Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1405 – MBS Item Number for Pulmonary Rehabilitation

Applicant: **Lung Foundation**

Date of MSAC consideration: **MSAC 68th Meeting, 24-25 November 2016**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application and links to other applications

An application requesting new Medicare Benefits Schedule (MBS) listings of a pulmonary rehabilitation (PR) program and pulmonary maintenance exercise (PME) program for patients with chronic lung disease was received from Lung Foundation Australia by the Department of Health.

2. MSAC's advice to the Minister

After considering the available evidence in relation to the comparative safety, clinical effectiveness and cost-effectiveness, MSAC deferred public funding for PR in chronic obstructive pulmonary disease (COPD), bronchiectasis and interstitial lung disease (ILD).

MSAC noted that there was low to moderate quality evidence indicating that PR may have clinically relevant benefits for patients with COPD, bronchiectasis and ILD. However, MSAC was concerned that the assessment report only considered the impact of these services in patients with stable disease and excluded those who have had a recent exacerbation. MSAC considered that this population was likely to have the greatest benefit from the proposed services.

MSAC requested the following information before it could finalise its advice with respect to PR for COPD, bronchiectasis and ILD:

- evidence of the effectiveness and cost-effectiveness of PR for patients with stable disease with respect to hospitalisation rates (including hospital in the home), length of stay, frequency of exacerbations and mortality;
- evidence of the effectiveness and cost-effectiveness of PR for patients who have had a recent exacerbation, also with respect to hospitalisation rates (including hospital in the home), length of stay, frequency of exacerbations and mortality;
- information about the durability of the effects of PR over time and whether this differs by the number of sessions or weeks required for service delivery;
- information to support the value and frequency of repeat courses of rehabilitation; and
- investigate the treatment effect modification of PR, for example with information about any variation in patient response to treatment according to the proximity of patients' most recent exacerbation.

The response should be provided to the next appropriate MSAC meeting via ESC.

MSAC did not support public funding for PR for the management of lung cancer nor PME for the management of COPD, bronchiectasis, ILD or lung cancer due to limited evidence to support the clinical effectiveness of the services in these populations and uncertain cost-effectiveness.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that PR was defined as a "comprehensive intervention based on thorough patient assessment followed by patient tailored therapies which include, but are not limited to, exercise training, education and behaviour change, designed to improve the physical and psychological condition of people with chronic respiratory disease and to promote the long-term adherence to health-enhancing behaviours". PME relates to exercise therapy delivered following a PR program to maintain benefit.

MSAC noted that there are no MBS item numbers for the delivery of PR or PME services. These services are currently provided by state-based Local Hospital networks, private providers and non-government organisations (NGOs), with approximately 275 centres offering PR and 180 offering PME services at present. An activity-based funding item for PR (Item 40.60), recently introduced by the Independent Hospital Pricing Authority (IHPA) and which allows service provision independent of service setting (i.e. hospital, community or home-based), can be accessed by patients only if referred by a specialist clinician. MSAC highlighted that in the current application, it was proposed that both general practitioners (GPs) and specialists would be eligible to refer patients for these services. It was proposed that the services would be delivered by eligible physiotherapists or exercise physiologists.

MSAC noted that four MBS items were proposed by the applicant which related to:

(i) patient assessment prior to a group PR service;
(ii) delivery of the PR group service;
(iii) individual patient assessment after completion of the group PR service; and
(iv) delivery of the PME group service.

MSAC acknowledged the applicant's clarification that additional patient assessment prior to participating in a PME group service would not be necessary, given that patients who complete the PR service would be required to complete a post-PR assessment before proceeding to the PME service.

MSAC noted that the proposed eligible population encompassed patients under the care of a GP or specialist who have been diagnosed with COPD, bronchiectasis, ILD or lung cancer and who have had their pharmacotherapy optimised. MSAC noted that for PR, the comparator was considered to be best care delivered by a GP or specialist without a PR program and for PME, the comparator was PR without PME. MSAC considered these to be appropriate.

MSAC noted that the application proposed that PR would be delivered as a one-hour program, in groups of eight participants, twice a week over eight weeks (i.e. 16 sessions), repeated every two years and for PME, groups of up to 12 participants for one hour per week over 16 weeks (i.e. 16 sessions). MSAC questioned the proposed frequency of these services, noting that a Cochrane review of PR for COPD highlighted that services delivered over the course of four weeks may be sufficient (McCarthy B et al 2015). MSAC noted that as per the agreed clinical management algorithm, PR services may be initiated at any stage of the disease i.e. during periods of clinical instability or directly following an exacerbation. In turn, MSAC was concerned that the assessment report only considered the impact of these services in patients with stable disease and excluded those who have experienced an acute exacerbation, despite these patients being able to currently access PR services via the public

hospital system, privately, or as offered by an NGO. MSAC also considered that this population was likely to have the greatest benefit from the proposed services.

MSAC acknowledged the need to provide greater PR and PME services for the proposed population, noting that only a small proportion of these patients have accessed these services and that there are extensive waiting lists for currently available services, a large number of which only accept referrals from specialist clinicians. However, MSAC was concerned about existing services' ability to respond to increased demand, noting that only approximately half of these have the capacity to accept more than 100 participants per year.

MSAC noted that there was limited evidence provided to support the comparative safety of the proposed services. MSAC acknowledged however, that the risk of harm is likely to be low given the nature of the interventions and noted that the services should be delivered by accredited and clinically competent physiotherapists or exercise physiologists in order to maintain patient safety.

In its consideration of the evidence provided to support the comparative effectiveness of the proposed services, MSAC noted that the majority of trials relevant to PR services related specifically to patients with COPD. MSAC noted that for PME, only three trials relating to COPD were identified and that no evidence to support the use of PME in any of the remaining populations was identified. MSAC highlighted that despite the potential for performance and detection bias associated with the fact that none of these trials blinded participants, some trials were still assigned a 'low' risk of bias in the assessment report. MSAC considered that this was likely to overestimate the benefit of the services, particularly for patient-reported outcomes.

MSAC noted that the primary measures of effectiveness reported in the assessment were: overall quality of life (QOL), measured using the St George's Respiratory Questionnaire (SGRQ); dyspnoea, fatigue, depression and anxiety-related QOL, measured using the Chronic Respiratory Disease Questionnaire (CRQ); and functional exercise capacity, measured with respect to the 6-minute walk test (6MWT) or the incremental shuttle walk test (ISWT). MSAC noted that no data or outcomes related to the rates of patient hospital admissions or readmissions, bed days, frequency of exacerbations or mortality were provided even though there was some limited data available in the trials presented.

With respect to PR services, MSAC noted that pooled data from relevant trials highlighted that there is:

- low to moderate quality evidence indicating that PR for COPD has clinically relevant benefits for overall QOL, dyspnoea and exercise capacity and may have benefits for fatigue and emotional function;
- low quality evidence indicating that PR for ILD has clinically relevant benefits for exercise capacity and possibly overall QOL, but not dyspnoea and that its benefit with respect to fatigue or emotional function is unknown;
- very low quality evidence derived from a single trial of PR ± inspiratory muscle training (compared to no intervention) did not allow any conclusions to be drawn regarding the impact of PR for bronchiectasis on QOL or exercise capacity; and
- low quality evidence indicating that PR for lung cancer may improve exercise capacity, but not overall QOL and that its benefit with respect to fatigue, dyspnoea or emotional function is unknown.

MSAC also considered the additional evidence subsequently provided by the applicant to support the benefit of PR for patients with stable bronchiectasis in the form of two RCTs (Lee AL et al 2014; Mandal P et al 2012) and one systematic review (Lee AL et al 2016). MSAC acknowledged that pooled data from the trials suggested that there is moderate quality evidence to support that PR may lead to clinically significant improvements in exercise capacity and potentially overall QOL in this population. However, MSAC was concerned that

the systematic review by Lee AL et al 2016 highlighted that the benefits of PR for patients with bronchiectasis were not sustained at six months and that the service did not reduce exacerbation frequency or mortality when initiated during an exacerbation.

MSAC noted that with respect to PME services, pooled data from the three COPD-specific trials highlighted that there is low quality evidence indicating that PME for COPD may not provide clinically relevant benefits for fatigue, emotional function, dyspnoea or exercise capacity and that its benefit with respect to overall QOL is unknown. MSAC noted that this suggested that there is no need for PME services, or that studies of this intervention require improvement.

MSAC considered the findings of the economic evaluation presented in the assessment report. MSAC noted that a cost-utility analysis was conducted on the basis of non-inferior safety and superior effectiveness using a 10-year time horizon and a cycle length of two years. MSAC noted that incremental costs and outcomes were calculated for: (i) PR compared to usual care in COPD and ILD; and (ii) PME + PR compared to PR in COPD and ILD. In the base case, MSAC noted that both services were found to be cost-effective, with ICERs of: $7,451/QALY and $4,095/QALY obtained for PR in COPD and ILD, respectively; and $43,304/QALY and $43,941/QALY for PME +PR COPD and ILD, respectively.

MSAC considered that the main drivers of uncertainty in the economic analysis related to the uncertainty about the clinical effectiveness of PR for conditions other than COPD and the effectiveness of PME over PR alone. MSAC noted that results were most sensitive to the benefit of decay function over time, estimates of effect size and treatment costs. MSAC noted that a multivariate sensitivity analysis conducted for PME in COPD revealed that if the benefits of PR were assumed to not decay over time, there was no extra benefit provided by PME.

MSAC was concerned that no data was provided to support repeat treatment every two years, noting that it was not clear whether the target populations' disease severity worsens over time and consequently, whether treatments would need to occur more frequently than this interval. Furthermore, MSAC was concerned about the transformation of SGRQ scores into utility values undertaken via mapping to the EQ-5D multi-utility instrument. MSAC noted that while the assessment report indicated that this transformation was based on the study by Oba Y 2007, little further detail was provided as to how the utility values were derived. Hence, MSAC highlighted that there was uncertainty regarding the cited utility values with the potential to have significant implications for the estimated ICERs.

MSAC reiterated that no data or outcomes related to the rates of patient hospital admissions or readmissions, bed days, frequency of exacerbations or mortality were provided. Hence, the impact of the proposed services on healthcare resource use is unknown. MSAC acknowledged the findings of a Cochrane review by Puhan MA et al 2011 as highlighted by the applicant, which indicated that after hospitalisation for an exacerbation of COPD, patients who received PR had 24% fewer hospital readmissions and reduced mortality rates compared to those who received usual care. MSAC also noted that there was further evidence to suggest that PR in patients with chronic lung disease significantly reduced the duration of patients' hospital days compared to controls (Griffiths T et al 2000). MSAC reiterated that this population was likely to have the greatest benefit from the proposed services and noted that in excluding cost offsets associated with healthcare utilisation, the economic evaluation was likely to be conservative.

MSAC noted that the net MBS expenditure associated with PR and PME services was projected to be $64.3 million in the first year, increasing to $72.3 million in the fifth year of listing. MSAC noted that there was a high level of uncertainty surrounding utilisation and uptake rates, the size of the eligible population and the ability of providers to respond to increased demand for these services. These uncertainties were reflected in the outcomes of the sensitivity analyses conducted, which highlighted that the average annual cost of these

services to the MBS may range between $40.2 million and $160.6 million (base case $80.3 million) and when the number of patients were constrained based on the existing number of providers, the cost ranged between $12.3 million and $22.0 million. MSAC also considered that there was potential for cost shifting from State/Territory governments, given that patients currently attending outpatient services may transition to community services.

4. Background

MSAC has not previously considered an application for delivery of a PR or PME program.

5. Prerequisites to implementation of any funding advice

This intervention does not require Therapeutic Goods Administration (TGA) approval.

There are currently no MBS item numbers for delivery of a pulmonary rehabilitation program. MBS Item 10960, physiotherapy, provides for individual physiotherapy, is a service provided to a person who has a chronic condition and complex care needs, requires a GP Management Plan (GPMP, MBS Item 721) and Team Care Arrangement (TCA, MBS Item 723), and provides for a maximum of five services per year (if reimbursed under MBS the patient cannot claim private reimbursement, if available).

A similar service is MBS item 10953 – Exercise Physiology. It is possible one-on-one pulmonary rehabilitation could be done under these MBS items (though it is more likely other interventions would be provided), but it does not provide for the delivery of the specified program in the proposal. MBS item 81315, exercise physiology health service and MBS item 81335, physiotherapist, provides for a person who is of Aboriginal or Torres Strait Islander (ATSI) descent, and has been identified by a medical practitioner a need for follow-up allied health services, provides for one on one service, requires a referral by their GP (referral form for follow-up allied health services under Medicare for ATSI) and provides for a maximum of five services per year per item. It is possible one-on-one pulmonary rehabilitation could be done under these MBS items (though it is more likely other services would be provided), but it does not provide for the delivery of the specified program.

6. Proposal for public funding

The application proposed that the MBS item for PR or PME be separate to the currently existing MBS items available for other allied health services. Therefore no limits are included in the MBS item descriptor or text that would tie this item to other MBS items for the provision of group services.

Both accredited eligible physiotherapists and exercise physiologists are able to provide the pre- and post-assessment as well as to deliver the PR programs. The optimum service would be if the same allied health professional (or organisation) delivering the PR programs also undertakes the pre- and post-assessments.

The application has not indicated that the provision of PR should be limited according to the severity of the chronic lung disease, although there will be a group of patients who will only be able to do PR at a hospital outpatient centre. Criteria that a patient would need to satisfy to continue with PME therapy has not been provided but it has been stated as a preference in the protocol that all patients who have completed PR continue to PME. It is expected that the post-assessment written letter to the referring medical practitioner would address whether the patient has obtained sufficient benefit from the PR program. If not it is unlikely the medical practitioner would refer the patient on to a PME program.

Patients under the care of their GP will be referred using MBS item 721, with the MBS items for PR and PME worded in such a way that this would not result in a reduction in the

availability of the other group allied health services. Data capture could be driven by the separate MBS item numbers claimed by the physiotherapist or accredited exercise physiologist.

Table 1 Proposed MBS item descriptor

Category 8 – Miscellaneous
MBS [item number] PULMONARY REHABILITATION SERVICE – INDIVIDUAL ASSESSMENT FOR GROUP SERVICES Pulmonary rehabilitation health service provided to a person by an eligible physiotherapist or exercise physiologist, for the purposes of ASSESSING a person's baseline respiratory status, including taking a medical history, testing of functional exercise capacity (six-minute walk test), assessment of health status (quality of life questionnaires) and a psychosocial assessment questionnaire, planning an individualised pulmonary rehabilitation program, if: (a) The service is provided to a person diagnosed with COPD, chronic irreversible asthma, bronchiectasis, interstitial lung disease or lung cancer (b) The person is being managed by a general practitioner under a GP Management Plan [i.e. item 721 or 732], or if the person is a resident of an aged care facility, their medical practitioner has contributed to a multidisciplinary care plan [i.e. item 731]; OR, the person is being managed by a specialist (respiratory, rehabilitation, general, consultant physician, surgeon) (c) The patient's pharmacotherapy for chronic lung disease (CLD) has been optimised by their medical practitioner (d) The person is referred to an eligible physiotherapist or exercise physiologist by the medical practitioner using a referral form that has been issued by the Department of Health, or a referral form that contains all the components of the form issued by the Department; and (e) The person is not an admitted patient of a hospital, and (f) The service is provided to the person individually and in person; and (g) The service is of at least 45 minutes duration; and (h) After the service, the eligible physiotherapist or exercise physiologist gives a written report to the referring medical practitioner mentioned in paragraph (b); and (i) In the case of a service in respect of which a private health insurance benefit is payable – the person who incurred the medical expenses in respect of the service has elected to claim the Medicare benefit in respect of the service, and not the private health insurance benefit. - To a maximum of one every two years Fee: $65.00 Benefit: 85% = $55.25 [Relevant explanatory notes]
MBS [item number] PULMONARY REHABILITATION SERVICE – GROUP SERVICE Pulmonary rehabilitation program provided to a person by an eligible physiotherapist or exercise physiologist as a GROUP SERVICE for the management of COPD chronic irreversible asthma, bronchiectasis, interstitial lung disease, lung cancer if: (a) The person has been assessed as suitable for a pulmonary rehabilitation program under assessment (b) The service is provided to a person who is part of a group of a maximum of 8 patients inclusive; and (c) The person is not an admitted patient of a hospital; and (d) The service is provided to a person involving the personal attendance by an eligible physiotherapist or exercise physiologist and (e) The service is of at least 60 minutes duration; and (f) After the last service in the group services program provided to the person under item [ ] , the eligible physiotherapist or exercise physiologist, prepares, or contributes to, a written report to be provided to the referring medical practitioner; and (g) An attendance record for the group is maintained by the eligible physiotherapist or exercise physiologist; and (h) In the case of a service in respect of which a private health insurance benefit is payable –

the person who incurred the medical expenses in respect of the service has elected to claim the Medicare benefit in respect of the service, and not the private health insurance benefit.

- To a maximum of sixteen GROUP SERVICES to be completed within a 10 week period

[Item descriptor]
Fee: $25.00: 85%=$21.25
[Relevant explanatory notes]

MBS [item number]
PULMONARY MAINTENANCE EXERCISE SERVICE – GROUP SERVICE
Pulmonary maintenance exercise provided to a person by an eligible physiotherapist or exercise physiologist, as a GROUP
SERVICE for the management of COPD, chronic irreversible asthma, bronchiectasis, interstitial lung disease, lung cancer
if:

(a) The person has completed a pulmonary rehabilitation program under assessment
(b) The service is provided to a person who is part of a group of a maximum of 12 patients inclusive; and
(c) The person is not an admitted patient of a hospital; and
(d) The service is provided to a person involving the personal attendance by an eligible physiotherapist or exercise physiologist; and
(e) The service is of at least 60 minutes duration; and
(f) An attendance record for the group is maintained by the eligible physiotherapist or exercise physiologist; and
(g) In the case of a service in respect of which a private health insurance benefit is payable – the person who incurred the medical expenses in respect of the service has elected to claim the Medicare benefit in respect of the service, and not the private health insurance benefit.

- To a maximum of sixteen GROUP SERVICES (to be completed within 6-months) in a calendar year

Fee: $12 85%=$10.20
[Relevant explanatory notes]

MBS [item number]
PULMONARY REHABILITATION SERVICE – INDIVIDUAL ASSESSMENT POST GROUP SERVICES
Pulmonary rehabilitation health service provided to a person by an eligible physiotherapist or exercise physiologist, for the
purposes of ASSESSING a person's POST pulmonary rehabilitation group service respiratory status, including taking a
medical history, testing of functional exercise capacity (six-minute walk test), assessment of health status (quality of life
questionnaires) and a psychosocial assessment questionnaire, if:

(a) The service is provided to a person diagnosed with COPD, chronic irreversible asthma, bronchiectasis, interstitial lung disease or lung cancer
(b) The person is being managed by a general practitioner, under a GP Management Plan [i.e. item 721 or 732, or if the person is a resident of an aged care facility, their medical practitioner has contributed to a multidisciplinary care plan [i.e. item 731]; OR, the person is being managed by a specialist (respiratory, rehabilitation, general, consultant physician, surgeon)
(c) The person WAS referred to an eligible physiotherapist or exercise physiologist by the medical practitioner using a referral form that has been issued by the Department of Health, or a referral form that contains all the components of the form issued by the Department; and
(d) The eligible physiotherapist or exercise physiologist provided PULMONARY REHABILITATION group service under item [item number for PR group service]; and
(e) The service is provided to the person individually and in person; and
(f) The service is of at least 45 minutes duration; and
(g) After the service, the eligible physiotherapist or exercise physiologist gives a written report to the referring medical practitioner mentioned in paragraph (b); and
(h) In the case of a service in respect of which a private health insurance benefit is payable – the person who incurred the medical expenses in respect of the service has elected to claim the Medicare benefit in respect of the service, and not the private health insurance benefit.

Fee: $65.00 Benefit: 85% = $55.25 [Relevant explanatory notes]

7. Summary of Public Consultation Feedback/Consumer Issues

The Protocol Advisory Sub-Committee (PASC) received 6 responses from peak bodies, 20 responses from organisations, 29 responses from specialists, 5 responses from researchers, 62 responses from consumer/care givers; and 6 responses from others.

Issues raised in the responses were:

- The population should be expanded to include: pulmonary fibrosis (e.g. following asbestosis); Alpha 1 antitrypsin deficiency; nontuberculosis mycobacteria; pulmonary arterial hypertension (contradictory views expressed); and pre-op for patients slated to undergo lung or heart-lung transplant
- Referrals for the medical service should be accepted from GPs, physicians (respiratory, rehabilitation, general) and surgeons
- Suggested removal of the requirement for an additional referral before the maintenance program
- Training required for practitioners
- The medical service should be overseen by a respiratory physician
- The ownership of business premises or of a business is unnecessary
- Tele-rehabilitation should be reimbursed for rural and remote Australia
- Follow up consultations by physiotherapist/exercise physiologists should be required.
- Suggested removal of limit of one medical service per patient each 2 years
- Difficulty in measuring 'reduced frequency in exacerbations'
- A broader range of functional exercise tests should be used to determine change in exercise capacity/tolerance
- Patient participation/adherence should be defined as attendance of at least 70% of pulmonary rehabilitation sessions
- The proposed MBS item fees are too low and should be aligned with the average rate charged in private practice.

8. Proposed intervention's place in clinical management

The proposed intervention is a PR program provided to eligible patients in a group setting. The intervention is expected to be provided in addition to other treatment options for their chronic lung disease (CLD).

PR is newly defined as a "comprehensive intervention based on a thorough patient assessment followed by patient tailored therapies which include, but are not limited to, exercise training, education, and behaviour change, designed to improve the physical and psychological condition of people with chronic respiratory disease and to promote the long-term adherence to health-enhancing behaviours" (Spruit 2013).

PR may be initiated at any stage of the disease, during periods of clinical stability or directly after an exacerbation, and is part of an integrated care model. It is proposed that the intervention will be individualised to the unique needs of the patients, based on initial and ongoing assessments, including disease severity, complexity and comorbidities. The intervention is proposed to be provided in community settings, in groups, to address unmet demand for PR and PME, and in locations where some of the barriers to accessing PR and PME can be reduced. The proposed format of the PR program is a one-hour program, delivered in groups of eight participants, for one hour twice a week over 8 weeks (i.e. 16 sessions), repeated every 2 years; and for PME groups of up to 12 participants, for one hour once per week over 16 weeks (i.e. 16 sessions).

The proposed CLD population for whom pulmonary rehabilitation would be prescribed are patients under the care of their GP who have been diagnosed with COPD, bronchiectasis, ILD, and lung cancer and have had their pharmacotherapy optimised. Patients with cystic fibrosis are excluded from the target population on the basis that their susceptibility to infection means they cannot exercise in a group. Patients for whom, based on the severity of their CLD, only hospital-based pulmonary rehabilitation would be viable are also excluded from the eligible population.

Pulmonary rehabilitation services are provided by an eligible physiotherapist or exercise physiologist. The person is being managed by a general practitioner under a GP Management Plan; or, if the person is a resident of an aged care facility, their medical practitioner has contributed to a multidisciplinary care plan; or, the person is being managed by a specialist (respiratory, rehabilitation, general, consultant physician, and surgeon).

9. Comparator

The proposed service, best care delivered by a GP/specialist with the addition of accredited physiotherapist or exercise physiologist, delivered PR in the community, is expected to substitute for:

- Best care delivered by a GP/specialist, without a PR program available.
  The proposed service, PME delivered by accredited eligible physiotherapists or exercise physiologists, is expected to substitute for:
- Best care delivered by a GP/specialist without a PME program available.
  For the purposes of this assessment, the comparator for PME is PR without PME, to determine the additional benefit of PME following a PR program.

10. Comparative safety

A total of 57 randomised trials were identified that met inclusion criteria to assess the effectiveness of PR in people with COPD (49 trials), ILD (six trials), bronchiectasis (one trial), and lung cancer (three trials), in outcomes of interest.

A total of three randomised trials were identified that met inclusion criteria to assess the effectiveness of PME in people with COPD in outcomes of interest; no randomised trials were identified that met the inclusion criteria to assess the effectiveness of PME in people with ILD, bronchiectasis or lung cancer.

There was limited evidence available to determine the safety of PR compared with usual care. Given the nature of the intervention, it is expected that risk of harm is low, and it is recognised that delivery of the program should be by accredited and clinically competent practitioners with the required skills and knowledge to maintain patient safety (McCarthy 2015).

In the case of the proposed program, to be able to deliver this intervention the eligible health professionals will require credentialing and will need to be registered as either a physiotherapist accredited by the Australian Health Practitioner Regulation Agency (AHPRA) or an Exercise and Sports Science Australia (ESSA) accredited exercise physiologist. In addition, physiotherapists or exercise physiologists accredited to provide PR or PME programs will require mandatory facility accreditation to provide these programs in a community setting.

11. Comparative effectiveness

Comparative effectiveness was assessed by meta-analysing randomised trials reporting each critical patient-relevant outcome.

Table 2 outlines the primary tools measuring these patient-relevant outcomes, and the corresponding minimal clinically important differences (MCID). The tools used to measure these outcomes have all been validated in the relevant patient cohorts.

Table 2 Outcome measurement tools and corresponding minimal clinically important difference (MCID)

Outcome	Measure	MCID
Overall quality of life	SGRQ	4 points (on the 100-point scale)[1]
Quality of life – dyspnoea	CRQ – dyspnoea	0.5 points (on the 7-point scale)[1]
Quality of life – fatigue	CRQ – fatigue	0.5 points (on the 7-point scale)[1]
Quality of life – depression and anxiety	CRQ – emotional function	0.5 points (on the 7-point scale)[1]
Functional exercise capacity	6MWT	30 metres[2]

[1] Make et al, 2005.[2] Holland et al, 2014. 6MWT = 6-minute walk test; CRQ = Chronic Respiratory Disease Questionnaire; SGRQ = St George's Respiratory Questionnaire

Pulmonary rehabilitation (PR)

On the basis of the evidence profile (summarised in Table 3), it is suggested that for patients with COPD, relative to usual care, PR has superior effectiveness in terms of patient relevant outcomes of quality of life, dyspnoea, fatigue, emotional function and functional exercise capacity.

Table 3 Balance of clinical benefits and harms of pulmonary rehabilitation, relative to usual care, and as measured by the critical patient-relevant outcomes in the key trials in COPD

Outcomes (units) Follow-up	Pooled participants (number of trials)	Quality of evidence (GRADE [a])	Relative effect (95%CI)	Comments
CRQ – Fatigue	702 PR / 607 control (19)	⊕⊕⊕⊙ **Moderate**	0.64 (0.32, 0.95)	Mean difference exceeded MCID (statistical significance)
CRQ – Emotional function	702 PR / 607 control (19)	⊕⊕⊕⊙ **Moderate**	0.72 (0.25, 1.20)	Mean difference exceeded MCID (statistical significance)
CRQ – Dyspnoea	702 PR / 607 control (19)	⊕⊕⊕⊙ **Moderate**	0.82 (0.63, 1.02)	Mean difference and lower limit of CI exceeded MCID (statistical and clinical significance)
SGRQ – Total	683 PR / 616 control (18)	⊕⊕⊕⊙ **Moderate**	-6.83 (-8.75, -4.91)	Mean difference and lower limit of CI exceeded MCID (statistical and clinical significance)
6MWT	1682 PR / 865 control (35)	⊕⊕⊙⊙ **Low**	43.95 (31.37, 56.54)	Mean difference and lower limit of CI exceeded MCID (statistical and clinical significance)

[a] GRADE Working Group grades of evidence (Guyatt et al., 2013)
⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimated effect.
⊕⊕⊕⊙ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimated effect, but there is a possibility that it is substantially different.
⊕⊕⊙⊙ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimated effect.
⊕⊙⊙⊙ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

On the basis of the evidence profile (summarised in Table 4), it is suggested that for patients with interstitial lung disease, relative to usual care, PR has non-inferior effectiveness in terms of quality of life and dyspnoea, and superior effectiveness in terms of functional exercise capacity.

Table 4 Balance of clinical benefits and harms of pulmonary rehabilitation, relative to usual care, and as measured by the critical patient-relevant outcomes in the key trials in interstitial lung disease

(units) Follow-up	Pooled participants (number of trials)	Quality of evidence (GRADE [a])	Relative effect (95%CI)	Comments
Dyspnoea (measured by Medical Research Council Dyspnoea Scale; a reduction in the MRC is considered an improvement)	41 PR / 40 control (2)	⊕⊕⊙⊙ **Low**	-0.61 (-1.14, -0.08)	The dyspnoea mean difference in effect did not exceeded the MCID of 1 point on the 5-point MRC scale
SGRQ - Total	52 PR / 50 control (3)	⊕⊕⊙⊙ **Low**	-9.33 (-3.38, -15.28)	Mean difference exceeded MCID; however lower limit did not exceed MCID; statistical significance only
6MWT	100 PR / 101 control (6)	⊕⊕⊙⊙ **Low**	48.47 (34.53, 62.41)	Mean difference and lower limit of CI exceeded 30 metres; statistical and clinical significance

[a] GRADE Working Group grades of evidence (Guyatt et al., 2013)
⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimated effect.
⊕⊕⊕⊙ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimated effect, but there is a possibility that it is substantially different.
⊕⊕⊙⊙ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimated effect.
⊕⊙⊙⊙ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

On the basis of the evidence profile (summarised in Table 5), it is suggested that for patients with bronchiectasis, relative to usual care, PR has non-inferior effectiveness in terms of quality of life, and superior effectiveness in terms of functional exercise capacity.

Table 5 Balance of clinical benefits and harms of pulmonary rehabilitation, relative to usual care, and as measured by the critical patient-relevant outcomes in the key trial in bronchiectasis

Outcomes (units) Follow-up	Pooled participants (number of trials)	Qualityof evidence (GRADE [a])	Absolute effect (95%CI)	Comments
SGRQ	PR-SHAM, n=11 / PR-IMT, n=12 / control n=9 (1)	⊕⊙⊙⊙ **Very Low**	PR-SHAM = 2.3 (-2.9, 7.4) PR-IMT = -7.7 (-16.6, 1.1) Control = -10.0 (-21.3, 1.3)	PR-SHAM, PR-IMT and control not statistically significant; PR-IMT and control clinically significant
ISWT (Incremental shuttle walk test)	PR-SHAM, n=11 / PR-IMT, n=12 / control n=9 (1)	⊕⊙⊙⊙ **Very Low**	PR-SHAM = 96.7 (59.6, 133.7) PR-IMT = 124.5 (63.2, 185.9) Control = 11.0 (-16.9, 38.9)	PR-SHAM and PR-IMT clinically and statistically significant, control not statistically or clinically significant

[a] GRADE Working Group grades of evidence (Guyatt et al., 2013)
⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimated effect.
⊕⊕⊕⊙ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimated effect, but there is a possibility that it is substantially different.
⊕⊕⊙⊙ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimated effect.
⊕⊙⊙⊙ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimated effect.

On the basis of the evidence profile (summarised in Table 6), it is suggested that for patients with lung cancer, relative to usual care, PR has non-inferior effectiveness in terms of quality of life and functional exercise capacity.

Table 6 Balance of clinical benefits and harms of pulmonary rehabilitation, relative to usual care, and as measured by the critical patient-relevant outcomes in the key trials in lung cancer

Outcomes (units) Follow-up	Pooled participants (number of trials)	Quality of evidence (GRADE [a])	Relative effect (95%CI)	Comments
SGRQ	40 PR / 39 control (2)	⊕⊕⊙⊙ **Low**	-1.51 (-9.97, 6.95)	Not statistically or clinically significant
6MWT	52 PR / 47 control (3)	⊕⊕⊙⊙ **Low**	50.11 (9.16, 91.06)	Mean difference exceeded MCID; however lower limit of CI below MCID (statistical significance)

[a] GRADE Working Group grades of evidence (Guyatt et al., 2013)
⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimated effect.
⊕⊕⊕⊙ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
⊕⊕⊙⊙ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimated effect.
⊕⊙⊙⊙ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Pulmonary maintenance exercise (PME)

On the basis of the evidence profile (summarised in Table 7), it is suggested that for patients with COPD, relative to PR alone, PME has non-inferior effectiveness in terms of patient relevant outcomes of dyspnoea, fatigue, emotional function and functional exercise capacity.

Table 7 Balance of clinical benefits and harms of PME, relative to usual care, and as measured by the critical patient-relevant outcomes in the key trials in COPD

Outcomes (units) Follow-up	Participants (number of trials)	Quality of evidence (GRADE [a])	Relative effect (95%CI)	Comments
CRQ – Fatigue Follow-up: median 9 months	30 PME/ 26 control (2)	⊕⊕⊙⊙ **Low**	0.56 (-0.07, 1.18)	Not statistically or clinically significant
CRQ – Emotional function Follow-up: median 9 months	30 PME/ 26 control (2)	⊕⊕⊙⊙ **Low**	0.37 (-0.02, 0.76)	Not statistically or clinically significant
CRQ – Dyspnoea Follow-up: median 9 months	30 PME/ 26 control (2)	⊕⊕⊙⊙ **Low**	0.41 (-0.5, 1.32)	Not statistically or clinically significant;
Change in functional exercise capacity (6MWT)) Follow-up: median 12 months	112 PME/ 105 control (3)	⊕⊕⊙⊙ **Low**	19.62 (-12.76, 52.00)	Not statistically or clinically significant;

[a] GRADE Working Group grades of evidence (Guyatt et al., 2013)
⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimated effect.
⊕⊕⊕⊙ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimated effect, but there is a possibility that it is substantially different.
⊕⊕⊙⊙ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimated effect.
⊕⊙⊙⊙ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

The assessment report stated there was insufficient evidence to determine whether the addition of PME provides additional benefit beyond PR for patients with interstitial lung disease, bronchiectasis or lung cancer.

12. Economic evaluation

The clinical evaluation suggested that, relative to standard care, the intervention has non-inferior safety and superior effectiveness. Since outcomes were assessed as having non-inferior safety compared with usual care, and likely superior effectiveness for both interventions, a cost utility analysis was undertaken for the economic evaluation. The base case of the economic evaluation was generated using a stepped process derived from the evidence**.** Table 8 provides an overview of the economic evaluation.

Table 8 Summary of the economic evaluation

Perspective	Healthcare payer
Comparator	PR versus usual care, and PM and PR versus PR
Type of economic evaluation	Cost utility
Sources of evidence	Selective review of literature and evidence in Section B (systematic review)
Time horizon	10 years, including 2 years and 5 years
Outcomes	Life years gained (QALYs)
Methods used to generate results	Decision analytic model
Cycle length	2 years
Discount rate	5% default, sensitivity at 0% and 10%
Software packages used	Microsoft Excel 2010

The model is a simple decision analytic model utilising a decision tree approach and a microsimulation where a hypothetical cohort of invidiual patients in the intervention and comparator arms are randomly assigned costs and a benefit which declines until the next treatment occurs.

An epidemiological approach was used to estimate the financial implications of the introduction of PR, or PME and PR. Prevalence, incidence and mortality were used to estimate the number of newly eligible patients and ongoing patients in each year for the proposed MBS listing. Prevalence, incidence and mortality were sourced from Australian data where available, or from international sources considered to have similar characteristics to Australia such as the United Kingdom.

The incremental costs and outcomes under the base case assumptions are outlined in Table 9. Costs and benefits were assessed over a period of 10 years.

Table 9 Incremental costs and effectiveness for treatment of COPD, horizon 10 years

	Incremental cost ($)	Incremental effectiveness (QALYs)	ICER ($/QALY)
COPD			
PR	2,361	0.317	7,451
PR with PME	2,244	0.052	43,304
ILD			
PR	1,823	0.445	4,095
PR with PME	1,753	0.040	43,941

ICER = Incremental cost effectiveness ratio

The base case of the economic evaluation was generated using a stepped economic evaluation derived from the randomised controlled trials. Bronchiectasis and lung cancer were excluded from the economic evaluation as there was limited evidence to assess the effectiveness of PR and PME programs for these groups. It is possible that the results for these groups would be similar to the economic evaluations for COPD and ILD included here; however, additional evidence is required before cost effectiveness analysis can be undertaken for these two indications.

13. Financial/budgetary impacts

The financial implications to the MBS resulting from the proposed listing of PR and PME services were estimated based on the proposed listing. The total cost of PR services was estimated to be $530.00 per patient. The MBS cost is 85% of the total fee, or $450.50. For PME, people are eligible to receive 16 sessions at a fee of $12 per session. The assessment fees are the same as for PR. The overall cost of PME, based on the proposed listing, is $322.00. The MBS cost is 85% of the total fee, or $273.70.

The financial implications to the MBS resulting from the proposed listing of PR and PME services are summarised in Table 10.

Table 10 Total costs to the MBS associated with PR and PME services, base case

	2015-16	2016-17	2017-18	2018-19	2019-20
PR					
Number of services	101,642	104,724	107,853	111,030	114,257
Sub-total cost ($m)	45.8	47.2	48.6	50.0	51.5
PME					
Number of services	67,638	69,689	71,771	73,885	76,033
Sub-total cost ($m)	18.5	19.1	19.6	20.2	20.8
Total cost of services ($m)	**64.3**	**66.3**	**68.2**	**70.2**	**72.3**

The assessment report stated there is a high degree of uncertainty surrounding the utilisation and uptake of PR and PME services, which is characterised by uncertainty surrounding the size of the eligible population given likely patient comorbidities, the uptake of PR and PME services, and the ability of PR providers to respond to the anticipated volume of the new services.

Sensitivity analyses showed that the average annual cost to the MBS and to patients of PR and PME services may range between $40.2 million and $160.6 million (base case $80.3 million). Capacity-constrained scenarios, in which the number of patients accessing the services was limited by the existing number of PR providers, projected to the MBS alone for PR and PME services in FY 2017-18 range from $12.3 million to $22.0 million.

14. Key issues from ESC for MSAC

ESC has advised that there were clinical uncertainties including:

- The majority of the evidence for pulmonary rehabilitation (PR) was found for the chronic obstructive pulmonary disease (COPD) population;
- Limited evidence was available regarding the effectiveness of PR in the interstitial lung disease (ILD), bronchiectasis or lung cancer (LC) populations. This resulted in small sample sizes, even when pooled, and a number of findings that did not reach statistical significance;
- Relatively limited evidence was available regarding the effectiveness of pulmonary maintenance exercise (PME) in the COPD population; and
- There were no studies that met the inclusion criteria that assessed the effectiveness of PME in the interstitial lung disease, bronchiectasis or lung cancer populations.

ESC advised MSAC that consideration should be given to limiting any MBS item listing to pulmonary rehabilitation for the COPD population.

ESC considered alternative means of searching the literature for relevant studies, and advised that the exclusion criteria used for the literature review resulted in the exclusion of observational studies with hospital admissions as outcomes. Although a stronger source of

evidence, the included randomised trials gave less attention to gauging whether there is an impact of PR on the use of healthcare resources.

ESC advised that the request to limit the proposed MBS items to a population with chronic stable disease rather than in the context of an acute exacerbation reduced the potential for substantial health gains and healthcare resource cost offsets. Accordingly, the evidence submitted in the pre-ESC response relating to these outcomes with PR following an acute exacerbation of COPD was not directly relevant to the application.

ESC noted that, in the absence of clear evidence of an offsetting impact of PR and PME on healthcare resource utilisation (such as avoidance of hospitalisation); the economic evaluation did not include cost offsets and was therefore conservative.

ESC noted that the main translation issues from the clinical to the economic evaluation related to the extrapolation assumptions regarding the durability of effect over time; whether the target population would change over time with respect to likely effect-modifying characteristics, such as disease severity; and whether repeated treatments would occur at different rates depending on these characteristics. ESC also noted the importance of the transformation of quality of life measured by the St George's Respiratory Questionnaire (SGRQ) to quality-adjusted life-years gain via mapping the SGRQ to the EQ-5D multi-utility instrument:

(EQ-5D = 1.102 – (0.01083 x SGRQ score).

ESC considered that the main driver of uncertainty with the cost-utility analyses arose from the clinical uncertainty regarding clinical effectiveness, especially for PME over PR alone (driven by an assumption in reduced retreatment rates over time), and for PR in CLD conditions other than COPD.

ESC noted that there was an apparently counter-intuitive result in the sensitivity analyses examining the decay function in the sensitivity analysis, and that no evidence was provided for the assertion that patients would need re-treatment every two years.

ESC advised that the potential unmet need for PR and PME services could have a significant financial impact on the MBS.

ESC advised that the main drivers of uncertainty with the large financial implications for the MBS budget related to the size of the eligible population given their likely comorbidities; the uptake of PR and PME services by this eligible population; and the ability of PR and PME providers to respond to the predicted rate of uptake. ESC also noted the potential for cost shifting by the State and Territory Governments. Such a cost shift would also involve potential out-of-pocket costs to patients for PR and PME services shifted to the private sector.

ESC noted the pre-ESC response from the applicant which foreshadowed new guidelines for Australia and New Zealand relevant to the application. ESC advised that the minor issues raised in relation to the clinical evidence base were not likely to affect the overall clinical conclusions. ESC acknowledged that an additional assessment may not be needed between the completion of PR and the commencement of PME, which would decrease the cost of rendering PME by $78.90, make the cost-effectiveness more favourable, and reduce the financial implications to the MBS.

15. Other significant factors

Nil

16. Applicant's comments on MSAC's Public Summary Document

We accept that there is limited evidence PR in lung cancer and for PME in stable chronic respiratory disease. As MSAC has pointed out, the evidence is strong for PR in COPD and we wish to stress that the evidence demonstrates similar benefits for patients in a stable condition[1] as well as immediately post-exacerbation[2,3,4]. The most recent Cochrane review[3] emphasizes the fact that trials that implemented an extensive PR program showed "mostly large and consistent effects on readmissions, health-related quality of life and exercise capacity while also suggesting an effect on mortality". The evidence also supports programs of 8 weeks or longer in duration as nearly all programs reported in the Cochrane review[5], which showed PR significantly improved exercise capacity and quality of life compared to usual care, were at least 8 weeks. As already acknowledged by MSAC, the provision of PR for people with COPD reduces length of hospital stay[6] and is cost-effective[7]. The Cochrane review[3] provides evidence that after hospitalisation for an exacerbation of COPD, patients who were randomised to PR had an OR 0.44 (0.21 to 0.91) for hospital readmissions compared to those randomised to usual care. Thus overall cost saving would be predicted, since the costs of an MBS item number for PR would be offset by reduced healthcare costs and hospital admissions for COPD. In addition, COPD is the second leading cause of avoidable hospital admissions in Australia[8]. If COPD was optimally managed in primary care, a proportion of costly hospital admissions could be avoided. PR is a key component of this optimal management as cited in the Australian Guidelines for the Management of COPD[9]. We support an early, 2 year review of the impact and outcomes of this new item number should it be introduced. We look forward to providing a detailed response to the request for further information.

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1 Griffiths T, Burr M, Campbell I, Lewis-Jenkins V, Mullins J, Shiels K, et al. Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial. *The Lancet.* 2000;355(9201):362-8

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4 Revitt O, Sewell L, Morgan MDL et al. Short outpatient pulmonary rehabilitation programme reduces readmission following a hospitalization for an exacerbation of chronic obstructive pulmonary disease. *Respirology.* 2013; 18.7. doi: 10.1111/resp.12141

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7 Griffiths T, Phillips C, Davies S, Burr M, Campbell I. Cost effectiveness of an outpatient multidisciplinary pulmonary rehabilitation programme. *Thorax.* 2001;56(10):779-84

8 Page A, Ambrose S, Glover J et al. Atlas of Avoidable Hospitalisations in Australia: ambulatory care-sensitive conditions. Adelaide: PHIDU, University of Adelaide; 2007

9 Yang IA, Dabscheck EJ, George J, Jenkins S, McDonald CF, McDonald VM, et al. The COPD-X Plan: Australian and New Zealand Guidelines for the Management of Chronic Obstructive Pulmonary Disease. Lung Foundation Australia; 2016

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website:
visit the MSAC website