; moderate-quality evidence

Abbreviations: COPD, chronic obstructive pulmonary disease.

While the guideline recommends ongoing lung function testing (spirometry), it notes that symptom severity may not correlate with spirometry criteria for severity (see Table 37). Furthermore, a history of previous exacerbations was identified as the best predictor of future exacerbations and possible decline in lung function.

Table 37 Abramson (2014): Guide to the severity of COPD

Severity	FEV_1 (% predicted)	Symptoms	History of exacerbations	Comorbid conditions
Mild	60-80	• Breathlessness on moderate exertion • Recurrent chest infections • Little or no effect on daily activities	Frequency may increase with severity	Present across all severity groups
Moderate	40-59	• Increasing dyspnoea • Breathlessness walking on level ground • Increasing limitation of daily activities • Cough and sputum production • Exacerbations requiring corticosteroids and/or antibiotics	Frequency may increase with severity	Present across all severity groups
Severe	< 40	• Dyspnoea on minimal exertion • Daily activities severely curtailed • Experiencing regular sputum production • Chronic cough	Frequency may increase with severity	Present across all severity groups

Source: Abramson et al (2014); Table 1, p. 6.
Note: Common comorbid conditions include cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, anxiety or depression, lung cancer, peripheral vascular disease and sleep apnoea.

Global Initiative for Chronic Obstructive Lung Disease (2016)

Like several other recent CPGs, the GOLD report emphasises that FEV_1 is a poor descriptor of disease status and recommends that long-term monitoring/management of COPD should be based on a broader strategy that considers both disease impact (e.g. symptom burden and activity limitation) and future risk of disease progression (especially future risk of exacerbations).

According to GOLD, assessing the impact of COPD on an individual patient over time should involve a comprehensive assessment of symptoms (e.g. using the COPD Assessment Test), spirometric

classification and/or risk of exacerbations. The guideline notes that spirometry should be performed at least once a year to identify patients whose lung function is declining quickly.

While future exacerbations are best predicted by a history of previous treated events, the guideline suggests that worsening airflow limitation is also associated with an increasing frequency of exacerbation and risk of death.

Data from several large medium-term clinical trials was collated to illustrate the effect of COPD severity on risk of exacerbations, hospitalisation and death using GOLD spirometric grading systems. The data indicate a correlation between increased severity using GOLD spirometric grades and increased risk of exacerbations, hospitalisation and death.

Table 38 GOLD (2016): Risk in COPD - Placebo-limb data from TORCH, UPLIFT and ECLIPSE

GOLD spirometric level	Exacerbations per year[a,b,c]	Hospitalisations per year[a,c]	3-year mortality
GOLD 1: Mild	?	?	?
GOLD 2: Moderate	0.7 – 0.9	0.11 – 0.2	11%[a,b]
GOLD 3: Severe	1.1 – 1.3	0.25 – 0.3	15%[a]
GOLD 4: Very severe	1.2 – 2.0	0.4 – 0.54	24%[a]

Source: GOLD 2016; p. 15.
Abbreviations: COPD, chronic obstructive pulmonary disease; GOLD, Global Initiative for Chronic Obstructive Lung Disease.
a Toward a Revolution in COPD Health (TORCH) study.
b Understanding Potential Long-Term Impacts on Function with Tiotropium (UPLIFT) study.
c Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints (ECLIPSE) study.

These data from the GOLD report suggest that while there are several factors that affect overall risk of exacerbations and adverse events, spirometry may be one important consideration and has value in long-term monitoring.

Department of Veterans Affairs / Department of Defense (2014)

The VA/DoD guideline advises against the routine measurement of spirometry in patients with COPD that has been previously confirmed using spirometry. Without citing any specific evidence, the guideline suggests that repeat spirometry has not been shown to contribute to management or classification of COPD.

Qaseem (2011) – American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society

The guideline did not find any evidence to support the use of routine periodic spirometry after initiation of therapy to monitor disease status or to modify therapy in COPD patients.

National Clinical Guideline Centre (2010)

Table 39 shows a recommendation from the NCGC guideline about the various prognostic factors that may be used to classify severity of COPD. While the recommendation does not clearly specify

that spirometry has a place in long-term monitoring, the inference from this recommendation is that FEV_1 should be monitored over time to assess changes in COPD severity and prognosis.

In addition, the guideline notes that all of the new recommendations relating to drug treatment made reference to FEV_1 being above or below 50%, which suggests that spirometry should be undertaken periodically to assess appropriateness of current treatment or to underpin decisions to alter treatment.

Table 39 NCGC (2010): Recommendation relating to the use of spirometry in long-term monitoring

Recommendation	Grading of recommendation
U3: Be aware that disability in COPD can be poorly reflected in the FEV_1. A more comprehensive assessment of severity includes the degree of airflow obstruction and disability, the frequency of exacerbations and the following known prognostic factors: • FEV_1 • T_LCO • Breathlessness (MRC scale) • Health status • Exercise capacity (for example, 6-minute walk test) • BMI • PaO_2 • Cor pulmonale. Calculate the BODE index (BMI, airflow obstruction, dyspnoea and exercise capacity) to assess prognosis where its component information is currently available.	Not reported

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; FEV, forced expiratory volume; MRC, Medical Research Council; NGCG, National Clinical Guideline Centre; PaO_2; partial pressure of oxygen in arterial blood; T_LCO, transfer factor for carbon monoxide; U, updated recommendation.

Summary

Table 40 summarises the guidance relating to the use of spirometry in long-term monitoring of asthma and COPD from the 11 included CPGs that were summarised in Section 2.6.2.

Several asthma guidelines (GINA 2015; NCGC 2016) noted that low FEV_1 is a strong independent predictor of risk of exacerbations, even after adjustment for symptom frequency, and therefore emphasises that lung function testing is a crucial part of the assessment of future risk of asthma exacerbation.

Few of the guidelines were explicit about whether reversibility testing would be conducted at follow-up; however the *Australian Asthma Handbook* (NAC 2015) advises that spirometry should be performed before and after bronchodilator, noting that MBS reimbursement is only available if pre- and post-bronchodilator reading are taken and a permanent recorded tracing is retained.

In the COPD guidelines, the general consensus is that FEV_1 is a poor predictor of disease status and prognosis, but that spirometry has a role alongside other tests in long-term monitoring.

Table 40 Summary of guidance from current CPGs relating to the use of spirometry in long-term monitoring of asthma and COPD

Condition	Guideline	Population	Pre- BD spirometry	Post-BD spirometry	Pre- and post-BD spirometry (reversibility)	Spirometry recommended, but timing not specified	Source of guidance
Asthma	NAC (2015)	Adults	NA	NA	Yes	NA	Consensus
		Children ≥6 yrs	NA	NA	NA	Yes	Consensus
	NAC (2013)	Adults >65 yrs	NA	NA	NA	Yes	Unclear
	NCGC (2016)	Adults	NA	NA	NA	Yes[a]	Consensus
		Children ≥5 yrs	NA	NA	NA	Yes[a]	Consensus
	GINA (2015)	Adults	NA	NA	NA	Yes	Evidence
		Children ≥6 yrs	NA	NA	NA	Yes	Evidence
	BTS/SIGN (2014)	Adults	NA	NA	NA	Yes[b]	Consensus
COPD	LFA/TSANZ (2015)	Adults	NA	NA	NA	Yes	Consensus[c]
	Abramson (2014)	Adults	NA	NA	NA	Yes	Not applicable
	GOLD (2016)	Adults	NA	NA	NA	Yes	Unclear
	VA/DoD (2014)	Adults	NA	NA	NA	No	Unclear
	Qaseem (2011)	Adults	NA	NA	NA	No	Evidence[d]
	NCGC (2010)	Adults	NA	NA	NA	Yes	Unclear

Note: Australian guidance is shaded white; international guidance is shaded blue. NA means not applicable.
Abbreviations: BD, bronchodilator; BTS, British Thoracic Society; COPD, chronic obstructive pulmonary disease; GINA, Global Initiative for Asthma; GOLD, Global Initiative for Chronic Obstructive Lung Disease; LFA, Lung Foundation Australia; NAC, National Asthma Council Australia, NCGC, National Clinical Guidelines Centre; SIGN, Scottish Intercollegiate Guidelines Network; TSANZ, The Thoracic Society of Australia and New Zealand.
a Despite a lack of evidence, the GDG felt that spirometry should be monitored due to ease of use and the additional information it provides over PEF. Nonetheless, the consensus recommendation indicates that either spirometry (FEV_1) or PEF could be used for monitoring purposes.
b Lung function may be monitored using spirometry or peak expiratory flow.
c The NHLBI/WHO Workshop report is cited as a reference.
d No evidence was found to support the use of routine periodic spirometry after initiation of therapy in order to monitor disease status or guide therapy modification.

2.7 What is the published evidence for the cost-effectiveness of spirometry for the diagnosis of people presenting with respiratory symptoms?

2.7.1 Systematic Reviews

Cranston et al (2006)[APHCRI]

The systematic review by Cranston et al (2006) included the following question:

> *How much does the performance of spirometry in primary care cost and is it cost-effective?*

All of the identified studies related to the use of spirometry for screening and opportunistic case-finding rather than as a diagnostic tool in general practice.

Although a cost-effectiveness analysis was not undertaken, the direct costs of the performance of spirometry in primary care in South Australia were estimated by Cranston and colleagues (2006). For the purpose of this MBS Review, these costs have been updated and are shown in 0.

Clinical Practice Guidelines

National Clinical Guideline Centre (2016)

The NCGC clinical guideline on asthma diagnosis and monitoring included two cost-effectiveness questions that specifically relate to spirometry:

> *In people under investigation for asthma, what is the cost-effectiveness of spirometry/flow volume loop measures?*
>
> *In people under investigation for asthma, what is the cost-effectiveness of bronchodilator response (using PEF or FEV_1)?*

The literature search did not identify any relevant economic evaluations. An original health economic model was therefore developed to assess the cost-effectiveness of several diagnostic pathways in adults, which included spirometry. The model assessed the additional costs of the tests against cost-savings from unnecessary asthma medication, and the increased health outcomes from providing correct treatment. The economic evaluation was a cost-utility analysis, where lifetime costs and quality-adjusted life years (QALYs) were considered from the perspective of the United Kingdom National Health Service (NHS) and personal social services. The model was based on two parts:

- A decision tree that used the sensitivity and specificity of each diagnostic test, combined with data on the prevalence of asthma in the defined population.
- A Markov model to fully evaluate the patients' health and cost outcomes after diagnostic testing, incorporating time spent misdiagnosed and the associated decrease in quality of life, higher mortality risks and wasted NHS resources.

The cost-effectiveness of six different diagnostic strategies was assessed. The diagnostic strategies were created using combinations of spirometry, bronchodilator reversibility, fractional exhaled nitric oxide (FeNO), PEF variability, and challenge tests. The GDG agreed that spirometry should be used as the first line diagnostic test in all six diagnostic pathways because it is a widely available test that can also help with the diagnosis of other conditions, such as COPD. The GDG agreed that a bronchodilator reversibility test should be used on all patients with an obstructive spirometry because it can be performed at a low cost immediately after initial spirometry, and a positive result is recognised as strong indication that the individual has asthma.

- Strategy 1 – involved spirometry, bronchodilator reversibility and FeNO.
- Strategy 2 – expanded on Strategy 1 to involve PEF variability.
- Strategy 3 – expanded on Strategy 2 to involve a methacholine challenge test.
- Strategies 4, 5, 6 – each of these strategies expanded on the use of challenge tests in Strategy 3.

The final strategy considered was current practice, which involved not giving the patient any tests and diagnosing without the use of objective tests. The only costs that are incurred in this strategy are those that occur after the diagnosis is made (e.g. the cost of asthma treatment). An assumption was made that all people with asthma are correctly diagnosed giving this strategy a sensitivity of 100%.

Table 41 shows the overall sensitivity and specificity of each diagnostic strategy, and the costs associated with objective tests for each strategy. The main limitations of the model concerned the lack of clinical data informing parameters associated with misdiagnosis.

Table 41 NCGC (2016): Diagnostic accuracy and cost of testing in each strategy

Sensitivity / Specificity / Cost	Current practice	Strategy 1	Strategy 2	Strategy 3	Strategy 4	Strategy 5	Strategy 6
Sensitivity	100%	90.3%	89.3%	86.3%	88.7%	87.7%	90.3%
Specificity	65.8%	69.1%	82.4%	89.5%	89.4%	89.4%	89.4%
Cost	£0	£42	£52	£92	£100	£95	£103

Source: NCGC (2016), Table 567 and Table 58

As shown in Table 42, Strategy 3 was deemed to be the most cost-effective (44% probability of being cost-effective at £20,000 threshold). In this strategy, all individuals with symptoms of asthma would undergo a spirometry and FeNO test; those who had an obstructive spirometry would also receive a bronchodilator reversibility test. Only those who had non-obstructive spirometry and conflicting FeNO and PEF variability test results would receive a methacholine challenge test. Further challenge testing on patients with an obstructive spirometry provided higher health outcomes however were not cost-effective at a £20,000 per QALY threshold.

The model results showed that the strategy that did no further testing after a positive bronchodilator reversibility test was dominated. Therefore, the cost-effectiveness of bronchodilator reversibility testing is contingent on the recommended diagnostic pathway being completed after the results are produced. Stopping the diagnostic pathway after the bronchodilator reversibility test is conducted will lead to higher costs and poorer health outcomes.

Table 42 NCGC (2016): Base case results (probabilistic) from NCGC (2016) economic model for diagnosis of adult asthma

Strategy	Mean QALYs per patient	Mean cost per patient (£)	NMB at £20,000 threshold	Rank at £20,000 threshold	Probability of being CE at £20,000 threshold
Current practice	16.7766	3,730	331,802	6	6%
Strategy 1	16.7760	3,753	331,768	7	0%
Strategy 2	16.7776	3,686	331,866	5	19%
Strategy 3	16.7783	3,683	331,882	1	44%
Strategy 4	16.7785	3,691	331,878	4	0%
Strategy 5	16.7784	3,686	331,881	2	23%
Strategy 6	16.7787	3,695	331,879	3	8%

Source: NCGC (2016), Table 56
Abbreviations: CE, cost-effectiveness; NCGC, National Clinical Guideline Centre; NMB, net monetary benefit; QALY, quality-adjusted life years.

The NCGC guideline stated that an economic model was not feasible for children; however, the unit cost of performing spirometry (with and without bronchodilator reversibility testing) was determined for children (see Appendix 10.1). The GDG acknowledged the high annual cost of drugs for the management of asthma in children; preventing these costs from occurring in children without asthma would be a large benefit derived from a diagnostic strategy with a high specificity.

Note that the most recent NCGC guideline on the management of COPD included a systematic review and the development of an economic model to evaluate the cost-effectiveness of opportunistic case-finding using spirometry linked to smoking cessation therapy (NCGC, 2010). This model is not relevant to this MBS Review and will not be discussed further.

2.8 What is the evidence that an increase in spirometry service fees (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

No systematic reviews or HTAs were identified that address this research question.

2.9 What is the evidence that financial incentives for performing spirometry over and above a fee for service (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

No systematic reviews or HTAs were identified that specifically address this research question. However, one recent systematic review (Langdown and Peckham 2014) was identified that examined the evidence on the efficacy of the UK Quality and Outcomes Framework (QOF) for improving health outcomes, its impact on non-incentivised activities, and the robustness of the clinical targets adopted in the scheme.

The QOF is a pay-for-performance scheme that was introduced in the UK in 2004 as part of a new GP contract that aimed to focus on quality and outcomes, incentivising practices to achieve higher

standards of quality care. It provides GPs an opportunity to increase practice income through a points-based system, which are awarded when a range of indicators are met, subject to attaining a minimum and maximum level of thresholds and targets. Indicators are based on three different domains ('Clinical', 'Public Health', 'Public Health–Additional Services'), with a maximum number of points available across the domains, which determine the amount each practice is paid. In the 2014-15 contract, the maximum number of points that could be achieved was 559. COPD and asthma are included as two separate 'Clinical' domains within the respiratory group. Asthma clinical indicators attract a total of 43 points, of which 15 are available for measures of variability or reversibility for initial diagnosis. For COPD, 35 points are available, 12 for a diagnosis confirmed by post-bronchodilator spirometry and a record of FEV_1 in the previous 12 months (see 0 for further details of the indicators).

Langdown and Peckham (2014)

On the basis of 11 identified studies, Langdown and colleagues concluded that the UK's payment incentive scheme has had only a limited impact on improving health outcomes due to its focus on process-based indicators, the ceiling placed on indicator thresholds, and the sub-optimal clinical targets when compared with the national clinical guidelines (Langdown et al, 2014).

Only one of the studies identified by Langdown and colleagues relates to the use of spirometry. Strong et al (2009) assessed the quality of the spirometry measures related to the QOF COPD indicators against the British Thoracic Society standards (BTS, 2005). The study obtained data from the records of 3,217 patients randomly sampled from 5,649 patients with COPD in 38 general practices in Rotherham, UK in the period between October 2006 and February 2007.

Practices in Rotherham achieved highly against the two QOF indicators that related to spirometry. The COPD9 criteria (which recorded the proportion of all patients with COPD in whom diagnosis has been confirmed by spirometry including reversibility testing) was met for 97.4% of the patients on the COPD registers, and the COPD10 criteria (which recorded the proportion of patients in whom there is a record of FEV_1 in the previous 15 months) was met for 89.5% of patients.[24] However, the proportion of patients whose spirometry met BTS standards (defined as three consistent readings of which the best two are within 100 mL, or 5%, of each other) was only 31%. Furthermore, 12% of patients on the COPD register had an FEV_1 (% predicted) that did not support the diagnosis of COPD according to NICE guidelines.

Strong and colleagues concluded that there was no association between quality measured by BTS standards and the achievement of QOF COPD indicators (previously known as COPD9 and COPD10), and that "the QOF assesses the quantity rather than the quality of spirometry".

[24] These were the indicators in place in 2006-07. See 0 for COPD indicators in 2014-15.

Support for an increase in the quantity of spirometry comes from a large general population-based study that showed that the recording of spirometry data increased markedly after the introduction of the 2003 QOF contract and 2004 NICE guidance (from 18% in 2003 to 62% in 2005) (Smith et al, 2008). The same study showed an increase in prescribing of combination inhalers to people with moderate to severe COPD. The extent to which these changes can be attributed to the QOF contract is unclear.

Of note, there have been substantial changes to the COPD indicators relating to spirometry following the 2010 release of the NCGC guideline on the management of COPD (see 0 for 2014-15 QOF indicators). In 2013 the NHS requested that NICE review the indicators within the clinical and public health domains of the QOF in order to retire and amend a significant number of indicators.[25] The impact of these amendments on improving the quality of care for patients with asthma and COPD remains unknown.

2.10 What is the evidence that introduction of an outcome based payment model that links provider payment to accurate diagnosis of asthma or COPD (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

No systematic reviews or HTAs were identified that address this research question.

[25] 2014/15 General medical services (GMS) contract Quality and Outcomes Framework (QOF). Guidance for GMS contract 2014/15, March 2015.

2.11 Summary of Findings

Q1) Does the use of spirometry improve diagnostic accuracy and health outcomes in people presenting with respiratory symptoms?

- Very low to moderate quality evidence suggests that high-quality spirometry may reduce rates of under-diagnosis and misdiagnosis of asthma, COPD and other causes of airflow limitation.
- According to international CPGs, **pre-bronchodilator spirometry**, **post-bronchodilator spirometry**, and reversibility testing (**pre-** ***and*** **post-bronchodilator spirometry**) all have a role in the diagnosis of patients presenting with respiratory symptoms suggestive of asthma, COPD or other causes of airflow limitation.
- On the basis of low quality evidence or consensus, the use of **bronchodilator reversibility testing** is recommended by international CPGs for the diagnosis of asthma in adults and children (>5 years of age) with evidence of airflow limitation according to **pre-bronchodilator spirometry**.
- On the basis of low level evidence or consensus, the use of **post-bronchodilator spirometry** is recommended by international CPGs for the diagnosis of COPD; however, **bronchodilator reversibility testing** may have a place where diagnostic doubt remains, or both COPD and asthma are suspected, particularly in elderly patients.
- Australian CPGs are less clear about a role for **pre-** ***or*** **post-bronchodilator spirometry** in the diagnosis of asthma and COPD. It could be interpreted from Australian guidance that **pre-** ***and*** **post-bronchodilator spirometry** should always be undertaken for the diagnosis of asthma and COPD; this guidance does not appear to be evidence-based.

Q2a) In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for assessing acute exacerbations?

- Due to a lack of evidence, there are no CPG recommendations relating to the use of spirometry for the assessment of acute exacerbations.
- While some asthma and COPD CPGs advised that spirometry is of little value in the management of acute exacerbations, others suggested that it may be useful for categorising severity and assessing patients during recovery.

Q2b) In patients diagnosed with asthma or COPD, what is the clinical utility of spirometry for long-term monitoring?

- Several asthma guidelines note that there is evidence to suggest that low FEV_1 is a strong independent predictor of risk of exacerbations and therefore support the use of lung function testing as part of long-term monitoring.
- For COPD, the general consensus from Australian and international CPGs is that FEV_1 is a poor predictor of disease status and prognosis, but that spirometry may still have a role alongside other tests in long-term monitoring because worsening airflow limitation is associated with an increasing frequency of exacerbations and adverse events.

- The only CPG that mentions bronchodilator reversibility testing at follow-up is the NAC handbook (2015), which notes that MBS reimbursement is only available if pre- *and* post-bronchodilator readings are taken and a permanently recorded tracing is retained.

Q3) What is the published evidence for the cost-effectiveness of spirometry for the diagnosis of people presenting with respiratory symptoms?

- A recent economic evaluation commissioned by NICE (2016) found that the cost-effectiveness of diagnostic strategies using spirometry and bronchodilator reversibility testing was contingent on further diagnostic tests being performed downstream.
- No evidence was identified that assessed the cost-effectiveness of spirometry for the diagnosis of COPD.

Q4) What is the evidence that an increase in spirometry service fees (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

Q5) What is the evidence that financial incentives for performing spirometry over and above a fee for service (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

Q6) What is the evidence that introduction of an outcome based payment model that links provider payment to accurate diagnosis of asthma or COPD (a) increases the number of accurate diagnoses of asthma or COPD in people presenting with respiratory symptoms, and (b) improves health outcomes?

- There is evidence from the UK to suggest that a financial incentive to undertake spirometry (over and above a fee for service) increases the quantity, but not necessarily the quality, of spirometry in primary care.
- No evidence was identified that addresses the impact of financial incentives for the use of spirometry in primary care, on diagnostic accuracy or patient health outcomes.

3. Conclusions

- **Pre-bronchodilator spirometry** is not reimbursed through the MBS but is recommended in international CPGs as a first line objective test to confirm airflow obstruction in adults and children (>5 years) who present with respiratory symptoms suggestive of asthma; **bronchodilator reversibility testing** should only follow if airflow limitation is detected.
- **Post-bronchodilator spirometry** is not reimbursed through the MBS but is recommended in international CPGs for the diagnosis of COPD, in cases where asthma or ACOS are not suspected.
- Despite a lack of clear evidence of benefit, international CPGs generally support the use of spirometry (pre- *or* post-bronchodilator) for long-term monitoring of patients with asthma or COPD; a role for spirometry in the assessment of acute exacerbations is less clear.
- Australian CPGs tend to support the use of **pre- *and* post-bronchodilator spirometry**, which is currently reimbursed on the MBS, to a greater extent than international CPGs.
- Financial incentives may increase the use of spirometry in primary care, but the extent to which it improves diagnosis and health outcomes is unknown.

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Appendix 2 MBS Information

The MBS items that are relevant to the review of spirometry are shown in Table A-2.1. Spirometry performed by general practitioners is reimbursed through item 11506. The other items are generally confined to specialist practice.

Table A-2.1 Spirometry services listed on the MBS

Item number	MBS item descriptor	MBS fee	Benefit
11500	BRONCHOSPIROMETRY, including gas analysis	$167.00	75% = $125.25; 85% = $141.95
11503	Measurement of the: (a) mechanical or gas exchange function of the respiratory system; or (b) respiratory muscle function; or (c) ventilatory control mechanisms. Various measurement parameters may be used including any of the following: (a) pressures; (b) volumes; (c) flow; (d) gas concentrations in inspired or expired air; (e) alveolar gas or blood; (f) electrical activity of muscles. The tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital. Each occasion at which 1 or more such tests are performed, not being a service associated with a service to which item 22018 applies.	$138.65	75% = $104.00; 85% = $117.90
11506	MEASUREMENT OF RESPIRATORY FUNCTION involving a permanently recorded tracing performed before and after inhalation of bronchodilator - each occasion at which 1 or more such tests are performed	$20.55	75% = $15.45; 85% = $17.50
11509	MEASUREMENT OF RESPIRATORY FUNCTION involving a permanently recorded tracing and written report, performed before and after inhalation of bronchodilator, with continuous technician attendance in a laboratory equipped to perform complex respiratory function tests (the tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital) - each occasion at which 1 or more such tests are performed	$35.65	75% = $26.75; 85% = $30.35
11512	CONTINUOUS MEASUREMENT OF THE RELATIONSHIP BETWEEN FLOW AND VOLUME DURING EXPIRATION OR INSPIRATION involving a permanently recorded tracing and written report, performed before and after inhalation of bronchodilator, with continuous technician attendance in a laboratory equipped to perform complex lung function tests (the tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital) - each occasion at which 1 or more such tests are performed	$61.75	75% = $46.35; 85% = $52.50

Source: Department of Human Services – Medicare Australia, accessed 05 January 2016.

Note: Explanatory note D1.14 clarifies that MBS item 11503 applies to spirometry performed before and after simple exercise testing undertaken as a provocation test for the investigation of asthma, in premises capable of performing complex lung function tests and equipped with a mechanical ventilator and defibrillator.

Table A-2.2 shows the start dates for the MBS item numbers that are relevant to spirometry, as well as the start dates for the item descriptors and fees.

Table A-2.2 Start dates for spirometry MBS item numbers

MBS item number	Type of date	Date
11500	Item Start Date	01 Dec 1975
	Current Descriptor Start Date	01 Dec 1991
	Current Schedule Fee Start Date	01 Nov 2012
11503	Item Start Date	01 Dec 1975
	Current Descriptor Start Date	01 Mar 2013
	Current Schedule Fee Start Date	01 Nov 2012
11506	Item Start Date	01 Dec 1976
	Current Descriptor Start Date	01 Dec 1991
	Current Schedule Fee Start Date	01 Nov 2012
11509	Item Start Date	01 May 1990
	Current Descriptor Start Date	01 May 1990
	Current Schedule Fee Start Date	01 Nov 2012
11512	Item Start Date	01 May 1990
	Current Descriptor Start Date	01 May 1990
	Current Schedule Fee Start Date	01 Nov 2012

Source: Department of Human Services – Medicare Australia, accessed 05 January 2016.

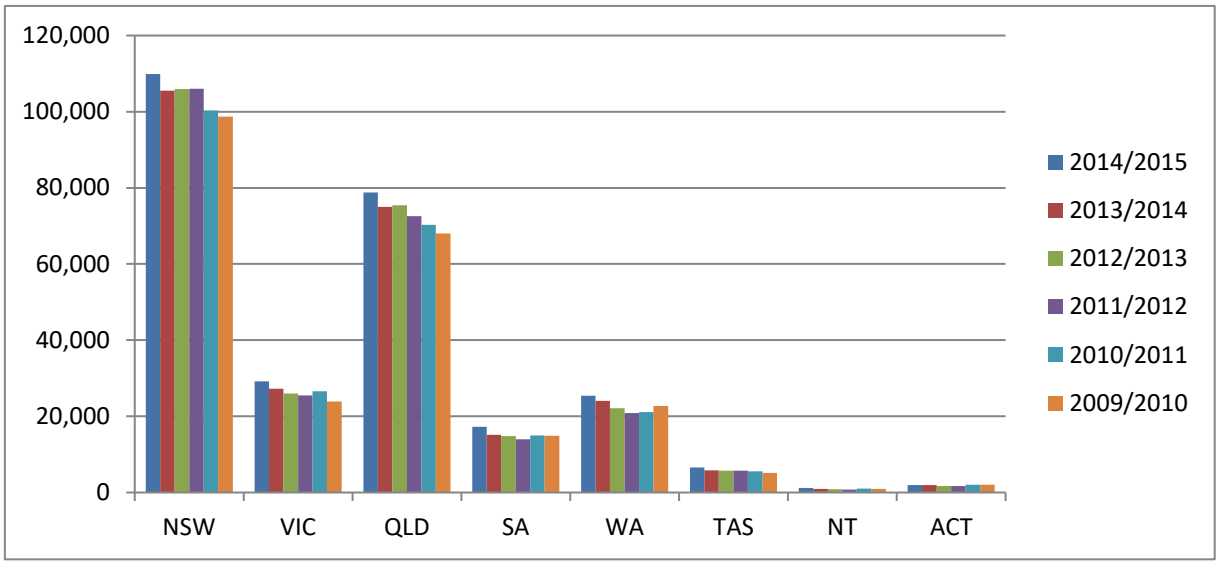
Appendix 3 MBS Data

Table A-3.1 Services and benefits paid for MBS item 11506, financial year 2014-15

MBS item	No. of services	No. of patients	No. of providers	OOH services	Bulk billing rate (OOH services)	Benefits paid ($)	Change in services 2011-12 to 2014-15
11506	270,258	231,878	18,358	100%	84%	5,372, 888	9%

Source: Department of Health, Medical Benefits Division, Medicare Financing & Listings Branch, MBS Analytics Section. Data received 11 January 2016.
Abbreviations: BB, bulk billing; OOH, out of hospital

Figure A-3.1 Number of Services by State/Territory for MBS item 11506, 2009-10 to 2014-15



Source: Department of Health, Medical Benefits Division, Medicare Financing & Listings Branch, MBS Analytics Section. Data received 11 January 2016.

Table A-3.2 Number of services per capita by state/territory for MBS item 11506, financial year 2014-15

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Australia
ERP [a]	7,565,497	5,886,436	4,750,513	1,691,503	2,581,250	515,235	244,265	387,640	23,625,561
11506	109,903	29,228	78,751	17,226	25,436	6,559	1,199	1,934	270,258
Service rate per 1,000	14.5	5.0	16.6	10.2	9.9	12.7	4.9	5.0	11.4

Source: Department of Health, Medical Benefits Division, Medicare Financing & Listings Branch, MBS Analytics Section. Data received 11 January 2016.
Abbreviations: ERP, estimated residential population
[a] At December 2014 (ABS)

Table A-3.3 Number of services for MBS item 11506 by age group, financial year 2014-15

Age group	Number of services	% provided to age group
0-4	461	0%
5-9	7,956	3%
10-14	11,506	4%
15-19	10,388	4%
20-24	9,705	4%
25-29	9,316	3%
30-34	10,348	4%
35-39	11,293	4%
40-44	14,289	5%
45-49	18,001	7%
50-54	19,607	7%
55-59	23,016	9%
60-64	26,536	10%
65-69	30,440	11%
70-74	26,547	10%
75-79	21,400	8%
80-84	12,916	5%
>=85	6,533	2%
Total	**270,258**	**100%**

Source: Department of Health, Medical Benefits Division, Medicare Financing & Listings Branch, MBS Analytics Section. Data received 11 January 2016.

Table A-3.4 Top ten item combinations with MBS item 11506, financial year 2014-15

Item combination	Number of Episodes	Number of services	% of total episodes	Description of episodes	Average Schedule fee paid for combination
11506	292,504	292,941	54%	Measurement of respiratory function after bronchodilator only	16.83
11506, 00023	85,177	170,865	16%	Measurement of respiratory function after bronchodilator & Level B GP consultation	50.47
11506, 00036	46,525	93,217	9%	Measurement of respiratory function after bronchodilator & Level C GP consultation	43.83
11506, 00116	21,222	42,455	4%	Measurement of respiratory function after bronchodilator & subsequent consultant physician consultation	86.42
11506, 00110	10,697	21,395	2%	Measurement of respiratory function after bronchodilator & initial consultant physician consultation	49.04
11700, 11506	10,111	20,251	2%	Measurement of respiratory function after bronchodilator & 12 lead ECG	119.84
11700, 11506, 00036	9,803	29,436	2%	Measurement of respiratory function after bronchodilator, 12 lead ECG & Level C ECG	155.17
11506, 00721	9,226	18,476	2%	Measurement of respiratory function after bronchodilator & Chronic Disease Management plan	79.18
11700, 11506, 00023	8,194	24,655	2%	Measurement of respiratory function after bronchodilator, 12 lead ECG & Level B GP consultation	122.91
11506, 00732	7,800	19,573	1%	Measurement of respiratory function after bronchodilator & review Chronic Disease Management plan	93.94

Source: Department of Health, Medical Benefits Division, Medicare Financing & Listings Branch, MBS Analytics Section. Data received 11 January 2016.

Appendix 4 Literature Search

MEDLINE (via PubMed)

Search date: 12th January, 2016

Limits: January 2005 – current

Key search term: spiromet*

Filter: PubMed systematic review filter (identifies systematic reviews, clinical practice guidelines, meta-analyses)

((systematic review [ti] OR meta-analysis [pt] OR meta-analysis [ti] OR systematic literature review [ti] OR this systematic review [tw] OR (systematic review [tiab] AND review [pt]) OR meta synthesis [ti] OR meta synthesis [ti] OR integrative review [tw] OR integrative research review [tw] OR rapid review [tw] OR consensus development conference [pt] OR practice guideline [pt] OR cochrane database syst rev [ta] OR acp journal club [ta] OR health technol assess [ta] OR evid rep technol assess summ [ta] OR drug class reviews [ti]) OR (clinical guideline [tw] AND management [tw]) OR ((evidence based[ti] OR evidence-based medicine [mh] OR best practice* [ti] OR evidence synthesis [tiab]) AND (review [pt] OR diseases category[mh] OR behavior and behavior mechanisms [mh] OR therapeutics [mh] OR evaluation studies[pt] OR validation studies[pt] OR guideline [pt] OR pmcbook)) OR ((systematic [tw] OR systematically [tw] OR critical [tiab] OR (study selection [tw]) OR (predetermined [tw] OR inclusion [tw] AND criteri* [tw]) OR exclusion criteri* [tw] OR main outcome measures [tw] OR standard of care [tw] OR standards of care [tw]) AND (survey [tiab] OR surveys [tiab] OR overview* [tw] OR review [tiab] OR reviews [tiab] OR search* [tw] OR handsearch [tw] OR analysis [ti] OR critique [tiab] OR appraisal [tw] OR (reduction [tw]AND (risk [mh] OR risk [tw]) AND (death OR recurrence))) AND (literature [tiab] OR articles [tiab] OR publications [tiab] OR publication [tiab] OR bibliography [tiab] OR bibliographies [tiab] OR published [tiab] OR unpublished [tw] OR citation [tw] OR citations [tw] OR database [tiab] OR internet [tiab] OR textbooks [tiab] OR references [tw] OR scales [tw] OR papers [tw] OR datasets [tw] OR trials [tiab] OR meta-analy* [tw] OR (clinical [tiab] AND studies [tiab]) OR treatment outcome [mh] OR treatment outcome [tw] OR pmcbook)) NOT (letter [pt] OR newspaper article [pt])

The Cochrane Library

Search date: 12th January, 2016

Limits: January 2005 – current

Key search term: spiromet*

Databases: Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effect, Health Technology Assessment Database, NHS Economic Evaluation Database

Clinical Practice Guideline databases

Search date: 12th January, 2016

Limits: January 2010 – current

Key search terms: spirometry, asthma, chronic obstructive pulmonary disease, COPD

Databases: Guidelines International Network (G-I-N), AHRQ National Guidelines Clearinghouse, Australian Clinical Practice Guidelines Portal, Scottish Intercollegiate Guidelines Network (SIGN)

Health technology assessment agencies

Search date: 12th January, 2016

Limits: January 2005 – current

Key search terms: spirometry, asthma, chronic obstructive pulmonary disease, COPD

Agencies: Agency for Healthcare Research and Quality (AHRQ), National Institute for Health and Care Excellence (NICE), Canadian Agency for Drugs and Technologies in Health (CADTH), Medical Services Advisory Committee (MSAC)

Other websites

Search date: 12th January, 2016

Limits: January 2005 – current

Key search terms: spirometry, guideline, asthma, chronic obstructive pulmonary disease, COPD

Websites: Lung Foundation Australia (LFA), The Thoracic Society of Australia and New Zealand (TSANZ), National Asthma Council Australia (NAC), Australian Primary Health Care Research Institute (APHCRI), British Thoracic Society (BTS), American College of Chest Physicians (ACCP), Canadian Thoracic Society (CTS), The College of Physicians and Surgeons of Ontario (CPSO)

Appendix 5 Evidence Quality Assessment

The methodological quality of included systematic reviews was assessed using the AMSTAR measurement tool (Shea et al, 2007). AMSTAR scores for the included systematic reviews are shown in Table A-5.1.

The MBS rapid review methodology specifies that, where appropriate, the quality of the body of evidence for each outcome will be examined according to the GRADE criteria (Guyatt et al, 2011). GRADE uses a step-wise, structural methodology to determine the overall quality of the body of evidence using the following definitions:

High High confidence in the effect estimate – the true effect lies close to the estimate of the effect

Moderate Moderate confidence in the effect estimate – the true effect is likely to be close to the estimate of the effect, but may be substantially different

Low Low confidence in the effect estimate – the true effect may be substantially different from the estimate of the effect

Very Low Very low confidence in the effect estimate – the true effect is likely to be substantially different from the estimate of the effect

Using the GRADE approach, the first consideration is study design; the starting assumption is that randomised controlled trials (RCTs) are high quality, whereas observational studies are low quality. Five additional factors are then taken into account: risk of bias, inconsistency, indirectness, imprecision, and publication bias. Limitations in these areas result in downgrading the quality of evidence. Finally, three main factors are considered that may raise the quality of evidence: the large magnitude of effect, the dose response gradient, and any residual confounding factors.

For this review of spirometry, no GRADE quality assessments were undertaken because the body of evidence in the included systematic reviews could no longer be considered contemporary, or it did not directly address the research questions and PICO criteria in Section 2.1.

Table A-5.1 AMSTAR scores of included systematic reviews

Author, Year	Overall AMSTAR Score [a]	(1) Provided study design	(2) Duplicate study selection	(3) Broad literature search	(4) Considered status of publication	(5) List of studies	(6) Provided study character-istics	(7) Assessed scientific quality	(8) Considered quality in report	(9) Methods to combine appropriate	(10) Assessed publication bias	(11) Stated conflict of interest
Cranston et al (2006)	6	1	0	1	1	1	1	0	1	NA	0	0
José et al (2014)	3	1	0	0	0	1	1	0	0	NA	0	0
Langdown and Peckham (2014)	7	1	0	1	1	1	1	1	1	NA	0	0
Wilt et al (2005) [HTA for AHRQ]	8	1	CA	1	1	1	1	1	1	1	0	0
Wilt et al (2007)	10	1	1	1	1	1	1	1	1	1	0	1

Abbreviations: AHRQ, Agency for HealthCare Research and Quality; AMSTAR, Assessment of Multiple Systematic Reviews; CA, can't answer; HTA, health technology assessment; NA, not applicable
a 1 = Yes, 0 = No; maximum possible score is 11. Details of AMSTAR Score are described in Shea et al (2007).

Appendix 6 Guideline General information

Appendix 6.1 Asthma

National Asthma Council Australia (2015)

The *Australian Asthma Handbook* provides best-practice recommendations based on published evidence for health professionals working in primary care. The Handbook focuses of the diagnosis of asthma in children and adults as well as acute and long-term asthma management. Evidence-based recommendations were graded using NHMRC grades A to D (see 0 for further details); however, the recommendations relevant to this review were all consensus recommendations, based on clinical experience and expert opinion, with occasional references to published sources.

National Asthma Council Australia (2013)

The NAC also developed an information paper for health professionals entitled *Asthma & the Over 65s.* This resource is not a full CPG; however, some recommendations of particular relevance to older patients were provided and are summarised in this Rapid Review.

National Clinical Guideline Centre (2016)

This NCGC guideline, commissioned by NICE, offers best-practice advice on the care of people with suspected asthma presenting with respiratory symptoms, and ongoing monitoring of asthma in people with a confirmed diagnosis.

Recommendations were drafted on the basis of evidence available up to 1 October 2014.[26] The included studies were assessed using an adaptation of GRADE. For studies of diagnostic accuracy, the Quality Assessment of Diagnostic Accuracy Studies version 2 (QUADAS-2) checklist was used. When clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on their expert opinion.

The version of this guideline that is currently available on the NICE website is marked as 'Interim findings'. From April to November 2014, the Adoption and Impact programme will run an implementation feasibility project in a variety of primary care settings that use different asthma service delivery models. According to the NICE website, the project will focus on the impact and feasibility of implementing two of the objective tests recommended in different diagnostic algorithms in the guideline (quality-assured spirometry and FeNO).

Global Initiative for Asthma (2015)

The *Global Strategy for Asthma Management and Prevention* provides up-to-date evidence-based guidance on the prevention, diagnosis and management of asthma. GINA conducts twice-yearly

[26] Health economic searches (NHS Economic Evaluation Database, the Health Technology Assessment database and the Health Economic Evaluations Database) were undertaken on the same day.

updates of the published literature using PubMed. New evidence, and the potential impact on existing recommendations are discussed by the GINA Science Committee at regular meetings.

Recent versions of the GINA report have emphasised the importance of confirming the diagnosis of asthma to minimise both under- and over-treatment. Specific advice was added about how to confirm the diagnosis in special populations including elderly patients and patients already on treatment.

Levels of evidence were assigned to management recommendations; however guidance relating to the diagnosis and assessment of asthma was not rated using this criteria and the evidence underpinning this guidance was not always clear.

British Thoracic Society / Scottish Intercollegiate Guidelines Network (2014)

The *British Guideline on the Management of Asthma* was originally published in 2003 and has been regularly updated (approximately annually) since that time. The most recent version (2014) provides evidence-based recommendations, the majority of which were about the management of asthma in children, adolescents and adults, including pregnant women. Evidence statements and recommendations were assigned a level of evidence or grade, respectively, according to SIGN criteria outlined in 0. The GDG also established 'good practice points' that were based on their collective clinical experience.

Appendix 6.2 Chronic Obstructive Pulmonary Disease (COPD)

Lung Foundation Australia / Thoracic Society of Australia and New Zealand (2015)

This joint Australian and New Zealand guideline is a regularly updated source of evidence-based guidance focusing on the optimal management of people with COPD. While the guideline deals mainly with the management of established disease, some guidance is given around case-finding and confirmation of diagnosis. Recommendations were provided with an accompanying rating of the level of evidence that underpins them. In previous versions of the LFA/TSANZ guideline, the level of evidence was assigned according to the system developed by the National Heart, Lung, and Blood Institute (NHLBI). In this version of the guideline, the evidence was reclassified according to the NHMRC levels of evidence (see 0).

Abramson (2014)

The *COPD-X Concise Guide for Primary Care* was based on the full LFA/TSANZ guideline[27] and was developed to assist with COPD management during daily practice. Each recommendation from the full guideline was discussed by a specially convened committee and modified based on the latest evidence available with the aim to provide practical and readily accessible recommendations and practice tips for GPs, practice nurses, and allied healthcare workers. Abramson et al (2014) stated

[27] It was unclear which version of this guideline was used to develop the 2014 Concise Guide.

that GRADE methodology was used to rate the strength of recommendations and, like the full guideline, NHMRC levels of evidence were provided to accompany evidence statements (see 0). Practice tips were included where there was insufficient evidence to make a recommendation, but where the committee were satisfied that the practice tip could benefit diagnosis and management of COPD.

Global Initiative for Chronic Obstructive Lung Disease (2016)

The *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease* was originally published in 2001. The guideline was developed with the aim of providing recommendations for management of COPD based on the best scientific information available. The most recent version of this guideline, published in January 2016, incorporated new evidence identified through PubMed up to 30 June 2015.

Each recommendation is assigned a level of evidence according to the criteria shown in 0; however, formal recommendations in the GOLD report were mostly about therapeutic management. None of the guidance surrounding diagnosis, assessment and long-term monitoring was accompanied by a level of evidence and was presented as general guidance rather than official, graded recommendations. Therefore, while advice was provided about the use of spirometry, the evidence base that underpinned that guidance was not always clear.

The latest version of the GOLD report incorporates a specific section about ACOS. This material was prepared jointly by the GOLD and GINA Science Committees.

Department of Veterans Affairs / Department of Defense (2014)

This guideline was an update of the 2007 VA/DoD guideline on the management of COPD. The aim of this guideline was to provide information and assist clinical decision-making, particularly for the use of providers within the VA/DoD health care systems. GRADE methodology was used to rate the quality of the evidence and assign a grade for each recommendation. Four domains were considered during the GRADE process: balance of desirable and undesirable outcomes; confidence in the quality of the evidence; values and preferences; other implications (see 0 for more information). Ultimately each recommendation was rated as ‘strong for’, ‘strong against’, ‘weak for’ or ‘weak against’.

Qaseem (2011)

This guideline represents a joint statement by the American College of Physicians (ACP), American College of Chest Physicians (ACCP), American Thoracic Society (ATS), and European Respiratory Society (ERS). The guideline addresses the value of history and physical examination for predicting airflow obstruction; the value of spirometry for screening or diagnosis of COPD; and provides guidance about the management of COPD.

The 2007 ACP guideline forms the basis of this CPG, which involved a targeted literature update from March 2007 to December 2009. The results of the systematic review were assessed by a Clinical

Guidelines Committee that included representatives from each of the four collaborating organisations. The Committee assessed the quality of the evidence using the ACP's Guideline Grading System, which was adopted from GRADE (see 0).[28]

National Clinical Guideline Centre (2010)

The NCGC guideline (commissioned by NICE) was a partial update of an original NICE COPD guideline published in 2004. The purpose of the guideline was to provide evidence-based guidance regarding best practice for the identification and care of patients with COPD. The update focused specifically on issues relating to diagnosis, clinical assessment, the management of stable disease with inhaled therapies, and the timing of pulmonary rehabilitation. The management of acute exacerbations, which is important in the context of this review, was specifically excluded from the 2010 update.

All included studies were critically appraised using GRADE for non-observational studies and a narrative summary (evidence statements) for observational and qualitative studies. Evidence statements were then assigned a level of evidence (see 0).

Where enough high-quality evidence was available, recommendations were developed and graded based on the strength of evidence underpinning them. The system used to grade recommendations is also summarised in 0. Finally, consensus statements were developed where there was a lack of evidence regarding a particular issue, but where the GDG felt that some guidance was warranted.

In February 2012, an evidence update was undertaken that did not identify any new key evidence regarding the diagnosis of COPD. Similarly, no new evidence about the value of spirometry in long-term management of COPD or the management of exacerbations was identified at that time.

[28] Specific details about the ACP guideline methodology was provided in Qaseem et al (2010).

Appendix 7 Grading of Recommendations

This appendix summarises the various methods used by the clinical practice guidelines to grade recommendations and/or to rate the level of evidence of a particular evidence base.

Table A-7.1 NAC (2015): Types and grading of recommendations

Type	Method
Evidence-based recommendation **Grade A** Body of evidence can be trusted to guide practice **Grade B** Body of evidence can be trusted to guide practice in most situations **Grade C** Body of evidence provides some support for recommendation but care should be taken in its application **Grade D** Body of evidence is weak an recommendation must be applied with caution	Systematic literature review Grading of recommendation according to NHMRC grades A to D
Consensus recommendation following inconclusive literature search	Based on clinical experience and expert opinion after systematic literature review yielded insufficient evidence for an evidence-based recommendation
Based on selected evidence	Based on a limited structured literature review or published systematic review
Adapted from existing guidance	Based on reliable clinical practice guideline(s) or position statement(s)
Consensus recommendation (with reference to named sources)	Based on clinical experience and expert opinion (informed by evidence, where available), with particular reference to named source(s)
Consensus recommendation	Based on clinical experience and expert opinion (informed by evidence, where available)

Abbreviations: NAC, National Asthma Council Australia; NHMRC, National Health and Medical Research Council.

Table A-7.2 GINA (2015): Levels and sources of evidence

Evidence category	Sources of evidence	Definition
A	RCTs or meta-analyses. Rich body of data.	Evidence is from endpoints of well-designed RCTs or meta-analyses that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of participants.
B	RCTs and meta-analyses. Limited body of data.	Evidence is from endpoints of intervention studies that include only a limited number of patients, post hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, they were undertaken in a population that differs from the target

Evidence category	Sources of evidence	Definition
		population of the recommendation, or the results are somewhat inconsistent.
C	Non-randomised trials. Observational studies.	Evidence is from outcomes of uncontrolled or non-randomized trials or from observational studies.
D	Panel Consensus Judgment.	This category is used only in cases where the provision of some guidance was deemed valuable but the clinical literature addressing the subject was deemed insufficient to justify placement in one of the other categories. The Panel Consensus is based on clinical experience or knowledge that does not meet the above-listed criteria.

Abbreviations: GINA, Global Initiative for Asthma; RCT, randomised controlled trial.

Table A-7.3 BTS/SIGN (2014): Key to evidence statements and grades of recommendations

Level of evidence	Definition
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, eg case reports, case series
4	Expert opinion

Table A-7.3 continued BTS/SIGN (2014): Key to evidence statements and grades of recommendations

Grades of recommendation	Definition
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Grades of recommendation	Definition
	Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
Good practice points	Recommended best practice based on the clinical experience of the Guideline Development Group

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.
Abbreviations: BTS, British Thoracic Society; RCT, randomised controlled trial; SIGN, Scottish Intercollegiate Guidelines Network.

Table A-7.4 LFA/TSANZ (2015) and Abramson (2014): NHMRC levels of evidence

Level	Basis of evidence
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies, or interrupted time series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel group.
IV	Evidence obtained from case series, either post-test or pre-test/post-test.

Abbreviations: LFA, Lung Foundation Australia; NHMRC, National Health and Medical Research Council; TSANZ, Thoracic Society of Australia and New Zealand.

Table A-7.5 GOLD (2016): Description of levels of evidence

Evidence category	Sources of evidence	Definition
A	RCTs. Rich body of data.	Evidence is from endpoints of well-designed RCTs that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of participants.
B	RCTs. Limited body of data.	Evidence is from endpoints of intervention studies that include only a limited number of patients, post hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, they were undertaken in a population that differs from the target population of the recommendation, or the results are somewhat inconsistent.
C	Non-randomised trials. Observational studies.	Evidence is from outcomes of uncontrolled or non-randomized trials or from observational studies.
D	Panel Consensus Judgment.	This category is used only in cases where the provision of some guidance was deemed valuable but the clinical literature addressing the subject was deemed insufficient to justify placement in one of the other categories. The Panel Consensus is based on clinical experience or knowledge that does not meet the above-listed criteria.

Abbreviations: GOLD, Global Initiative for Chronic Obstructive Lung Disease; RCT, randomised controlled trial.

Table A-7.6 NCGC (2010): Level of evidence and grading of recommendations

Hierarchy of evidence	Definition of evidence level	Grading of recommendations	Basis of grading
Ia	Evidence from systematic reviews or meta-analysis of randomised controlled trials	A	Based on hierarchy I evidence
Ib	Evidence from at least one randomised controlled trial	A	Based on hierarchy I evidence
IIa	Evidence from at least one controlled study without randomisation	B	Based on hierarchy II evidence or extrapolated from hierarchy I evidence
IIb	Evidence from at least one other type of quasi experimental study	B	Based on hierarchy II evidence or extrapolated from hierarchy I evidence
III	Evidence from non experimental descriptive studies, such as comparative studies, correlation studies and case control studies	C	Based on hierarchy III evidence or extrapolated from hierarchy I or II evidence
IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities	D	Directly based on hierarchy IV evidence or extrapolated from hierarchy I, II or III evidence.

Abbreviations: NCGC, National Clinical Guideline Centre.

Table A-7.7 Qaseem (2011): The American College of Physicians' Guideline Grading System

Quality of evidence	Strength of recommendation	
	Benefits clearly outweigh risks and burden OR risks and burden clearly outweigh benefits	Benefits finely balanced with risks and burden
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak

Source: Qaseem et al, 2010; p. 196.
Note: Adopted from the classification developed by the GRADE workgroup.

Table A-7.8 Qaseem (2011): The American College of Physicians' Guideline Grading System

Grade of recommendation	Burden versus risks and burdens	Methodological quality of supporting evidence	Interpretation	Implications
Strong recommendation; high-quality evidence	Benefits clearly outweigh risks and burden or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation; can apply to most patients in most circumstances without reservation	For patients, most would want the recommended course of action and only a small proportion would not; a person should request discussion if the intervention was not offered. For clinicians, most patients should receive the recommended course of action. For policymakers, the recommendation can be adopted as a policy in most situations.
Strong recommendation; moderate-quality evidence	Benefits clearly outweigh risks and burden or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation; can apply to most patients in most circumstances without reservation	For patients, most would want the recommended course of action and only a small proportion would not; a person should request discussion if the intervention was not offered. For clinicians, most patients should receive the recommended course of action. For policymakers, the recommendation can be adopted as a policy in most situations.
Strong recommendation; low-quality evidence	Benefits clearly outweigh risks and burden or vice versa	Observational studies or case series	Strong recommendation, but may change when higher-quality evidence becomes available	For patients, most would want the recommended course of action and only a small proportion would not; a person should request discussion if the intervention was not offered.

Grade of recommendation	Burden versus risks and burdens	Methodological quality of supporting evidence	Interpretation	Implications
				For clinicians, most patients should receive the recommended course of action. For policymakers, the recommendation can be adopted as a policy in most situations.
Weak recommendation; high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation; best action may differ depending on circumstances or patients' or societal values	For patients, most would want the recommended course of action but some would not—a decision may depend on an individual's circumstances. For clinicians, different choices will be appropriate for different patients, and a management decision consistent with a patient's values, preferences, and circumstances should be reached. For policymakers, policymaking will require substantial debate and involvement of many stakeholders.
Weak recommendation; moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation; best action may differ depending on circumstances or patients' or societal values	For patients, most would want the recommended course of action but some would not—a decision may depend on an individual's circumstances. For clinicians, different choices will be appropriate for different patients, and a management decision consistent with a patient's values, preferences, and circumstances should be reached.

Grade of recommendation	Burden versus risks and burdens	Methodological quality of supporting evidence	Interpretation	Implications
				For policymakers, policymaking will require substantial debate and involvement of many stakeholders.
Weak recommendation; low-quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risks, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable	For patients, most would want the recommended course of action but some would not—a decision may depend on an individual's circumstances. For clinicians, different choices will be appropriate for different patients, and a management decision consistent with a patient's values, preferences, and circumstances should be reached. For policymakers, policymaking will require substantial debate and involvement of many stakeholders.
Insufficient	Balance of benefits and risks cannot be determined	Evidence is conflicting, poor quality, or lacking	Insufficient evidence to recommend for or against routinely providing the service	For patients, decisions based on evidence from scientific studies cannot be made; for clinicians, decisions based on evidence from scientific studies cannot be made; for policymakers, decisions based on evidence from scientific studies cannot be made.

Source: Qaseem et al, 2010; p. 196.
Abbreviations: RCT, randomised controlled trial.

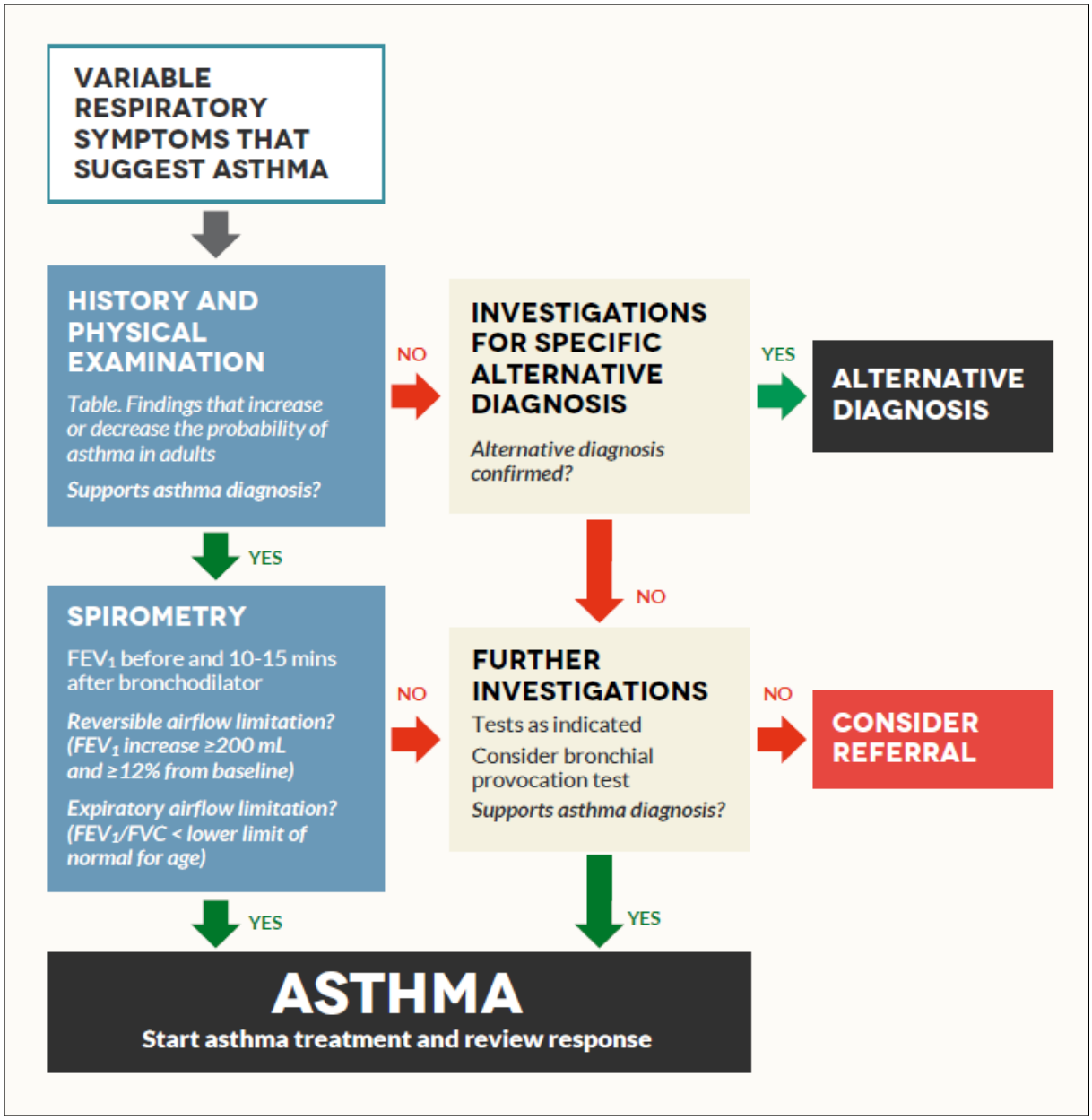
Table A-7.9 VA/DoD (2014): Evidence to recommendation framework

Decision domain	Consideration	Judgment
Balance of desirable and undesirable outcomes	• Given the best estimate of typical values and preferences, are you confident that the benefits outweigh the harms and burden or vice versa? • Are the desirable anticipated effects large? • Are the undesirable anticipated effects small? • Are the desirable effects large relative to undesirable effects?	• Benefits outweigh harms/burden • Benefits slightly outweigh harms/burden • Benefits and harms/burden are balanced • Harms/burden slightly outweigh benefits • Harms/burden outweigh benefits
Confidence in the quality of the evidence	Is there high or moderate quality evidence that answers this question? What is the overall certainty of this evidence?	• High • Moderate • Low • Very low
Values and preferences	Are you confident about the typical values and preferences and are they similar across the target population? What are the patient's values and preferences? Are the assumed or identified relative values similar across the target population?	• Similar values • Some variation • Large variation
Other implications	Are the resources worth the expected net benefit from the recommendation? What are the costs per resource unit? Is this intervention generally available? Is this intervention and its effects worth withdrawing or not allocating resources from other interventions? Is there lots of variability in resource requirements across settings?	Various considerations

Abbreviations: DoD, Department of Defense; VA, Veterans Affairs.

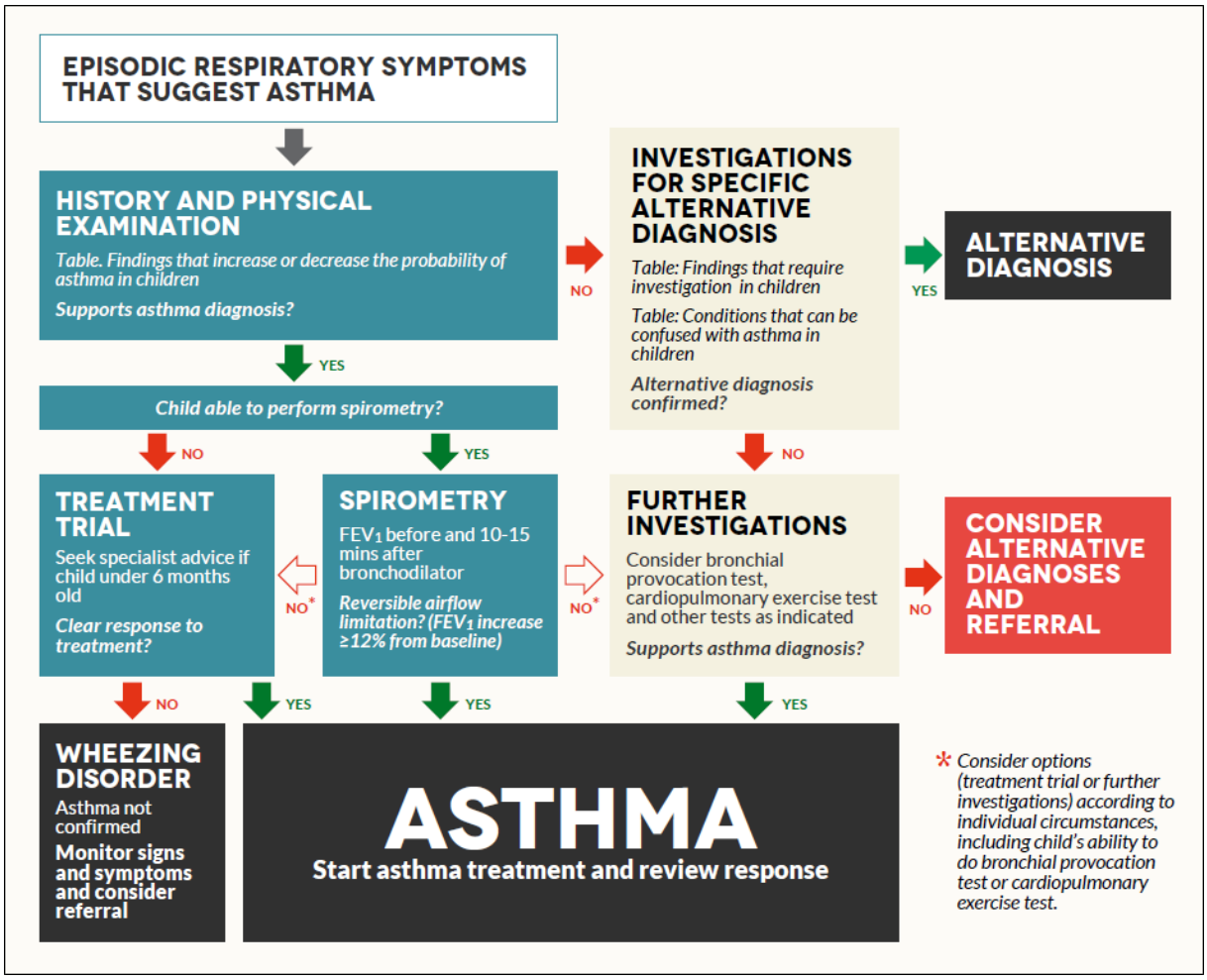
Appendix 8 Additional information from NAC (2015)

Figure A-8.1 NAC (2015): Steps in the diagnosis of asthma in adults



Source: Australian Asthma Handbook, Version 1.1; Section 1.1; p. 1.
Abbreviations: FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; NAC, National Asthma Council Australia.

Figure A-8.2 NAC (2015): Steps in the diagnosis of asthma in children



Source: Australian Asthma Handbook, Version 1.1; Section 1.2; p. 1.
Abbreviations: FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; NAC, National Asthma Council Australia.

Table A-8.1 NAC (2015): Definitions of asthma patterns in children 6 years and over not taking regular preventer

Category	Pattern and intensity of symptoms (when not taking regular treatment)
Infrequent intermittent asthma	Symptom-free for at least 6 weeks at a time (flare-ups up to once every 6 weeks on average but no symptoms between flare-ups)
Frequent intermittent asthma	Flare-ups more than once every 6 weeks on average but no symptoms between flare-ups
Persistent asthma	**Mild** • FEV_1 ≥80% predicted and at least one of: • Daytime symptoms[a] more than once per week but not every day • Night-time symptoms[a] more than twice per month but not every week
	Moderate Any of: • FEV_1 <80% predicted[a] • Daytime symptoms[a] daily • Night-time symptoms[a] more than once per week • Symptoms sometimes restrict activity or sleep
	Severe Any of: • FEV_1 ≤60% predicted[a] • Daytime symptoms[a] continual • Night-time symptoms[a] frequent • Flare-ups frequent Symptoms frequently restrict activity or sleep

Abbreviations: FEV_1, forced expiratory volume in 1 second; NAC, National Asthma Council Australia.
a Symptoms between flare-ups. A flare-up is defined as a period of worsening asthma symptoms, from mild (e.g. symptoms that are just outside the normal range of variation for the child, documented when well) to severe (e.g. events that require urgent action by parents and health professionals to prevent a serious outcome such as hospitalisation or death from asthma).

Table A-8.2 NAC (2015): Frequency of follow-up in various patient groups

Check-up interval	Criteria
4-6 weeks	Pregnant women
1-3 months	After each adjustment to medications
At least every 3 months	Patients with severe asthma, work-exacerbated asthma, poor perception of airflow limitation, frequent rhinosinusitis symptoms, or other comorbid conditions that affect asthma control
6 months	Patients who have had a flare-up within the past 12 months or who has other risk factors for flare-ups or life-threatening asthma (e.g. smoking, previous recording of poor lung function on spirometry, history of admission to an intensive care unit for asthma)
Yearly	Patients with no flare-up in the past 12 months and good symptom control for at least a year

Abreviations: NAC, National Asthma Council Australia.

Appendix 9 Additional information from BTS/SIGN (2014)

Table A-9.1 BTS/SIGN (2014): Relevant key questions that underpinned the systematic literature review

Key questions
In children (under 5 and 5-12 years of age), what are the most effective objective tests for diagnosing reversible airway disease including airway disease that will respond to bronchodilators? • peak expiratory flow variability (amplitude % mean) • bronchodilator response (using PEF, FEV_1 and other lung function tests).
In children (under 5 and 5-12 years of age), what are the most effective objective tests for diagnosing airway disease that will respond to inhaled corticosteroids? • exhaled nitric oxide • induced sputum eosinophil count • airway responsiveness to methacholine, exercise, and indirect challenges such as mannitol and AMP • lung function tests (PEF, FEV_1; home based, lab based).
In children (under 5 and 5-12 years of age) with asthma, what is the best method for monitoring their asthma control? • symptom scores • lung function tests (e.g. spirometry, impulse oscillometry, airway resistance) • bronchial reactivity/airway challenge (e.g. methacholine, histamine, adenosine, cold air, etc) • exhaled nitric oxide • sputum eosinophilia • endobronchial biopsy • exhaled breath condensate • urinary metabolites (LT4, ECP) • combinations of the above
In adults (> 12 years), what are the most effective objective tests for diagnosing reversible airway disease including airway disease that will respond to bronchodilators? • peak expiratory flow variability (amplitude % mean) • bronchodilator response (using PEF, FEV_1 and other lung function tests).
In adults (> 12 years), what are the most effective objective tests for diagnosing airway disease that will respond to inhaled corticosteroids? • exhaled nitric oxide • induced sputum eosinophil count • airway responsiveness to methacholine, exercise, and indirect challenges such as mannitol and AMP • lung function tests (PEF, FEV_1; home based, lab based).
In adults (> 12 years) with asthma, what is the best method for monitoring their asthma control? • symptom scores • lung function tests • exhaled nitric oxide • sputum eosinophilia • endobronchial biopsy

Abbreviations: AMP; adenosine 5'-diphosphate; BTS, British Thoracic Society; ECP; eosinophil cationic protein; FEV_1; forced expiratory volume in 1 second; LT4, levothyroxine; PEF; peak expiratory flow; SIGN, Scottish Intercollegiate Guidelines Network.

Appendix 10 Direct costs of the performance of spirometry

Appendix 10.1 Australian Evidence

A systematic review from the APHCRI (Cranston et al, 2006) estimated the direct costs of the performance of spirometry in primary care in South Australia. The estimates took into consideration the cost of the clinical equipment, the cost of GP or practice nurse test time, the cost of reporting the test, together with the number of tests performed during the effective useful clinical lifetime of the equipment. The following assumptions were made:

- the costs are based on performance of spirometry according to the Australian COPD-X Plan (McKenzie et al, 2003);
- calculations were made assuming two patients per day or 500 patients per year undergo spirometry testing and a useful clinical life of the equipment of five years;
- the total cost represents the minimum cost of spirometry, based on a total test time of 23 minutes (4 minutes pre-bronchodilator test time, 15 minutes between pre- and post-bronchodilator tests, and 4 minutes post-bronchodilator test time);
- additional time must be allowed for preparation, including priming of the spacer in diluted detergent, clean-up, interpretation of test results and reporting;
- no maintenance or calibration time is required for the type of spirometer costed, although other spirometers may require regular maintenance;
- the cost of four metered-dose inhaler actuations (400 micrograms) of salbutamol, to assess bronchodilator response, is included (McKenzie et al, 2003);
- attendance, by the GP or practice nurse, at a spirometry training course is essential for the performance of clinically useful spirometry and interpretation of the results.

Cranston and colleagues assumed a test time of 4 minutes, which was taken from a cross-sectional study from general practices in the Netherlands (van Schayck et al, 2002). An allowance of 4 minutes for three acceptable spirometric manoeuvres represents the time taken if all variables are optimal, and would underestimate test time in sub-optimal situations, such as poor reproducibility, poor exhalation, cough or the patient unwilling or unable to cooperate with the performance of the test. An Italian RCT evaluating office spirometry in standard general practice reported that the average time required to instruct patients for spirometry was 5.6 ± 3.1 minutes and the performance of spirometry took an average 6.4 ± 3.5 minutes (Lusuardi et al, 2006).

The COPD-X Plan advocates reversibility testing 15 to 30 minutes after bronchodilator is given (McKenzie et al, 2003). Cranston and colleagues assumed a minimal time allowance of 15 minutes between pre- and post-bronchodilator testing.

A training time of 6 hours or 1 day (attendance at one spirometry training course) was included in the costs, assuming practice staff perform 500 spirometric tests per year over a five-year period. Practice staff performing fewer spirometry tests may require attendance at a refresher course, which would

increase total cost. However, the cost of spirometry training may be covered by external sources such as the National Asthma Council Australia, or through pharmaceutical or medical equipment companies.

An estimate of the costs of spirometric testing, including response to inhalation of bronchodilator and according to whether the test is performed by a GP or a practice nurse, is provided in Table A-10.1. The authors noted that majority of the costs described are variable costs and are approximates only.

Table A-10.1 Estimated direct costs of performing spirometry in primary care in South Australia – Cranston (2006), updated to reflect current costs

Item	Item details – Cranston (2006)	Cost per test (2006) – PN	Cost per test (2006) – GP	Item details - 2015	Source	Cost per test (2015) – PN	Cost per test (2015) – GP
Salary cost: nurse/GP per hour[a]	$21.60/$125.80	$8.28	$48.22	$29.20/$170.10 per hour[b]	*ABS 6345.0 Wage Price Index, Australia*[b]	$11.19	$65.21
Spirometer	$3,250 (ndd EasyOne Stand Alone)[c]	$1.30	$1.30	$3,100 (EasyOne-line)[c]	*John et al (2015) NAC Spirometry Users and Buyers Guide*	$1.24	$1.24
Consumables (mouth piece)	Not applicable	$2.75	$2.75	$3.20 (Spirette - disposable per patient)	*John et al (2015) NAC Spirometry Users and Buyers Guide*	$3.20	$3.20
Bronchodilator (salbutamol) (4 actuations)	$16.39 each inhaler 200 meter doses per inhaler	$0.33	$0.33	$6.25 (Ventolin Salbutamol 100 mcg Inhalation CFC-free inhaler)	*eMedical Pharmacy Online*	$0.13	$0.13
Volumatic spacer (single use)	Not applicable	$10.69	$10.69	$10.69 per patient	*Chemist Warehouse*	$10.69	$10.69
Cleaning/preparation costs	$21.60 per hour, 5 minutes per test	$1.80	$1.80	$29.20 per hour, 5 minutes per test	*Practice nurse salary cost*	$2.43	$2.43
GP time to report test	125.80 per hour, 5 minutes per test	$10.48	$10.48	$170.10 per hour, 5 minutes per test	*GP salary cost*	$14.18	$14.18
Printer	$88.00 (Canon Pixma iP2200)[c]	$0.04	$0.04	$119.00 (Canon Pixma MX726 Colour Inkjet MFC)[c]	*Officeworks*	$0.05	$0.05
Printer consumables (ink cartridge, paper)	$76.75	$0.03	$0.03	$337.00 (paper: 5 x $4.99/500 sheets; ink: 2 x $115.00, 2 x $53.50)	*Officeworks*	$0.13	$0.13
Training (time)	6 hours	$0.05	$0.30	Spirometry Principles and Practice' extensive 2-day (14	*The Lung Health Promotion Centre at The Alfred, Melbourne*	$0.16	$0.95

Item	Item details – Cranston (2006)	Cost per test (2006) – PN	Cost per test (2006) – GP	Item details - 2015	Source	Cost per test (2015) – PN	Cost per test (2015) – GP
				hour) course endorsed by ANZSRS and TSANZ			
Training (course cost)	$650 per hour	$0.26	$0.26	$730	*The Lung Health Promotion Centre at The Alfred, Melbourne*	$0.29	$0.29
Total cost	Not applicable	**$36.01**	**$76.20**	Not applicable	Not applicable	**$43.69**	**$98.50**

Source: Cranston et al (2006), Table 6, p63; includes updated costs for 2015 calculated for MBS Review.
Abbreviations: ABS, Australian Bureau of Statistics; ANZSRS, Australia and New Zealand Society of Respiratory Science; GP, General Practitioner; NAC, National Asthma Council Australia; PN, Practice Nurse; TSANZ, Thoracic Society of Australia and New Zealand.
a Based on a total test time of 23 minutes
b Calculated using annual percentage change from June 2006 to June 2015 from ABS Wage Price Index [Table 5a. Total Hourly Rates of Pay Excluding Bonuses: Sector by Industry, Original (Financial Year Index Numbers for year ended June quarter]; Australia; Private; Total Hourly Rates of Pay Excluding Bonuses; Health care and social assistance.
c Based on an effective clinically useful life of the equipment of 5 years, and the performance of 500 spirometry tests per year.

Appendix 10.2 Evidence from the UK

The NCGC guideline on the diagnosis and monitoring of asthma in adults, children and young people (2016) contains an estimate of the unit cost of performing spirometry and bronchodilator reversibility in children. This unit cost for spirometry is presented in Table A-10.2 and the unit cost for bronchodilator reversibility is presented in Table A-10.3.

Table A-10.2 NCGC (2016): Cost of performing spirometry in children by practice nurse

Item	Quantity[c]	Unit cost	Total cost (quantity unit cost)	Source of unit cost
Time of GP practice nurse to conduct the test[a]	10-15 minutes	£0.73 per minute	£7.30 - £10.95	PSSRU[29]
Micro-lab spirometer[b]	1/1500	£1498.90 per spirometer	£1.00	NHS supply catalogue[30]
Bacterial filter, 3-litre syringe for calibration[b]	1/1500	£295.77	£0.20	NHS supply catalogue
Bacterial filter	1	£0.99 per filter	£0.99	NHS supply catalogue
Total	Not applicable	Not applicable	**£9.49 – £13.14** ***($19.59 – $27.13)***	Not applicable

Source: NCGC (2016), Table 25, p93; with currency converted to AUD using exchange rate at 10 February 2016.
Abbreviations: AUD, Australian dollar; GP, General Practitioner; NHS, National Health Service; PSSRU, Personal Social Services Research Unit.
a This range reflects the differing levels of experience of the nurse conducting the test but also the age of the child. The test is likely to be conducted quicker in older children.
b To calculate the marginal cost it was assumed that the equipment lasts for 5 years and is used on average 1500 times in this period.
c Based on GDG opinion.

[29] Curtis L. Unit costs of health and social care 2013. Canterbury: Personal Social Services Research Unit, University of Kent; 2013.
[30] Department of Health. NHS Supply Chain Catalogue. 2014. Accessed: 21 November 2014.

Table A-10.3 NCGC (2016): Cost of performing bronchodilator reversibility testing in children by practice nurse

Item	Quantity[c]	Unit cost	Total cost (quantity unit cost)	Source of unit cost
Time taken to administer bronchodilator and check for reversibility[a]	8-17 minutes	£0.73 per minute	£5.84 - £12.41	PSSRU
Volumatic spacer	1	£3.81 per spacer	£3.81	NHS supply catalogue
MDI	1	£5.50 per MDI	£5.50	NHS supply catalogue
Spirometry equipment to check for reversibility[b]	1	£2.20	£2.20	NHS supply catalogue
Total	Not applicable	Not applicable	**£17.35 – £23.92** ***($35.82 – $49.39)***	Not applicable

Source: NCGC (2016), Table 29, p102; with currency converted to AUD using exchange rate at 10 February 2016.
Abbreviations: AUD, Australian dollar; MDI, metered-dose inhaler; NHS, National Health Service; PSSRU, Personal Social Services Research Unit.
a This range reflects the differing levels of experience of the nurse conducting the test but also the age of the child. The test is likely to be conducted quicker in older children.
b When a bronchodilator reversibility test is being performed the first spirometry reading will have already been taken.
c Based on Guideline Development Group opinion.

Appendix 11 UK Quality and Outcomes Framework

The QOF is the UK's voluntary annual reward and incentive programme for GPs. The objective of the QOF is to improve the quality of care patients are given, by rewarding practices for the quality of care they provide to their patients. QOF includes performance indicators based on the best available research evidence. The QOF currently contains three domains: Clinical, Public Health; and Public Health – Additional Services. Each domain consists of a set of achievement measures, known as indicators, against which practices score points according to their level of achievement. The 2014-15 QOF measured achievement against 81 indicators; practices scored points on the basis of achievement against each indicator, up to a maximum of 559 points. The higher the score, the higher the financial reward for the practice. The final payment is adjusted to take account of surgery workload, local demographics and the prevalence of chronic conditions in the practice's local area.

COPD and asthma are included as two separate clinical domains within the respiratory group. The COPD domain includes six indicators (described in more detail in Table A-11.1), with spirometry related indicators (COPD002 and COPD004) allocated a total of 12 points. The asthma domain includes four indicators, with the AST002 indicator related to the diagnosis of asthma as per the BTS/SIGN guideline for the management of asthma (2014). The BTS/SIGN guideline recommends spirometry as the preferred initial test to assess the presence and severity of airflow obstruction in adults (Grade of recommendation, D). The QOF asthma and COPD indicators are classified as 'process' indicators; there are no QOF indicators related to health outcome measures, such as reduction in exacerbation rate.

Table A-11.1 Current QOF COPD indicators targets for COPD and asthma, 2014-15

Indicator	Code	Details	Points	Achievement thresholds
Records	COPD001	The contractor establishes and maintains a register of patients with COPD.	3	Not applicable
Initial diagnosis	COPD002	The percentage of patients with COPD (diagnosed on or after 1 April 2011) in whom the diagnosis has been confirmed by **post bronchodilator spirometry** between 3 months before and 12 months after entering on to the register.	5	45-80%
Ongoing management	COPD003	The percentage of patients with COPD who have had a review, undertaken by a healthcare professional, including an assessment of breathlessness using the Medical Research Council dyspnoea scale in the preceding 12 months.	9	50-90%
	COPD004	The percentage of patients with COPD with a record of FEV_1 in the preceding 12 months.	7	40-75%
	COPD005	The percentage of patients with COPD and Medical Research Council	5	40-90%

Indicator	Code	Details	Points	Achievement thresholds
		dyspnoea grade ≥3 at any time in the preceding 12 months, with a record of oxygen saturation value within the preceding 12 months.		
	COPD007	The percentage of patients with COPD who have had influenza immunisation in the preceding 1 August to 31 March.	6	57-97%
		Total	35	Not applicable

Abbreviations: AST, asthma; COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; na, not applicable; RCP, Royal College of Physicians.
FEV_1 is a common parameter measured in spirometry and is a useful measure of how quickly full lungs can be emptied.
a Further information about the diagnosis of asthma is provided in the BTS/SIGN asthma guideline, which recommends spirometry as the preferred initial test to assess the presence and severity of airflow obstruction in adults (Grade of recommendaton, D

Table A-11.1 continued Current QOF COPD indicators targets for COPD and asthma, 2014-15

Indicator	Code	Details	Points	Achievement thresholds
Records	AST001	The contractor establishes and maintains a register of patients with asthma, excluding patients with asthma who have been prescribed no asthma-related drugs in the preceding 12 months.	2	Not applicable
Initial diagnosis	AST002	The percentage of patients aged 8 or over with asthma (diagnosed[a] on or after 1 April 2006), on the register, with measures of variability or reversibility recorded between 3 months before or anytime after diagnosis.	15	45-80%
Ongoing management	AST003	The percentage of patients with asthma, on the register, who have had an asthma review in the preceding 15 months that includes an assessment of asthma control using the 3 RCP questions.	20	45-70%
	AST004	The percentage of patients with asthma aged 14 or over and who have not attained the age of 20, on the register, in whom there is a record of smoking status in the preceding 15 months.	6	50-80%
		Total	43	Not applicable

Source: NICE Indicator Menu for the QOF
Abbreviations: AST, asthma; COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; na, not applicable; RCP, Royal College of Physicians.
FEV_1 is a common parameter measured in spirometry and is a useful measure of how quickly full lungs can be emptied.
a Further information about the diagnosis of asthma is provided in the BTS/SIGN asthma guideline, which recommends spirometry as the preferred initial test to assess the presence and severity of airflow obstruction in adults (Grade of recommendation, D).

The annual QOF data report published for the period between April 2014 and March 2015 found that 98.7% of GP practices in the UK participated in the QOF.[31] The percentage of patients receiving the specified level of care for COPD was 96.1%.

[31] Quality and Outcomes Framework – Prevalence, Achievements and Exceptions Report, England 2014-15. Primary Care Domain, Health and Social Care Information Centre. Published 29 October 2015.

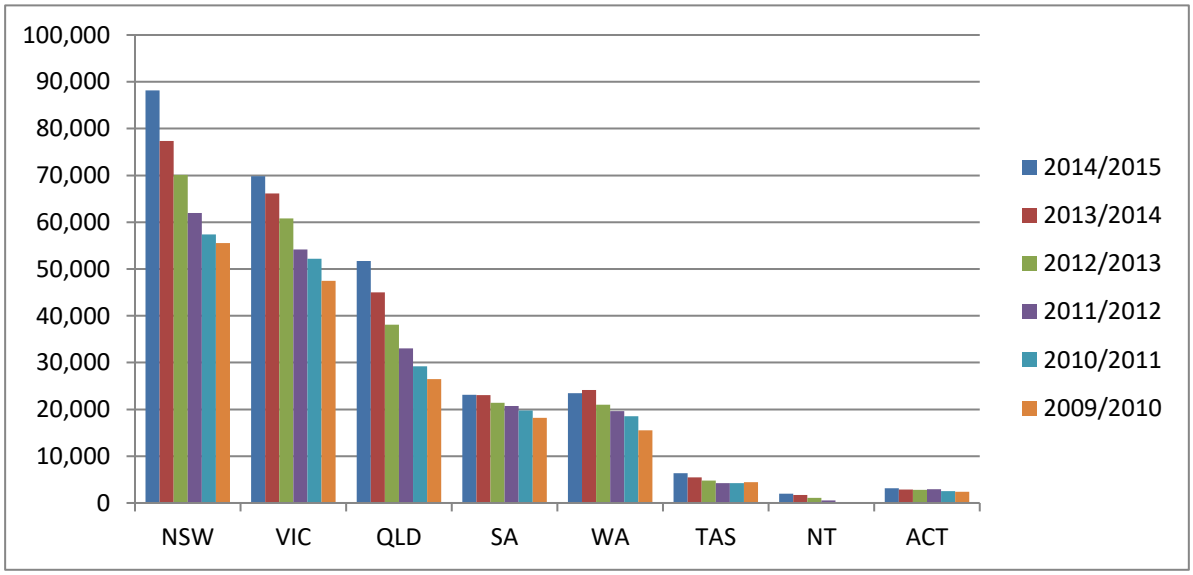
Appendix D Spirometry data

Data on item 11503: Laboratory Respiratory Function Tests

Table D1: Number of services by age group – item 11503, 2014-15

Age Group	Number of Services	% provided to the age group
0-4	3,422	1%
5-9	2,053	1%
10-14	2,934	1%
15-19	4,430	2%
20-24	4,503	2%
25-29	5,630	2%
30-34	7,437	3%
35-39	9,500	4%
40-44	13,074	5%
45-49	15,609	6%
50-54	20,678	8%
55-59	25,129	9%
60-64	30,307	11%
65-69	36,444	14%
70-74	33,136	12%
75-79	27,426	10%
80-84	17,595	7%
>=85	8,381	3%

Unpublished data (Department of Health)
Note: Total number of services is 267,688.



Public data (Department of Human Services website)

Figure D1: Number of services by state, 2009-10 to 2014-15, item 11503

Table D2: Top 10 same day item combinations - item 11503 with other MBS items, 2014-15

Item combination	Number of Episodes	Number of services	% of total episodes	Description of episodes
11503	395,485	395,532	75%	Various respiratory function tests only
11503, 00116	32,416	64,927	6%	Various respiratory function tests and subsequent consultant physician consultation
12203, 11503	26,479	52,962	5%	Various respiratory function tests and overnight sleep study over 18 years
73802, 11503	21,067	42,136	4%	Various respiratory function tests and simple pathology test - Leucocyte count, erythrocyte sedimentation rate, examination of blood film (including differential leucocyte count), haemoglobin, haematocrit or erythrocyte count - 1 test
11503, 00110	17,656	35,316	3%	Various respiratory function tests and initial consultant physician consultation
11503, 00132	9,310	18,624	2%	Various respiratory function tests and consultant physician treatment and management plan
13882, 11503	4,558	9,118	1%	Various respiratory function tests and ventilatory support in a ICU
11503, 00133	4,536	9,072	1%	Various respiratory function tests & consultant physician review of treatment and management plan
73802, 11503, 00116	3,857	11,573	1%	Various respiratory function tests, simple pathology test - Leucocyte count, erythrocyte sedimentation rate, examination of blood film (including differential leucocyte count), haemoglobin, haematocrit or erythrocyte count - 1 test and subsequent consultant physician consultation
13876, 13873, 11503	2,837	11,102	1%	Various respiratory function tests, Central venous pressure, pulmonary arterial pressure, systemic arterial pressure or cardiac intracavity pressure, continuous monitoring by indwelling catheter in an ICU and management of a patient in a ICU

Unpublished data (Department of Health)

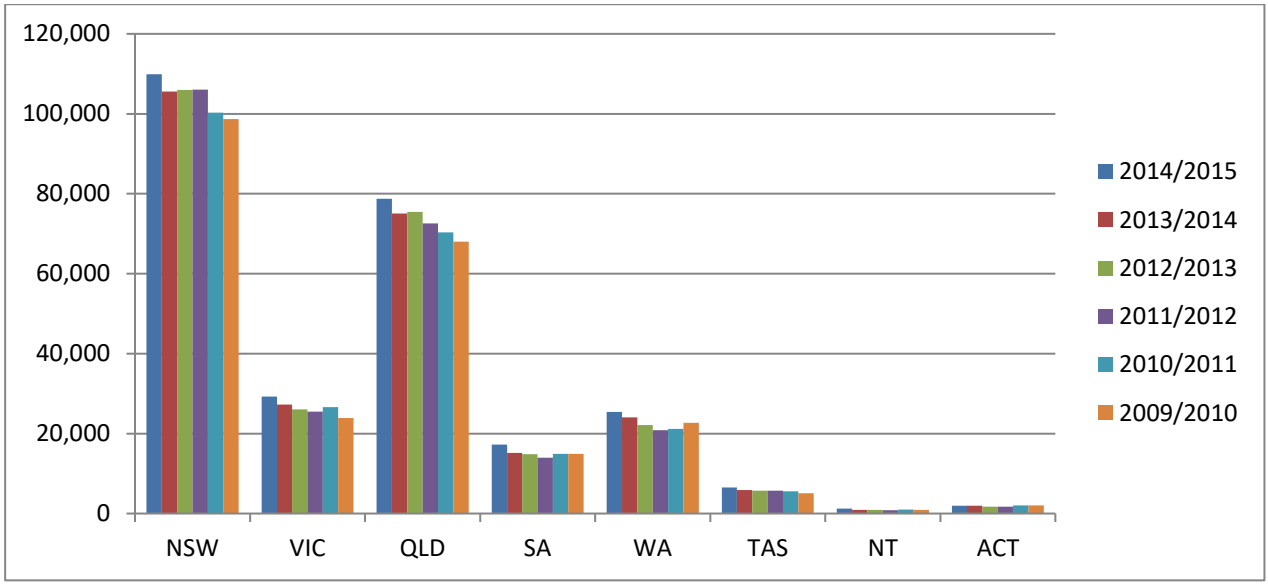
MBS Data on item 11506

Table D3: Number of services by age group – 11506, 2014-15

Age Group	Number of Services	% provided to the age group
0-4	461	0%
5-9	7,956	3%
10-14	11,506	4%
15-19	10,388	4%
20-24	9,705	4%
25-29	9,316	3%
30-34	10,348	4%

Age Group	Number of Services	% provided to the age group
35-39	11,293	4%
40-44	14,289	5%
45-49	18,001	7%
50-54	19,607	7%
55-59	23,016	9%
60-64	26,536	10%
65-69	30,440	11%
70-74	26,547	10%
75-79	21,400	8%
80-84	12,916	5%
>=85	6,533	2%

Unpublished data (Department of Health)
Note: Total number of services is 270,258.



Public data (Department of Human Services website)

Figure D2: Number of services by state, 2009-10 to 2014-15, item 11503

Table D4: Top 10 same day item combinations - item 11506 with other MBS items, 2014-15

Item combination	Number of Episodes	Number of services	% of total episodes	Description of episodes
11506	292,504	292,941	54%	Measurement of respiratory function after bronchodilator only
11506, 00023	85,177	170,865	16%	Measurement of respiratory function after bronchodilator & Level B GP consultation
11506, 00036	46,525	93,217	9%	Measurement of respiratory function after bronchodilator & Level C GP consultation
11506, 00116	21,222	42,455	4%	Measurement of respiratory function after bronchodilator & subsequent consultant physician consultation

Item combination	Number of Episodes	Number of services	% of total episodes	Description of episodes
11506, 00110	10,697	21,395	2%	Measurement of respiratory function after bronchodilator & initial consultant physician consultation
11700, 11506	10,111	20,251	2%	Measurement of respiratory function after bronchodilator & 12 lead ECG
11700, 11506, 00036	9,803	29,436	2%	Measurement of respiratory function after bronchodilator, 12 lead ECG & Level C GP consultation
11506, 00721	9,226	18,476	2%	Measurement of respiratory function after bronchodilator & Chronic Disease Management plan
11700, 11506, 00023	8,194	24,655	2%	Measurement of respiratory function after bronchodilator, 12 lead ECG & Level B GP consultation
11506, 00732	7,800	19,573	1%	Measurement of respiratory function after bronchodilator & review Chronic Disease Management plan

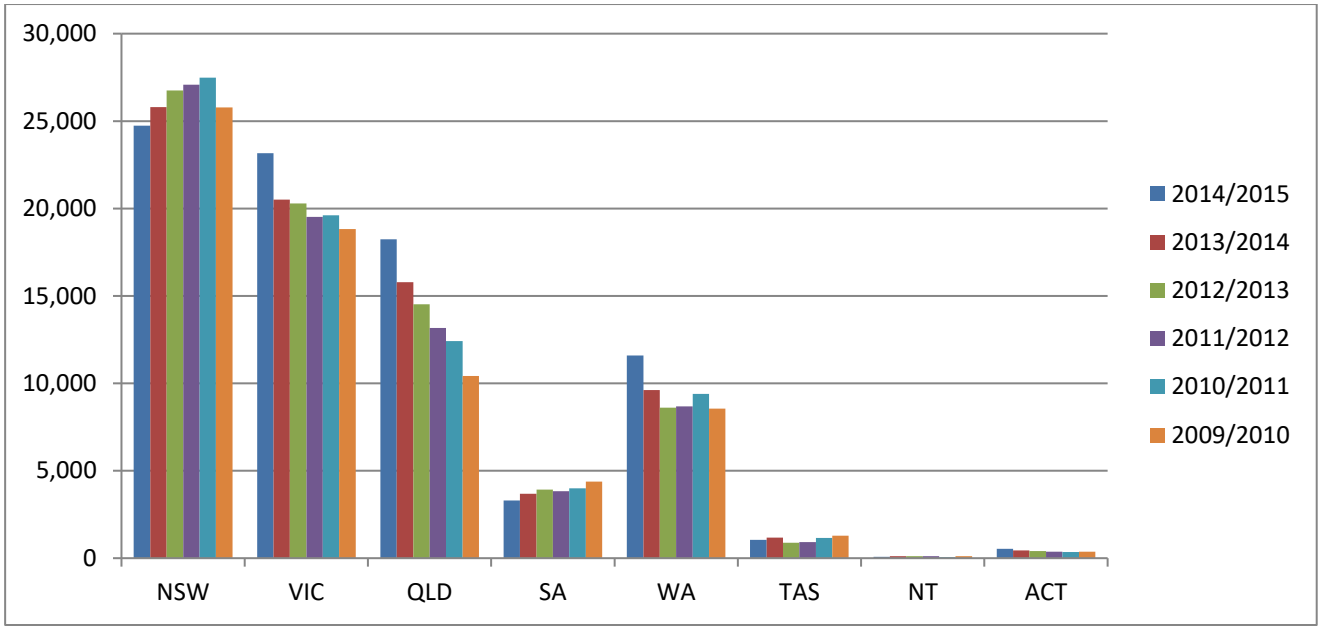
Unpublished data (Department of Health)

MBS Data on Item 11512 – Spirometry laboratory based

Table D5: Number of services by age group – 11512, 2014-15

Age Group	Number of Services	% provided to the age group
0-4	277	0%
5-9	5,263	6%
10-14	5,393	7%
15-19	3,118	4%
20-24	1,739	2%
25-29	1,864	2%
30-34	2,208	3%
35-39	2,456	3%
40-44	3,232	4%
45-49	3,816	5%
50-54	4,888	6%
55-59	6,397	8%
60-64	8,141	10%
65-69	9,617	12%
70-74	9,129	11%
75-79	7,393	9%
80-84	4,984	6%
>=85	2,790	3%

Unpublished data (Department of Health)
Note: Total number of services is 82,705.



Public data (Department of Human Services website)

Figure D3: Number of services by state, 2009-10 to 2014-15, item 11512

Table D6: Top 10 same day item combinations - item 11512 with other MBS items, 2014-15

Item combination	Number of Episodes	Number of services	% of total episodes	Description of episodes
11512	36466	36480	44%	Continuous measurement of flow and volume only
11512, 00116	25563	51201	31%	Continuous measurement of flow and volume & subsequent consultant physician consultation
11512, 00110	8440	16880	10%	Continuous measurement of flow and volume & initial consultant physician consultation
11512, 00132	4432	8864	5%	Continuous measurement of flow and volume & consultant physician treatment and management plan
11512, 00133	2085	4170	3%	Continuous measurement of flow and volume & review of consultant physician treatment and management plan
11713, 11610, 11512, 00116	1495	5981	2%	Continuous measurement of flow and volume & measurement of ankle brachial indices and arterial waveform analysis, subsequent consultant physician consultation & signal averaged ECG recording.
11512, 11503	924	1851	1%	Continuous measurement of flow and volume & Various respiratory function tests
12000, 11512	306	612	0%	Continuous measurement of flow and volume & Skin sensitivity testing (less than 20 allergens)
11713, 11610, 11512	281	843	0%	Continuous measurement of flow and volume & measurement of ankle brachial indices and arterial waveform analysis & signal averaged ECG recording.

Item combination	Number of Episodes	Number of services	% of total episodes	Description of episodes
12003, 11512	278	556	0%	Continuous measurement of flow and volume & Skin sensitivity testing (more than 20 allergens)

Unpublished data (Department of Health)

Appendix E Summary for consumers

Thoracic medicine item recommendations

The following tables describe the medical service, recommendation of the Clinical Experts and why the recommendation has been made.

Table E1: MBS items for respiratory function tests

Item	What it does	Committee Recommendation	What would be different	Why
11503 – Laboratory based Complex Lung Function Tests	A number of common, complex tests which are performed in a laboratory and which are used to diagnose and manage a range of lung diseases.	The list of tests has been updated to describe which tests can be undertaken under the item and to include more modern tests.	This change: • introduces a new test for patients who need subsidised medicines or portable oxygen; • removes some tests that are not used often because more modern tests are available; and • provides a clear description of each test in the item description. The item will include all the tests that can be performed under this item. The current item suggests which tests may be performed but doctors may choose to perform others.	These changes will improve the quality of the service patients receive as they ensure access to modern tests, performed in a suitable setting by a specially trained provider so that an appropriate diagnosis can be made.
Δ **11500** – Office based spirometry Δ **11506** – Office based spirometry Δ 11509 – Laboratory based spirometry Δ **11512** – Laboratory	Δ Spirometry measures the amount and speed of air that is breathed in and out before and after using an inhaler such as Ventolin. For diagnosis and monitoring of asthma and COPD. Δ At present, there are four items – two for testing in a doctor's surgery (11500; 11506) and two	Δ Remove items 11500 and 11509. Δ Increase the MBS Fee for item 11506. Δ Keep item 11512.	Δ For item 11500, more modern tests are available under MBS items 11506, 11512 and 11503. Δ Item 11509 services will be provided under existing MBS item 11512. Δ For item 11506 an MBS fee of approx $40-$45. The current fee is $20.55	These changes will improve the quality of the service as they: • reflect recommendations of the Australian Asthma Handbook (2015) and Lung Foundation Australia (2015) COPD-X guidelines; and • support improved diagnosis of asthma in general practice. At present, the test is underused and some people may not be properly diagnosed.

Item	What it does	Committee Recommendation	What would be different	Why
based spirometry	for testing in a laboratory (11509; 11512).			
New item – Spirometry pre OR post bronchodilator	Similar to the test done in a doctor's surgery (item 11506) but done either before OR after using an inhaler such as Ventolin. For diagnosing and monitoring asthma and other lung diseases.	Create a new MBS item.	Δ This service will be billed under its own MBS item. Δ The Committee has suggested a MBS fee of $20.55.	This test is done currently but there is no MBS payment for it. The new item and rebate will improve the assessment and monitoring of patients with asthma and other lung diseases.
New item – Laboratory based spirometry with Fraction of Exhaled Nitric Oxide (FeNO)	FeNO is a test to measure airway inflammation which may help in finding the best treatment.	Create a new MBS item for FeNO with spirometry.	This test is used for patients with more complex lung disease who are under the care of a specialist. It is laboratory based. FeNO is not useful if it is performed alone.	This will provided a separate MBS fee for FeNO with spirometry for patients who have airway inflammation as a cause of their symptoms.
New item Cardiopulmonary Exercise Testing	A relatively non-invasive way to assess how the heart and lungs work at the same time and during exercise.	Introduce a new item with a higher MBS fee than for MBS 11503.	Δ This test is currently billed under two existing items. It would now be billed under one item and be available for patients: • with breathlessness but standard tests do not result in a diagnosis; or • who are having major surgery and are at high risk of a complication due to their lung or heart disease. Δ An MBS fee that is equivalent to that for item 11503 plus item 1172 is recommended for the new item as these are the items doctors are currently using.	Δ At present, when doctors perform this test they bill two items (11503 and 1172). The new item, with fee equivalent to item 11503 plus item 1172, will mean that doctors will only need to bill one item. Δ The test will target patients with specific symptoms who might benefit the most from the test

Table E2: MBS items for sleep studies

Item	What it does	Committee Recommendation	What would be different	Why
Sleep studies				
12203 Diagnostic laboratory based adult sleep study 12250 Diagnostic home based adult sleep study	Δ During a sleep study, sensors attached to the scalp, face, chest, fingers and legs monitor how the body functions during sleep. This information is used to decide whether a patient has a sleep disorder including sleep apnoea. Δ The study may be done overnight in a sleep studies centre and with a trained sleep technician present OR it may be performed at home.	Δ Improve access to appropriate testing. GPs will be able to refer people with symptoms of sleep apnoea for a sleep study. Δ The person will not have to consult with a specialist before the test. Δ Enable testing for an increased range of sleep disorders following assessment by a specialist Δ Improve the quality of sleep studies by ensuring that: • patients have the right test for their symptoms • the patient will be personally assessed by a sleep or respiratory doctor if they are diagnosed with a sleep disorder but need further testing to decide on treatment • the performance of the sleep studies meets appropriate standards.	These changes mean that: • patients will receive the most appropriate sleep studies for their symptoms • patients do not have unnecessary testing • the testing is high quality patients have opportunity to discuss the results of tests and treatment options with a doctor	While the introduction of sleep studies to the MBS has improved access to testing, there is concern that: • this may have led to a decrease in the quality of testing • patients are sold expensive sleep devices when less costly, more appropriate treatment options might relieve their symptoms. • many patients who are having supervised testing at a sleep centre or hospital could have the testing done at home. If more patients have tests at home, waiting lists for patient who need a more complex supervised test in a sleep centre or hospital should be reduced The changes reflect the current Australasian Sleep Association guidelines.

Item	What it does	Committee Recommendation	What would be different	Why
New item Laboratory based adult treatment initiation study	Δ A positive airway pressure (PAP) machine delivers air to the nose via mask that keeps the airway open to ensure unobstructed breathing. Δ A treatment initiation test occurs in a sleep centre following diagnosis of a sleep disorder and the recommending of PAP therapy.	A new MBS item specifically for PAP initiation which may be claimed once in a 12 month period.	At present, there are no items for treatment initiation. However, some initiation studies are billed under MBS 12203. These services will transfer to the new item.	This test helps doctors to work out the correct air pressure in PAP treatment that is needed to ensure the patient's airway stays open.
New item – Laboratory based adult treatment effectiveness study	This test is used when a patient has been diagnosed with a sleep disorder and received treatment but symptoms recur or there is a significant change in weight or other medical conditions.	A new MBS item specifically for treatment effectiveness which may be claimed once in a 12 month period.	At present, there are no items for this service. However, some effectiveness studies may be being billed under MBS 12203. These services are expected to transfer to the new item.	A change in symptoms, weight or other medical conditions may affect how well the PAP treatment works for a patient. An effectiveness study is used to check whether the air pressure needs to be changed.
New item – Home based adult automatic positive airway pressure (APAP) titration study	Δ Titration is a process used with PAP treatment where the air pressure is adjusted until the right pressure to keep the airway open is identified. Δ This item will allow patients who are diagnosed with uncomplicated sleep apnoea to undergo titration at home.	The Committee noted that this proposal should be placed on hold for 2-3 years until the impact of the changes to items 12203 and 12250 is known.	Not applicable at this stage.	Not applicable at this stage.
New item – Laboratory	This study involves an assessment of excessive daytime	The Committee recommend that vigilance testing be evaluated by the Medical	Not applicable at this stage.	Not applicable at this stage.

Item	What it does	Committee Recommendation	What would be different	Why
based adult vigilance testing	sleepiness or the ability to stay alert using several tests.	Services Advisory Committee as this service is not currently funded.		

Appendix F High level review of Cardiopulmonary Exercise Testing (CPET)

Cardiopulmonary Exercise Testing

Questions

1. Is CPET clinically effective (diagnostic accuracy) compared to the comparator?
2. Is CPET comparatively safe when measured against the comparator?
3. Are the clinical indications for CPET in paediatric patients different to those for adults?

Introduction

Cardiopulmonary exercise testing (CPET) provides a relatively noninvasive global assessment of functional capacity involving multiple organ systems, allowing the evaluation of both submaximal and peak exercise responses. [1] It provides data as to respiratory gas exchange, including oxygen uptake (VO_2), carbon dioxide output (VCO_2), tidal volume (VT) and minute ventilation (VE) as well as other variables such as ECG, BP and oxygen saturation.[2] Placing stress on respiratory mechanisms by way of exercise, may reveal abnormal cardiac or respiratory pathology that is not apparent at rest. In addition, pulmonary and cardiac function tests at rest cannot accurately determine exercise capacity or identify mechanisms underlying exercise intolerance in patients with cardiac or pulmonary disease. [3] CPET also has the potential to provide objective measures of task-related energy expenditure and associated cardiopulmonary responses, although data relating to this purpose is lacking.[3] CPET with metabolic monitoring is considered the gold standard modality for assessment of exercise capacity.[4, 5]

In basic terms, interpretation of CPET involves a comparison between the data from individual patients and that of healthy and disease populations.[6] VO_{2max} is considered the best indicator of aerobic activity, and the gold standard for cardiorespiratory fitness.[1] Generally the best evidence of VO_{2max} is the attainment of a clear plateau in VO_2. However, in many clinical scenarios, a clear plateau may not be reached prior to symptom limitation of exercise, and VO_{2peak} is used as an estimate of VO_{2max}.[1] For practical purposes, VO_{2peak} and VO_{2max} are used interchangeably. The VE/VCO_2 slope is an indication of ventilation efficiency and has been stated to be an independent prognostic indicator of poor outcome in particular patient groups including heart failure. [1]

CPET is generally performed by way of treadmill or cycle ergometer. In the US, treadmill is preferred as subjects may terminate cycle exercise due to quadriceps fatigue (at a lower VO_2 than treadmill peak), or may have difficulty maintaining desired pedal speed. Cycle ergometry, though tending to produce lower peak VO_2 (by around 10%), may be preferable in subjects with gait or balance instability, severe obesity or orthopaedic limitations, or when simultaneous cardiac imaging is planned.[3] Cycle may also be preferred, as it tends to produce less movement artifact, facilitates the taking of arterial blood samples, and provides a smooth increase in load. [2]

Comparative tests include functional exercise assessments such as the 6-minute walk test (6MWT), the incremental shuttle walk test (ISWT), and exercise stress testing.

Submaximal exercise tests tend to be used more commonly due to reduced complexity in administration and supervision, reduced cost and perceived improvement in safety profile. There are numerous studies comparing CPET to submaximal tests, however they vary in terms of population group and parameters under comparison. It is not possible, in a brief review, to comprehensively cover all of the comparative evidence, however a more in depth review may be warranted if a more detailed analysis of the application of CPET in specific disease populations is required.

Table 1 below summarises some of the indications for use of CPET.

Table 1: Indications for CPET

Clinical purpose	**Indication**
Diagnostic	Assists in the differentiation of cardiac versus pulmonary causes of exercise induced dyspnoea or impaired exercise capacity, including diagnoses of exercise-induced arrhythmias, chronotropic incompetence, PFO with exercise induced R-L shunt, myocardial ischaemia, early pulmonary vascular disease, diastolic HF, chronic hyperventilation and psychogenic dyspnoea
Diagnostic	CPET can detect exercise-induced myocardial ischaemia more accurately compared with standard ECG stress test.[7]
Diagnostic	CPET can detect L to R shunting via PFO in patients with PPH.[8]
Evaluative	CPET evaluates exercise capacity and response to therapy, for example in patients with chronic heart failure who are in consideration for transplantation.
Evaluative	CPET is also used in assessing suitability for surgery, particularly pulmonary resection as exercise capacity is predictive of related perioperative morbidity and mortality. [3]
Evaluative	Prescription of exercise for rehabilitation
Evaluative	Assessment of impairment and disability
Optimisation of therapy	Eg peak VO_2 can be used to optimise settings on rate-responsive and biventricular pacemakers
Prognostic	eg chronic lung disease, pulmonary hypertension, congenital heart disease, exercise-induced myocardial ischaemia

Diagnostic Accuracy

CPET is commonly used as a diagnostic tool, particularly in the assessment of exertional dyspnoea. Resting investigations such as pulmonary function tests and echocardiograms may not provide sufficient information to form a diagnosis. This may occur where exertional symptoms correlate poorly with resting measurements.[9] CPET enables a more accurate estimate of functional capacity, and provides more useful data that encompasses multiple organ systems.[9] Derangements in physiologic parameters during exertion can explain exercise limitation and assist in diagnosis by forming patterns in ventilatory responses that are consistent with particular disease processes. Advantages of CPET include the ability to obtain direct, objective measures of ventilatory capacity that are reproducible.[10] It enables quantification of work capacity, which in turn improves its diagnostic accuracy.[1] It is also less susceptible to factors which may contribute to an inaccurate assessment of capacity, such as patient effort.

Utility of CPET

The utility of CPET has been demonstrated in a number of conditions, a few of which are summarized below.

Heart Failure

Reduction in exercise capacity, which is a cardinal feature of heart failure, may be objectively assessed by CPET. Numerous studies have shown peak VO_2 to predict prognosis in patients with heart failure, with strong correlations between maximal cardiac output, peak VO_2 and mortality risk.[3, 6] Exercise testing reveals inefficiencies in gas exchange, reflected in a steep VE/VCO_2 slope during incremental exercise, decreased partial pressure of end tidal CO_2 ($PETCO_2$) and elevation of the ratio of ventilatory dead space to tidal volume. [6] Strong correlations have also been found between reduction in peak VO_2 and reduction in muscle mass and inspiratory muscle weakness (seen in heart failure).[11, 12]

Congenital Heart Defects, Valve Disease and Hypertrophic Cardiomyopathy

Whilst the role of routine CPET in these patients is not established, there is emerging evidence as to its potential clinical value in these populations in terms of assessment of disease severity, response to intervention and the provision of prognostic information. [6] In a study comprising 475 patients with congenital heart disease who underwent CPET, Frederiksen et al[13] reported significantly reduced maximal oxygen consumption compared with healthy subjects, even in those undergoing surgical treatment. The authors considered the routine use of CPET in follow up of these patients to be vital in revealing significant changes in oxygen consumption and to enable efficient initiation of therapy. [13]

Left ventricular dysfunction secondary to myocardial ischaemia

Although not routinely used for this purpose, CPET may indicate left ventricular dysfunction secondary to myocardial ischaemia through patterns of VO2 response to exercise. [14]

Unexplained dyspnoea

A common use of CPET is in the assessment of patients with unexplained dyspnoea. Interpretative algorithms are used to identify patterns of findings typical of conditions that may cause dyspnoea on exercise testing, by comparing results with findings from healthy populations or those previously diagnosed with specific conditions (exercise-induced arrhythmias, chronotropic incompetence, myocardial ischaemia and hyperventilation syndromes etc). [1, 3] For example, in unexplained dyspnea, a VE/VCO2 >/= 60 with a PETCO2 </= 20 mmHg at ventilation threshold is highly suggestive of pulmonary hypertension. [6] Such analyses depend upon the appropriateness of reference values chosen for comparison and by the specificity and sensitivity of abnormal findings for specific disease states.

COPD

Reduction in exercise tolerance is a common complaint in COPD patients, with significant impact on quality of life. A significant contributor is said to be dynamic hyperinflation during exercise, which is often measured by reference to the rate of change of inspired capacity.[1, 15] Exercise induced hypoxaemia can also contribute to exercise limitations in COPD, and may be measured by arterial gas analysis or non-invasively by pulse oximetry.[1] Although the latter is less accurate, it is generally accepted that a drop in Spo2 by >5% is abnormal, with sustained <88% a justification for oxygen therapy. The 6MWT is frequently used to assess the functional status of COPD patients, however it is not as useful in assessment of treatment outcomes due to the lack of fixed exercise stimulus.[15]

Skeletal muscle fibre and mitochondrial myopathy

CPET may be modified to increase diagnostic resolution of skeletal muscle abnormalities, particularly mitochondrial myopathy.[3]

Interstitial Lung Disease (ILD)

ILD results in parenchymal damage and fibrosis resulting in an impairment of gas exchange which is identified by calculating the ratio of physiological dead space to tidal volume from arterial blood gas and expired gas analyses.[1] Reduced peak oxygen uptake and exercise induced hypoxaemia during CPET are sensitive markers of mortality in patients with ILD, though is not however currently recommended in routine monitoring. [16] Instead the 6MWT tends to be utilized in this population group for staging of disease and evaluation of treatment responses. [16] A study by Holland et al found the 6MWT to elicit the same or higher VO2peak than CPET in the subpopulation of severe ILD.[16]

Other information gained from CPET

In addition to diagnostic utility, there is evidence that the VE/VCO_2 slope determined from CPET is a good predictor of mortality, particularly in heart failure, structural heart disease and pulmonary vascular disease.[6] It has particular use in pre-transplantation assessment and risk stratification of heart failure patients and potential predictive value for the risk of adverse events. [1] Pollentier et al found a moderate correlation between 6MWT and VO_{2peak} in heart failure patients referred for transplantation, but that the former was inferior in terms of predicting long term survival.[17]

CPET also has uses in many other areas, such as rehabilitation and occupational health medicine, although these are beyond the scope of this review.

Comparators with CPET

CPET is often used as the gold standard when assessing the ability of other tests such as the 6MWT to predict functional capacity. Below is a brief overview of two major comparators.

6 minute walk test (6MWT)

The 6MWT involves subjects walking as far as possible along a 30 m corridor, and ascertaining the maximum distance covered in 6 minutes. [16] It is a considered a practical and inexpensive test of exercise tolerance and is often used to stage disease and evaluate treatment, particularly where CPET is unavailable or impractical. As a self-paced test, the 6MWT can be heavily influenced by patient or tester motivation, and, in contrast to CPET, is said to be unable to estimate how close a patient is to their maximal capacity.[3] It is generally considered a submaximal test, although some studies do suggest that in particular cases (eg severe interstitial lung disease), the peak VO_2 elicited in the 6MWT may be comparable that of CPET.[8] There is however, a need for further, higher powered studies to confirm this assertion.

Studies have demonstrated consistent correlations between the metabolic parameters of 6MWT and CPET, with varying strengths of association. For example, Sperandio et al[18] in 2015 found that the VO_{2peak} in the 6MWT corresponded to 78+/-13% of that in CPET, whilst maximum heart rate corresponded to 80 +/-23% of that in CPET. A year earlier, in a study comprising patients with interstitial lung disease, Holland et al[16] found 6MWT VO_{2peak} to average 94% of CPET VO_{2peak}, with much lower correlation between other parameters. There is evidence that the relationship between 6MWT and CPET variables is much weaker in specific populations, such as patients with cerebral palsy.[19] It appears that whilst the 6MWT is able to provide some information relating to functional ability, CPET is able to provide specific and detailed measurements of maximal exercise performance.[20] Some studies have employed the use of predictive equations to enable an estimate of peak VO_2 from 6MWT results. [18] A systematic review by Kirkham et al in 2015 however, found poor to moderate agreement between measured peak VO_2 and peak work rate and estimates from equations using 6MWT parameters. [21] It must be noted that this review was restricted to COPD patients, indicating a need for further evidence as to the utility of predictive equations in other population groups.

As mentioned, although studies consistently report a correlation between the two tests, the degree of association found is variable both between and within specific disease groups. Though plentiful, studies have tended to contain small numbers of subjects and other potential methodological weaknesses that make a quantification of association difficult. It is the overwhelming view that the 6MWT, whilst providing valuable information, is still a submaximal test and is not a blanket substitute for CPET. The American Thoracic Society's view is that the 6MWT is unable to determine peak oxygen uptake, diagnose causes of dyspnoea on exertion, or evaluate mechanisms of exercise limitation, and information derived from it should be considered as complementary to, and not a replacement for, CPET.[22]

Incremental Shuttle Walk test (ISWT)

This test records distance completed, where patients are required to walk a series of 10 m 'shuttles' with incrementally decreasing times in which to complete each shuttle. The test continues until the patient is unable to complete the shuttle in the required time. Measurements of resting and recovery heart rate, oxygen saturations and arterial pressures are recorded.[4] The American Thoracic Society considers the shuttle walk test to have a better correlation with peak oxygen uptake than the 6MWT, although notes the comparative lack of validation, reduced usage and greater potential for cardiovascular problems.[22]

One study by De Boer et al found a strong correlation between MSWT distance and measured peak VO2 and between maximum heart rate during MSWT and CPET in patients with sarcoidosis.[23] A much earlier study by Singh et al also found a strong correlation between distance walked and peak VO2, though a poor correlation between shuttle performance and FEV1. [24] Pulz et al found ISWT to be similar in terms of reproducibility and accuracy in predicting peak VO2 compared with the 6MWT. [25] It also found peak VO2, and not distance walked, to be a good predictor of survival, and concludes that although both ISWT and 6MWT are useful in obtaining a safe estimate of functional capacity, CPET remains the preferable procedure to predict survival in CHF patients. [25]

Safety

CPET is generally considered a safe procedure, with risk of mortality between 2 and 5 per 100,000 tests (US figures).[1] Serious complications (including MI) have been reported as occurring in between < 1 to 5 per 10,000 tests, although incidence tends to vary dependent upon the study population.[1] A retrospective study by Skalski et al reviewed 4250 patients who underwent CPET, including 1289 with congestive heart failure, 598 with hypertrophic cardiomyopathy, 194 with pulmonary hypertension and 212 with aortic stenosis. [26] 24% of subjects had a peak VO_2 consistent with severe functional impairment. There were a total of 8 adverse events, 6 of which were sustained ventricular tachycardia with spontaneous resolution. 1 patient with a history of CAD developed severe and persistent dyspnea, and 1 patient who was 6 years post cardiac transplant, suffered a myocardial infarction. There were no fatalities. [26] This and other studies have reported on the safety of CPET even in high-risk populations. [27-29] There are also numerous studies reporting the safety of CPET in specific conditions such as multiple sclerosis, pulmonary hypertension and chronic heart failure.[28, 30, 31]

To maintain its safety profile, CPET requires the use of highly trained, qualified personnel, with appropriate preparation of both equipment and patients.[1] There are also numerous relative and absolute contraindications to be taken into consideration when determining suitability of subjects for testing as well as specified criteria for termination of exercise testing (taken from ACCP Statement[1])

Absolute contraindications for cardiopulmonary exercise testing (taken from ACCP Statement[1])

- Acute myocardial infarction (3-5 days)
- Unstable angina
- Uncontrolled arrhythmias causing symptoms or haemodynamic compromise
- Syncope
- Active endocarditis
- Acute myocarditis or pericarditis
- Symptomatic severe aortic stenosis

- Uncontrolled heart failure
- Acute pulmonary embolus or pulmonary infarction
- Thrombosis of lower extremities
- Suspected dissecting aneurysm
- Uncontrolled asthma
- Pulmonary oedema
- Room air desaturation at rest <= 85%
- Respiratory failure
- Acute non cardiopulmonary disorder that may affect exercise performance or be aggravated by exercise (eg infection, renal failure, thyrotoxicosis)

Relative contraindications for cardiopulmonary exercise testing (taken from ACCP Statement[1])

- Left main coronary stenosis or equivalent
- Moderate stenotic valvular heart disease
- Severe untreated hypertension at rest (>200 mmHg sys, >120 mmHg diast)
- Tachyarrhythmias or bradyarrhythmias
- High degree atrioventricular block
- Hypertrophic cardiomyopathy
- Significant pulmonary hypertension
- Advanced or complicated pregnancy
- Electrolyte abnormalities
- Orthopaedic impairment that compromises exercise performance

Indications for exercise termination (taken from ACCP Statement[1])

- Chest pain suggestive of ischaemia
- Ischaemic ECG changes
- Complex ectopy
- Second or third degree heart block
- Fall in systolic pressure > 20 mmHg from the highest value during the test
- Hypertension (>250 mmHg systolic; >120 mmHg diastolic)
- Severe desaturation: Spo2 <=80% when accompanied by symptoms and signs of severe hypoxaemia
- Sudden pallor
- Loss of coordination
- Mental confusion
- Dizziness or faintness
- Signs of respiratory failure

CPET In Children

Exercise testing in children differs from adults in terms of indications, technical considerations in conducting the test, and in the interpretation of results. There are limited numbers of studies involving the use of CPET in children, however the available evidence has found it to be safe and effective in

healthy children as young as four years old. [32] A summary of the indications for exercise testing in children is as follows: [33, 34]

Indications for exercise testing in children[33, 34]

- Evaluation of symptoms or signs induced or aggravated by exercise
- Diagnoses disease
- Provides indications for surgery, therapy or additional tests
- Identify abnormal or adaptive responses in children with cardiac or other disorders
- Assess effectiveness of treatments
- Estimation of functional capacity for recreational and athletic recommendations
- Prognostic estimates
- Assessment of risk for future complications in existing disease
- Evaluation of fitness
- Baseline and follow-up of cardiac rehabilitation.

Diseases in which CPET may provide useful information include congenital heart disease, acquired valvular heart disease, cardiomyopathy, chronic lung disease, Kawasaki disease, systemic or pulmonary hypertension, and sickle cell disease.[33] CPET in children is generally considered safe when conducted under adequate supervision with adherence to relevant safety precautions. However there are conditions where the risk of testing is likely to outweigh the significance of information gained. Listed below are the absolute and relative contraindications for exercise testing in the paediatric population, followed by a list of reasons for test termination.

Absolute Contraindications for exercise testing in children[34]

- Active inflammatory heart disease
- Active hepatitis
- Acute myocardial infarction
- Active pneumonia
- Severe systemic hypertension for age
- Acute orthopaedic injury to exercise muscle group

Relative Contraindications for exercise testing in children[34]

- Severe left or right ventricular outflow obstruction
- Congestive heart disease
- Pulmonary vascular obstructive disease
- Severe aortic stenosis
- Severe mitral stenosis
- Ischaemic coronary artery disease
- Cardiomyopathy
- Certain inherited arrhythmia syndromes (LQTS, CPVT)
- Complex acquired ventricular arrhythmias

Indications for exercise test termination

- Where diagnostic findings have been established or a pre-determined end point has been reached
- In the event of failure of monitoring equipment
- When signs or symptoms indicate a potential hazard to the patient which may result in injury –
    - **Symptoms** - pain, headache, dizziness, syncope, excessive dyspnoea or fatigue
    - **Signs** – ST segment depression or elevation > 3 mm, significant arrhythmia precipitated or aggravated by test, progressive decrease in blood pressure

Although VO_{2max} is widely considered to be the best single indicator of cardiorespiratory function in adults and children, up to 50% of children fail to reach a VO_2 plateau. The VO_{2peak} is therefore considered more appropriate as a marker of maximal exertion. [34] The VE/VCO_2 slope has been studied in the paediatric population, but requires further research. Studies investigating ventilatory efficiency in children have tended to have small numbers of subjects and often suffered from methodological flaws such as lack of control group for comparison or a heterogeneic patient population.[35]

A prospective study by Karila et al[36] argued the feasibility of individualized protocols for increasing workload during CPET in children, finding that it was safe and well tolerated regardless of whether treadmill or cycle ergometer were used.

The available evidence pertaining to CPET use in children appears to conclude that it is safe and well tolerated when performed by appropriately trained staff under closely monitored conditions. Indications for use of CPET in the paediatric population may differ slightly to adults, though this is likely attributable to the differences in physiological parameters and prevalence of specific diseases.

Summary

The evidence demonstrates that CPET is able to provide valuable information relating to functional capacity of both adults and children in full health as well as varying disease states. It has utility in diagnosis, prognosis and assessment of therapeutic interventions in numerous conditions, as well as being a useful tool to assess functional capacity in healthy subjects. The available literature suggests that CPET is significantly underutilised, a fact that may be attributable to its more complex infrastructure requirements and increased cost. Comparative submaximal tests such as the 6MWT have been shown to be useful in functional assessment, but are not replacements for CPET where specific data is required for clinical decisions.[1] Conversely, the complexity and expense of CPET ensures that the 6MWT and other comparative exercise tests will continue their widespread use, as despite being submaximal, they continue to provide reliable information in a number of clinical scenarios. There is scope to increase the clinical utility of CPET and more research is required into areas such as the development of reference values and specific protocols, particularly the role of constant work tests.[1]

The safety of CPET has been studied extensively. It is found to be a safe and well tolerated procedure when conducted according to accepted guidelines, by qualified personnel. Absolute and relative

contraindications to testing are well established, although there is evidence as to its safety even in high risk populations.

CPET in the paediatric population is also considered a safe and accurate method of assessing functional capacity. Whilst the evidence in this population is not as vast, there is considerable scope for further research into utility and interpretation in paediatric patients. Indications for CPET in children do not differ significantly from adults, and relate mainly to differences in physiology and prevalence of specific conditions.

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Addendum to the Report from the Thoracic Medicine Clinical Committee

December 2016

G.1 Public Consultation

The Thoracic Medicine Clinical Committee report was released for public consultation on 9 September 2016 for three weeks.

Responses were received from:

- Thoracic Society of Australia and New Zealand
- Australasian Sleep Association
- Australian & New Zealand Society of Respiratory Science
- Australian Centre for Airways disease Monitoring
- Air Liquide Healthcare
- Sleep Health Foundation
- Oventus
- Australian and New Zealand Rhinologic Society
- Australian College of Nurse Practitioners
- Australian Private Hospitals Association
- Individuals and organisations who used the online consultation survey

G.2 Overview of public consultation submissions

A total of 87 submissions were received from a range of respondents, including:

- 27 private and public organisations
- 55 health practitioners
- 5 consumers

The table below summarises the per cent of respondents who agree, did not agree, or agreed but with changes, to each recommendation.

Table G1: Summary of public consultation responses

Recommendation	% agree	% not agreed	% agreed with some changes
Spirometry – recommendation 1.1	78	5	16
Spirometry – recommendation 1.2	93	-	7
Spirometry – recommendation 1.3	91	3	6
Spirometry – recommendation 1.4	85	-	15
Other respiratory function tests – recommendation 2.1	52	9	39
Other respiratory function tests – recommendation 2.2	50	13	38
Other respiratory function tests – recommendation 2.3	74	5	21
Other respiratory function tests – recommendation 2.4	79	3	18
Sleep studies – recommendations 3.1 and 3.2	41	11	48
Sleep studies – recommendation 3.3	51	10	40
Sleep studies – recommendation 3.4	42	42	16
Sleep studies – recommendation 3.5	33	17	50

Recommendation	% agree	% not agreed	% agreed with some changes
Sleep studies – recommendation 3.6	56	5	39
Sleep studies – recommendation 3.7	64	3	33
Diagnostic and therapeutic procedures – lung, trachea and bronchus – recommendation 4.1	77	12	12
Diagnostic and therapeutic procedures – lung, trachea and bronchus – recommendation 4.2	93	7	-
Thoracic medicine recommendations overall	**61**	**10**	**29**

G.3 Thoracic Medicine Clinical Committee review of public consultation submissions

The Thoracic Medicine Clinical Committee met on 27 October 2016 and assessed the submissions from public consultation.

The Committee noted the main themes included:

- Suggestions that the international standards should apply to item 11506
- Overnight oximetry and the need for it to be funded
- The sleep study Stop Bang score level should be lowered

G.4 Summary of changes to items and explanatory notes

The following table is a final list of changes to item descriptors and explanatory notes recommended by the Thoracic Medicine Clinical Committee

Table G2: Final list of changes to item descriptors and explanatory notes

Recommendation number	Change overview	See section	Page number/s
1.1	Changes to the item descriptor for item 11506 (office-based reversibility testing) to better target its use to diagnose asthma and chronic obstructive pulmonary disease (COPD). It is recommended that the item be available once a year and that the fee and rebate be doubled to $40 to encourage use in primary care	G.6.1(a) 4.1	219 17 to 18 and 21
1.2	Introduction of a new item for pre or post bronchodilator spirometry to be used to confirm diagnosis of COPD, assess acute asthma episodes and monitor patients with asthma, COPD and other cause of airflow limitation. The recommended fee of $20 is the same as current item 11506.	G.6.1(a) 4.1	219 17 to 18 and 22
1.3	Subsume item 11509 (laboratory based spirometry) into current item 11512 (more complex laboratory based spirometry).	8.2	59
1.4	Introduce enhanced quality requirements for all spirometry items.	G.6.1(a) 4.1	219 22

Recommendation number	Change overview	See section	Page number/s
2.1	The Committee has revised the list of respiratory function tests that are able to be claimed under item 11503. It suggests that the list represents those tests that are necessary in contemporary practice. It does not include some niche tests used in research settings. The Committee recommends that the list be included in the item descriptor to remove any uncertainty about what tests are claimable.	G6.1&(a) 5.1 5.2	218 to 221 26 to 27 32 to 33
2.2	Fractional exhaled nitric oxide (FeNO) testing cannot be claimed under MBS item 11503. When laboratory based spirometry (item 11512) is performed on the same day as a test approved under item 11503, then 11503 should be claimed. When spirometry is the only laboratory test performed then 11512 should be claimed.	G.6.1(a) 5.1	219 to 220 27, 30
2.3	A new item for laboratory based spirometry with FeNO with a MBS fee set between the current fee for 11512 and 11503. FeNO, as a single stand-alone test, in the absence of spirometry, does not attract an MBS benefit.	G.6.1(a) 5.1	219 to 220 28 to 29
2.4	A new item for cardio pulmonary exercise testing (CPET) in defined clinical circumstances with a fee of approximately $300.	5.3	33 to 34
3.1 & 3.2	GP referral without need for pre-test specialist attendance for patients who have a high pre-test probability for moderate to severe obstructive sleep apnoea (OSA) using validated assessment tools. Referral to testing for a wider range of sleep disorders than currently permitted when the patient has been assessed by a respiratory or sleep specialist.	G.6.1(b) 6.1	221 to 223 226 to 227 41 to 44
3.3	Better triage of patients to the most suitable test, noting that patients who have high pre-test probability for uncomplicated OSA are generally suitable for unattended sleep studies. Referral to testing for a wider range of sleep disorders than currently permitted when the patient has been assessed by a respiratory or sleep specialist.	G.6.1(b) 6.1	226 to 227 43 to 44
3.4	Addition of new items to the MBS for APAP titration and vigilance testing following MSAC appraisal. The Committee recommends that these new services should be considered once the impact of the other proposed changes to sleep study items can be assessed.	6.1	44 to 45
3.5	Amendment to item 12203 to restrict payment to once in a 12 month period; with a second attended sleep study permitted when required immediately prior to vigilance testing.	G.6.1(b) 6.1	221 to 223 225 to 228 44
3.6	Better use of follow up studies with closer involvement of sleep or consultant respiratory physicians in determining the need for follow up testing.	G.6.1(b) 6.1	227 44

Recommendation number	Change overview	See section	Page number/s
3.7	Determination of the need for testing should conform with Australasian Sleep Association guidelines.	G.6.1(b) 6.1	226 43
4.1	The Committee recommends that no changes be made to the items relating to diagnostic and therapeutic procedures for lung, trachea and bronchus 30696, 30710, 41889, 41892, 41893, 41898 and 41905.	7.1 and 7.2	55 to 57
5.1	The Committee suggests that Item 11509 should be subsumed into item 11512, which also provides for spirometry performed in a respiratory laboratory.	8.2	59

G.5 Amended recommendation

Recommendation 3.5: Sleep Studies

The Committee considered public consultation feedback in response to recommendation -3.5 and amended it to include implementation of a new sleep study item for circumstances where the previous attended sleep study failed. The amended description and explanatory notes are listed in section A.5.

G.6 Amended item descriptions and explanatory notes

The Committee considered public consultation feedback and made changes to item descriptors and explanatory notes to provide clarity and address concerns.

Spirometry changes overview

To support best practice and service quality, the Committee updated the explanatory note for items 11506, 11512 and the new spirometry item to reference the recommended standards. The new item is also amended to allow spirometry to be performed both before and after inhalation of bronchodilator.

The term ‘technician’ is amended to ‘respiratory scientist’ in the new item for fractional exhaled nitric oxide (FeNO).

Item 11503 has been amended to re-include and re-word the test listed as ‘(l)’ on page 27. The re-worded test is now listed as ‘(i)’ on page 220. The explanatory notes for item 11503 have been amended to clarify when item 11503 is payable.

Sleep studies changes overview

In response to public consultation feedback, the Committee reworded item descriptors 12203 and 12250 for clarity and reduced the STOP-BANG score from 5 to 4 to enable access for patients with moderate to severe symptomatic OSA. The term ‘technician’ in item 12203 and the treatment initiation item was amended to ‘sleep scientist’.

The Committee noted concern about the new time limitation restriction of item 12203 and recommended a new item, requiring pre-approval, for an additional sleep study where the patient failed the original study. It should be noted that when this item is implemented, it is also the intent to remove existing item 12207 as it will be redundant.

G.6.1 Amended and final recommended Items and explanatory notes.

G.6.1(a) Respiratory Function Tests including Spirometry

Item 11506 descriptor:

MEASUREMENT OF SPIROMETRY involving a permanently recorded tracing performed before and after inhalation of bronchodilator to confirm diagnosis of asthma, COPD or other causes of airflow limitation - each occasion at which three or more recordings are performed that meet best practice guidelines

Payable once in 12 months.

New spirometry item descriptor:

MEASUREMENT OF SPIROMETRY involving a permanently recorded tracing, performed before and / OR after inhalation of bronchodilator to

1) confirm diagnosis of COPD
2) assess acute exacerbations of asthma
3) monitor asthma and COPD.
4) assess other causes of obstructive lung disease or the presence of restrictive lung disease

- each occasion at which the spirometry recordings that meet international quality standards (Eur Respir J 2005; 26: 319–338) are performed.

Explanatory notes for items spirometry items 11506, 11512 and the new item:

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 11506 should not be repeated when diagnosis has been previously confirmed by properly performed spirometry. To meet quality requirements patients should 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).

FeNO item descriptor:

Measurement of:

(a) spirometry including continuous measurement of the relationship between flow and volume during expiration or during expiration and inspiration, performed before and after inhalation of bronchodilator; and

(b) fractional exhaled nitric oxide (FeNO) concentration in exhaled breath

The tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital, with continuous respiratory scientist attendance in a respiratory laboratory equipped to perform complex lung function tests:

(c) a permanently recorded tracing and written report is provided

(d) three or more spirometry recordings are performed unless difficult to achieve for clinical reasons

(e) each occasion at which 1 or more such tests are performed, not being a service associated with a service to which items 11503, 11512 or 22018 applies.

Item 11503

Complex measurement of properties of the respiratory system including the lungs and respiratory muscles performed in a respiratory laboratory under the supervision of a specialist in Respiratory Medicine who is responsible for staff training, supervision, quality assurance and the issuing of written reports on tests performed. Tests for this service are:

(a) Absolute lung volumes by any method

(b) Carbon monoxide diffusing capacity by any method

(c) Measurement of airway or pulmonary resistance by any method

(d) Inhalation provocation testing, including pre-provocation spirometry, the construction of a dose response curve, using recognised direct or indirect bronchoprovocation agent and post-bronchodilator spirometry

(e) Provocation testing involving sequential measurement of lung function at baseline and after exposure to specific sensitising agents, including drugs, or occupational asthma triggers

(f) 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

(g) Measurement of the strength of inspiratory and expiratory muscles at multiple lung volumes

(h) 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

(i) 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.

(j) Six minute walk test for the purpose of determining eligibility for medications subsidised under the Pharmaceutical Benefits Scheme or eligibility for the provision of portable oxygen

Each occasion at which one or more tests are performed and not to be claimed with spirometry and sleep study items (numbers to be inserted)

Fee: $138.65

Benefit: 75% = $104; 85% = $117.90

Explanatory notes for item 11503

Fractional exhaled nitric oxide (FeNO) testing cannot be claimed under MBS item 11503.

When laboratory based spirometry (item 11512) is performed on the same day as a test approved under item 11503, then 11503 should be claimed. When spirometry is the only laboratory test performed then 11512 should be claimed.

Maximum inspiratory and expiratory flow-volume loop testing for the purpose of diagnosing central airways obstruction is to be performed under MBS 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.

G.6.1(b) Investigation of sleep disorders

Item 12203 descriptor:

Overnight diagnostic assessment of sleep for a period of at least 8 hours duration in an adult aged 18 years and over to confirm diagnosis of a sleep disorder where:

(a) the patient has been referred by a medical practitioner to a qualified adult sleep medicine practitioner or a consultant respiratory physician who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea based on:

    (i) one of the following

        1. a STOP-BANG score of 4 or more; or
        2. an OSA-50 score of 5 or more; or
        3. a high risk score on the Berlin Questionnaire; and
        4. an Epworth Sleepiness Scale score of 8 or more;

OR

(b) Following personal attendance, a qualified adult sleep medicine practitioner or a consultant respiratory physician determines that testing to confirm the diagnosis of a sleep disorder is necessary,

AND

(c) the overnight investigation is performed for:

(i) suspected obstructive sleep apnoea syndrome where the patient is assessed as not suitable for an unattended sleep study or

(ii) suspected central sleep apnoea syndrome; or

(iii) suspected sleep hypoventilation syndrome; or

(iv) suspected sleep-related breathing disorders in association with non-respiratory co-morbid conditions including heart failure, significant cardiac arrhythmias, neurological disease, acromegaly or hypothyroidism; or

(vi) unexplained hypersomnolence which is not attributed to inadequate sleep hygiene or environmental factors; or

(vii) suspected parasomnia or seizure disorder where clinical diagnosis cannot be established on clinical features alone (including associated atypical features, vigilance behaviours or failure to respond to conventional therapy); or

(viii) suspected sleep related movement disorder, where the diagnosis of restless legs syndrome is not evident on clinical assessment;

AND

(d) a sleep scientist is in continuous attendance under the supervision of a qualified sleep medicine practitioner;

AND

(e) continuous monitoring and recording of the following studies which are to be performed in accordance with current Australasian Sleep Association guidelines for the performance of Type I sleep studies:

(i) airflow;

(ii) submental electro-myogram (EMG);

(iii) anterior tibial electro-myogram (EMG);

(iv) continuous electro-cardiogram (ECG);

(v) continuous electro-encephalogram (EEG);

(vi) electro-oculogram (EOG);

(vii) oxygen saturation;

(viii) respiratory movement (chest and abdomen);

(ix) position;

AND

(f) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events, cardiac abnormalities and limb movements) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report;

AND

(g) interpretation and preparation of a permanent report is provided by a qualified adult sleep medicine practitioner with direct review of raw data from the original recording of polygraphic data from the patient.

AND

(h) data gathered during the investigation cannot be used for the purpose of claiming any of items 11000 to 11005, 11503 , 11700 to 11709 and 11713.

Payable only once in a 12 month period. A second attended sleep study is permitted, when required immediately prior to vigilance testing.

Item 12250 descriptor:

Overnight investigation of sleep for a period of at least 8 hours in a patient aged 18 years or over to confirm diagnosis of obstructive sleep apnoea, where:

(a) the patient has been referred by a medical practitioner to a qualified adult sleep medicine practitioner or a consultant respiratory physician who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea based on:
    1. a STOP-BANG score of 4 or more; or
    2. an OSA-50 score of 5 or more; or
    3. a high risk score on the Berlin Questionnaire; AND
    4. an Epworth Sleepiness Scale score of 8 or more

OR

(b) Following personal attendance, a qualified adult sleep medicine practitioner or a consultant respiratory physician determines that testing to confirm the diagnosis of obstructive sleep apnoea is necessary;

AND

(c) during a period of sleep, the investigation involves the monitoring of at least seven physiological parameters which must include:

    (i) airflow; and

    (ii) chin electro-myogram (EMG); and

    (iii) continuous electro-cardiogram (ECG); and

    (iv) continuous electro-encephalogram (EEG); and

    (v) electro-oculogram (EOG); and

    (vi) oxygen saturation; and

    (vii) respiratory effort.

AND

(d) The investigation is performed under the supervision of an accredited sleep medicine practitioner; AND

(e) The equipment is applied to the patient by trained technicians; AND

(f) Polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events and cardiac abnormalities) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report; AND

(g) Interpretation and preparation of a permanent report is provided by a qualified adult sleep medicine practitioner with direct review of raw data from the original recording of polygraphic data from the patient.

AND

(h) data gathered during the investigation cannot be used for the purpose of claiming any of items 11000 to 11005, 11503, 11700 to 11709 and 11713.

Payable once in a 12 month period.

Treatment initiation study item descriptor :

Overnight assessment of positive airway pressure for a period of at least 8 hours duration in an adult aged over 18 where:

(a) the necessity for an intervention sleep study is determined by a qualified adult sleep medicine practitioner or consultant respiratory physician where a diagnosis of a sleep-related breathing disorder has been made; and the patient has not undergone positive airways pressure therapy in the previous 6 months; and

(b) the patient has had a professional attendance (either face-to-face or by video conference) and it is established that the sleep-related breathing disorder is responsible for symptoms; and

(c) a sleep scientist is in continuous attendance under the supervision of a qualified sleep medicine practitioner; and

(d) continuous monitoring and recording of the following studies which are to be performed in accordance with current Australasian Sleep Association guidelines for the performance of Type I sleep studies:

(i) continuous electro-encephalogram (EEG);

(ii) electro-oculogram (EOG);

(iii) submental electro-myogram (EMG);

(iv) anterior tibial (EMG);

(v) respiratory movement;

(vi) airflow;

(vii) oxygen saturation;

(viii) position;

(e) continuous electro-cardiogram (ECG); and

(f) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events, cardiac abnormalities and limb movements) with manual scoring, or manual correction of computerised scoring in epochs not more than one minute, and the data are stored for interpretation and preparation of a report; and

(g) interpretation and preparation of a permanent report are provided by a qualified adult sleep medicine practitioner with direct review of raw data from the original recording of polygraphic data from the patient.

One in a 12-month period.

New item 122XX for an additional sleep study where initial item 12203 has failed.

OVERNIGHT INVESTIGATION FOR SLEEP APNOEA FOR A PERIOD OF AT LEAST 8 HOURS DURATION, FOR AN ADULT AGED 18 YEARS AND OVER WHERE:

(a) a sleep scientist is in continuous attendance under the supervision of a qualified sleep medicine practitioner; AND

(b) continuous monitoring and recording of the following measures which are to be performed in accordance with current Australasian Sleep Association guidelines for the performance of Type 1 sleep studies:

(i) airflow;

(ii) submental electro-myogram (EMG);

(iii) anterior tibial electro-myogram (EMG);

(iv) continuous electro-cardiogram (ECG);

(v) continuous electro-encephalogram (EEG);

(vi) electro-oculogram (EOG);

(vii) oxygen saturation;

(viii) respiratory movement (chest and abdomen);

(ix) position;

AND

(c) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events, cardiac abnormalities and limb movements) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report;

AND

(d) interpretation and preparation of a permanent report is provided by a qualified adult sleep medicine practitioner with direct review of raw data from the original recording of polygraphic data from the patient;

AND

(e) the necessity for the investigation is determined by a qualified adult sleep medicine practitioner or consultant respiratory physician prior to the investigation;

AND

(f) where it can be demonstrated that a further investigation is indicated in the same 12 month period to which item 12203 applies, when a prior attended sleep study has been performed with insufficient sleep acquired, as evidenced by a sleep efficiency of 25% or less.

Explanatory note D.1.18 for sleep studies items D.1.18 Investigations for sleep disorders – (Items 12203, 12210, 12213, 12215, 12217, 12250 and 122XX)

Items 12250 and 12203:

Items 12250 and 12203 are applicable for patients who have not been previously diagnosed with a sleep disorder. They enable direct GP referral to testing without personal assessment by a sleep or respiratory physician, when validated screening tools suggest a high pre-test probability for diagnosis of symptomatic, moderate to severe OSA. The screening questionnaires must be administered by the referring practitioner. Alternatively, the need for testing can be determined by a sleep or respiratory physician following direct clinical assessment.

Determination of the need for testing should conform with Australasian Sleep Association guidelines.

Unattended sleep studies are suitable for many patients with suspected OSA but patients with other sleep disorders should undergo an attended study.

Assessment for potential contraindications to an unattended sleep study can be undertaken by either the referring practitioner, qualified adult sleep medicine practitioner or consultant respiratory physician. Standardised referrals should request sufficient information to enable such assessment.

In accordance with the Australasian Sleep Association's Guidelines for Sleep Studies in Adults, relative contraindications for an unattended sleep study to investigate suspected OSA include but are not limited to:

(a) intellectual disability or cognitive impairment;

(b) physical disability with inadequate carer attendance;

(c) significant co-morbid conditions including neuromuscular disease, heart failure or advanced respiratory disease where more complex disorders are likely;

(d) suspected respiratory failure where attended measurements are required, including measurement of carbon dioxide partial pressures;

(e) suspected parasomnia or seizure disorder;

(f) suspected condition where recording of body position is considered to be essential and would not be recorded as part of an unattended sleep study;

(g) previously failed or inconclusive unattended sleep study;

(h) unsuitable home environment including unsafe environments or where patients are homeless; and

(i) consumer preference based on a high level of anxiety about location of study or where there is unreasonable cost or disruption based on distance to be travelled, or home circumstances;

Patients who have these features may be suitable for either attended (Level 1) or unattended (Level 2) studies.

The results and treatment options following any diagnostic sleep study should be discussed during a professional attendance with a medical practitioner before the initiation of any therapy. If there is uncertainty about the significance of test results or the appropriate management for that individual then referral to a sleep or respiratory medicine specialist is recommended**.**

Any personal attendance by a qualified adult sleep medicine practitioner or consultant respiratory physician associated with this service may be undertaken face-to-face or by video conference.

Where the date of service for a sleep study item is the same as the date of service of any items 11000 to 11005, 11503, 11700 to 11709 and 11713, for a benefit to be payable, there must be written notification on the account identifying that the service under any of those items was not provided on the same occasion as the sleep study item.

Polygraphic data:

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.

Where it can be demonstrated – items 12215 and 12217:

Claims for benefits in respect of items 12215 and 12217 should be accompanied by clinical details confirming the presence of the conditions set out above. Claims for benefits for these services should be lodged with the Department of Human Services for referral to the National Office of the Department of Human Services for assessment by the Medicare Claims Review Panel (MCRP) and must be accompanied by sufficient clinical and/or photographic evidence to enable the Department of Human Services to determine the eligibility of the service for the payment of benefits.

Where it can be demonstrated – new adult item item 122XX:

For item 122XX, where it can be demonstrated that a further investigation is indicated in the same 12 month period to which item 12203 applies, when a prior attended sleep study has been performed with insufficient sleep acquired, as evidenced by a sleep efficiency of 25% or less. Claims for benefits in respect of item 122XX should be lodged with the Department of Human Services for referral to the National Office of the Department of Human Services for assessment by the Medicare

Claims Review Panel (MCRP); and must be accompanied by a copy of the initial sleep study report and sufficient clinical evidence to enable the Department of Human Services to determine the eligibility of the service for the payment of benefits.

Applications for approval should be addressed in a sealed envelope marked “Medical-in-Confidence” to:

The MCRP Officer

PO Box 9822

SYDNEY NSW 2001