



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1405.1 – MBS Item Number for Pulmonary Rehabilitation

Applicant: Lung Foundation Australia

Date of MSAC consideration: MSAC 74th Meeting, 22-23 November 2018

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting Medicare Benefit Schedule (MBS) listing of pulmonary rehabilitation (PR) for the management of chronic lung diseases (including chronic obstructive pulmonary disease (COPD), bronchiectasis and interstitial lung disease (ILD)) was received from the Lung Foundation of Australia by the Department of Health.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support the creation of specific items for the MBS funding of pulmonary rehabilitation for the management of chronic lung diseases. MSAC accepted there was a short-term clinical benefit, but the duration of benefit was uncertain, as were the optimum number of treatments and the benefits of retreatment. MSAC noted that pulmonary rehabilitation services can already be provided under the existing MBS items for chronic disease management (allied health) at no net cost to government.

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

MSAC noted the application was a resubmission to seek MBS listing of PR for patients with chronic lung disease, including COPD, bronchiectasis and ILD. PR is delivered in the community setting over 8 weeks (16 sessions of 1 hour twice weekly). PR is run with groups of up to 8 patients who have stable disease or recent exacerbation, and treatment is individualised to each patient.

MSAC recalled that it considered Application 1405 at its November 2016 meeting. Application 1405 requested public funding for PR and pulmonary maintenance exercise (PME) for the management of COPD, bronchiectasis, ILD and lung cancer. MSAC did not support the application due to limited evidence to support the clinical effectiveness of the services in these populations and uncertain cost-effectiveness. In addition, the assessment report only considered the impact of these services in patients with stable disease and excluded those who had had a recent exacerbation (the population with potentially the

greatest benefit from the proposed services). MSAC requested that a resubmission should exclude lung cancer and PME, and include additional information regarding hospitalisation rates, durability of effects and retreatment.

MSAC noted that ESC had considered the additional information to have been addressed in the resubmission, except where there was no literature to inform an update. However, MSAC noted that the ESC report had not acknowledged there were no clinically important differences in emergency department presentations, hospital admissions or length of stay between the PR and no-PR groups, and there were no data on mortality or frequency of exacerbations.

For the COPD population, MSAC noted the low to moderate quality of evidence that PR has clinically relevant benefits for dyspnoea, overall quality of life and exercise capacity, and may have benefits for fatigue and emotional function. PR did not have clinically relevant benefits for emergency department presentations, hospital admissions or hospital length of stay for patients with COPD.

For the ILD population, MSAC noted the very low-quality evidence that PR has clinically relevant benefits for exercise capacity and overall quality of life. For the bronchiectasis population, MSAC noted the very low quality evidence that PR might improve exercise capacity. There were no data to inform other outcomes.

MSAC considered that the short-term benefits of PR in terms of exercise capacity and patient-reported outcomes may be overestimated due to lack of blinding in the studies. MSAC also noted that there appeared to be no difference in outcome between the 8 and 12 week programs but no data were provided for shorter programs. MSAC noted the evidence indicating no benefit of PR at 12 months in terms of quality of life and exercise capacity. MSAC considered that PR was potentially suitable for referral to the Medical Research Future Fund (MRFF) as data on the number of sessions required, the value and frequency of repeat PR, and the effect modification on stable disease versus recent exacerbation were either unclear or no data were identified. MSAC also considered it would be informative to have Australian evidence regarding any benefits with respect to frequency of exacerbations and hospital admissions.

MSAC considered that the comparator – best care delivered by a GP or specialist without a PR program – was appropriate. MSAC noted the limited evidence to support the comparative safety of the proposed services, but considered that the risk of harm is low given the nature of the interventions.

MSAC noted that the economic analysis for the COPD population included substantial cost savings due to reduced emergency department visits and hospital admissions, but that this was not supported by the clinical evidence. There was uncertainty regarding the conversion of quality of life effect size measured using the SGRQ score to utility values for both the COPD and ILD populations. Key drivers of the economic model were effect size, decay of benefits over time and medical costs. MSAC noted uncertainties in the estimates of utilisation and uptake, and the size of the eligible population. Overall, MSAC considered that the cost-effectiveness of PR was highly uncertain. MSAC also noted the substantial cost to the MBS in the base case of \$44.6 million to \$58.7 million per year over 5 years.

MSAC noted the large number of submissions (60) from consumers supporting the application, as well as the substantial unmet clinical need in patients eligible for PR.

Overall, MSAC accepted that PR has short-term clinically important benefits with respect to patient-reported outcomes and exercise capacity, but effects wane over 6–12 months. MSAC

noted the uncertain benefit in terms of reduced hospitalisation, no benefit in terms of reduced mortality and the uncertain cost-effectiveness of PR.

MSAC considered that PR programs may best be offered under the existing MBS items for chronic disease management (CDM). As a complex intervention combining exercise and psychological aspects, PR may be similar to cardiac rehabilitation programs or back pain management programs, where it is not always known which components of the package are the most effective. CDM items allow access to a range of allied health providers, capped at 5 visits per calendar year. MSAC noted that including PR in CDM items would result in no net cost to government.

4. Background

MSAC considered Application 1405 at its November 2006 meeting. After considering the available evidence in relation to the comparative safety, clinical effectiveness and cost-effectiveness, MSAC deferred public funding for PR in COPD, bronchiectasis and ILD.

MSAC did not support public funding for PR for the management of lung cancer nor pulmonary maintenance (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.

Further information is available from the Public Summary Document (PSD) on the MSAC website at www.msac.gov.au.

5. Prerequisites to implementation of any funding advice

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

6. Proposal for public funding

The resubmission proposed three MBS items for the PR program.

Table 1 Proposed MBS item descriptors

<p>Category 8 – Miscellaneous</p> <p>MBS [item number]</p> <p>PULMONARY REHABILITATION SERVICE – INDIVIDUAL ASSESSMENT FOR GROUP SERVICES</p> <p>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:</p> <ul style="list-style-type: none"> (a) The service is provided to a person diagnosed with COPD, chronic irreversible asthma, bronchiectasis or interstitial lung disease (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
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Category 8 – Miscellaneous

- (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 or interstitial lung disease 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 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 or interstitial lung disease
- (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

Sixty consumers/care givers submitted feedback through the public consultation process conducted by PASC. The summary of findings did not identify any specific consumer impact issues that would arise from the listing of PR on the MBS; consumer feedback was supportive of the listing to improve access and affordability in the community.

8. Proposed intervention's place in clinical management

The proposed intervention is a PR program provided to eligible patients in a group setting, in the community. The intervention is expected to be provided in addition to other treatment options for their CLD.

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 (Figure 1).

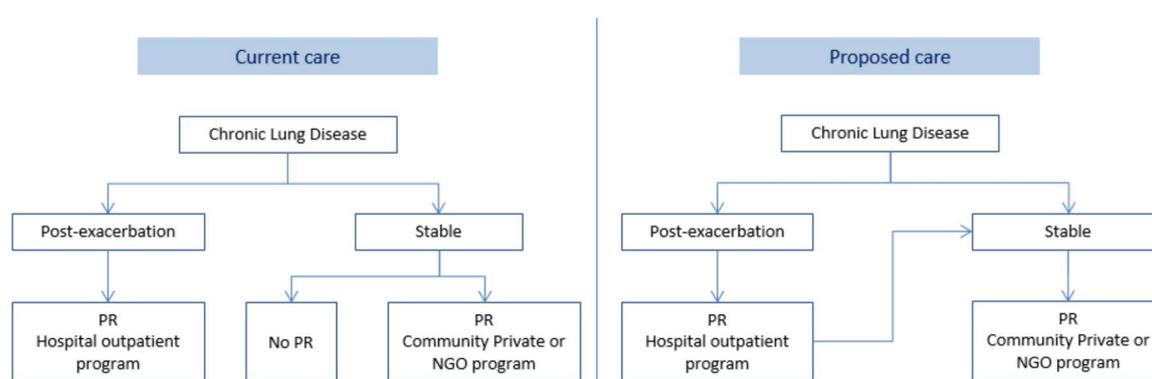


Figure 1 Clinical management algorithm for pulmonary rehabilitation (PR) relative to usual care

The intervention is proposed to be provided in community settings, in groups, to address unmet demand for PR and in locations where some of the barriers to accessing PR can be reduced such as minimising travel and improving physical access. It is proposed that the format of the PR program is a one-hour program, delivered in groups of eight, twice a week over 8 weeks (i.e. 16 sessions), repeated every 2 years.

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 programs will require mandatory facility accreditation to provide these programs in a community setting.

9. Comparator

The resubmission nominated best care (i.e. usual care) delivered by a general practitioner (GP)/specialist without PR program as the main comparator.

10. Comparative safety

The resubmission included 15 additional studies assessing the effectiveness of PR in people with COPD (n=12), and ILD (n=3). No additional studies were available for bronchiectasis.

The resubmission stated that there was limited evidence available to determine the safety of PR compared with usual care. However, given the nature of the intervention, it is expected

that risk of harm is low, and it is recognised that delivery of the PR program should be by accredited and clinically competent practitioners with the required skills and knowledge to maintain patient safety.

11. Comparative effectiveness

Table 2 outlines the primary measures used, and the corresponding minimal clinically important difference (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

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

PR vs. usual care (COPD population)

On the basis of the evidence profile (Table 3), the resubmission 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, functional exercise capacity, emergency department (ED) presentations, hospital admissions and hospital length of stay.

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	749 PR / 675 control	⊕⊙⊙⊙ Very low	0.65 (0.33, 0.97)	Mean difference exceeded MCID (statistical significance)
CRQ – Emotional function	731 PR / 659 control	⊕⊙⊙⊙ Very low	0.84 (0.23, 1.46)	Mean difference exceeded MCID (statistical significance)
CRQ – Dyspnoea	783 PR / 711 control	⊕⊙⊙⊙ Very low	1.04 (0.71, 1.37)	Mean difference and lower limit of CI exceeded MCID (statistical and clinical significance)
SGRQ – Total	649 PR / 599 control	⊕⊙⊙⊙ Very low	-8.16 (-10.31, -6.02)	Mean difference and lower limit of CI exceeded MCID (statistical and clinical significance)
6MWT	839 PR / 737 control	⊕⊙⊙⊙ Very low	51.42 (39.45, 63.40)	Mean difference and lower limit of CI exceeded MCID (statistical and clinical significance)
ED presentations	665 PR / 1228 control	⊕⊙⊙⊙ Very low	-0.58 (-1.61, 0.44)	Mean difference was not statistically significant. No MCID provided for this outcome.
Hospital admissions	665 PR / 1228 control	⊕⊙⊙⊙ Very low	-0.62 (-1.60, 0.36)	Mean difference was not statistically significant. No MCID provided for this outcome
Hospital length of stay	145 PR / 136 control	⊕⊙⊙⊙ Very low	-5.32 (-15.52, 4.88)	Mean difference was not statistically significant. No MCID provided for this outcome

6MWT = 6-minute walk test; ED = Emergency Department; CI = confidence interval; CRQ = Chronic Respiratory Disease Questionnaire; MCID = minimal clinically important difference; SGRQ = St George's Respiratory Questionnaire

^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.

PR vs. usual care (ILD population)

On the basis of the evidence profile (Table 4), the resubmission suggested that for patients with ILD 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

Outcomes (units) Follow-up	Pooled participants (number of trials)	Quality of evidence (GRADE ^a)	Relative effect (95%CI)	Comments
SGRQ - Total	40 PR / 42 Control	⊕⊕⊕⊖ Very low	-12.52 (-23.19, 1.85)	Mean difference exceeded MCID; however lower limit did not exceed MCID; statistical significance only
6MWT	57 PR / 59 Control	⊕⊕⊕⊖ Very low	47.80 (30.97, 64.62)	Mean difference and lower limit of CI exceeded 30 metres; statistical and clinical significance

6MWT = 6-minute walk test; CI = confidence interval; MCID = minimal clinically important difference; SGRQ = St George's Respiratory Questionnaire

^a GRADE Working Group grades of evidence (Guyatt et al., 2013)

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⊕⊕⊖⊖ **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.

PR vs. usual care (bronchiectasis population)

On the basis of the evidence profile (Table 5), the resubmission 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)	Quality of evidence (GRADE ^a)	Absolute effect (95%CI)	Comments
SGRQ (St George's Respiratory Questionnaire)	PR-SHAM, n=11 / PR-IMT, n=12 / control n=9	⊕⊕⊕⊖ 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	⊕⊕⊕⊖ 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

IMT = inspiratory muscle training; PR = pulmonary rehabilitation

^a GRADE Working Group grades of evidence (Guyatt et al., 2013)

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⊕⊕⊖⊖ **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.

Clinical Claim

The resubmission's proposed clinical claim is that PR in the community setting will be superior to no PR in patients with chronic lung diseases, and PR in the community setting will be at least as safe as no PR.

12. Economic evaluation

Since outcomes were assessed as having non-inferior safety compared with usual care, and likely superior effectiveness for PR, 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. The model is a simple decision analytic model utilising a decision tree approach and a microsimulation where a hypothetical cohort of individual patients in the intervention and comparator arms are randomly assigned costs and a benefit which declines until the next treatment occurs (Table 6).

Table 6 Summary of the economic evaluation

Perspective	Healthcare payer
Comparator	PR versus usual care
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 6 years
Outcomes	Life years gained (QALYs), reduction in healthcare resource use
Methods used to generate results	Decision analytic model using a decision tree.
Cycle length	2 years
Discount rate	5% default, sensitivity at 0% and 10%
Software packages used	Microsoft Excel 2016 16.0.4549.1000

PR = pulmonary rehabilitation; QALY = quality-adjusted life year

Three economic evaluations were undertaken for this assessment: patients with stable COPD at the start of PR compared with usual care; patients with a recent exacerbation of COPD at the start of PR compared with usual care; and patients with ILD at the start of PR compared with usual care. Cost and benefits were assessed over a period of 10 years (Table 7).

Table 7 Incremental costs and effectiveness for treatment of COPD and ILD, horizon 10 years

	Incremental cost (\$)	Incremental effectiveness (QALYs)	ICER (\$/QALY)
Stable COPD - PR	-8,311	0.147	Dominant
Exacerbated COPD - PR	-8,311	0.296	Dominant
ILD - PR	2,282	0.525	\$4,347

COPD = chronic obstructive pulmonary disease; ILD = interstitial lung disease; ICER = incremental cost-effectiveness ratio; PR = pulmonary rehabilitation; QALY = quality-adjusted life year

The results of the economic modelling indicate that PR is cost-effective for patients for both COPD and ILD. Incremental cost per QALY for stable and exacerbated COPD patients was dominant and \$4,347 for ILD patients. The results of the model were most sensitive to the estimates of the effect size, the benefit decay function, the time horizon and the treatment costs.

13. Financial/budgetary impacts

An epidemiological approach has been used to estimate the financial implications of the introduction of PR to the MBS (Table 8). 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.

Table 8 Total costs to the MBS associated with pulmonary rehabilitation (PR) services, base case

-	2017-18	2018-19	2019-20	2020-21	2021-22
Number of services	99,019	107,048	114,520	122,260	130,338
Sub-total cost (\$m)	52.5	56.7	60.7	64.8	69.1
Total cost of services (\$m)	44.6	48.2	51.6	55.1	58.7

It is recognised that implementing PR services may have financial implications for other parts of the Australian Government's health budget. This includes potential flow on effects for hospitals, other MBS services, potential medication usage and the like. Evidence was only available to assess the impact of PR on emergency department presentations and hospital admissions for COPD patients (Table 9).

Table 9 Reduction in Emergency Department and Hospital Admissions costs

-	2017-18	2018-19	2019-20	2020-21	2021-22
Base case					
Reduction in Emergency Department costs (\$m) ^a	18.9	19.2	19.6	20.0	20.3
Reduction in Hospital Admission costs (\$m) ^a	148.2	150.9	153.6	156.6	159.6
Total reduction in costs (\$m)	167.12	170.12	173.22	176.51	179.90
Medical costs 20% higher					
Reduction in Emergency Department costs (\$m)	22.7	23.1	23.5	23.9	24.4
Reduction in Hospital Admission costs (\$m)	177.9	181.1	184.4	187.9	191.5
Total reduction in costs (\$m)	200.54	204.14	207.87	211.81	215.89
Medical costs 20% lower					
Reduction in Emergency Department costs (\$m)	15.1	15.4	15.7	16.0	16.3
Reduction in Hospital Admission costs (\$m)	118.6	120.7	122.9	125.2	127.7
Total reduction in costs (\$m)	133.70	136.10	138.58	141.21	143.92

^a Pooled results were not statistically significant (COPD population)

There is a high degree of uncertainty surrounding the utilisation and uptake of PR services, which is characterised by uncertainty surrounding the number of patients that would be eligible due to comorbidities, the uptake of PR services, as well as the ability of PR providers to respond to the introduction of the new services. The resubmission stated that the evidence was only available to assess the impact of PR on ED presentations and hospital admissions for patients with COPD. Sensitivity analyses showed that the average annual cost of PR services may range between \$30.4 million to \$121.5 million. Capacity constrained scenarios where the number of patients accessing the services was limited based on the existing number of PR providers suggested that the average annual cost to the MBS of PR services may be around \$59.4 million to \$124.0 million.

14. Key issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
Narrowed patient population and intervention	Compared with the original application, the removal of the pulmonary maintenance exercise component mitigates some of MSAC's previous concerns regarding the strength of the evidence supporting the application.
Evidence of pulmonary rehabilitation (PR) effectiveness	<p>There is good evidence for effectiveness of pulmonary rehabilitation (PR) in patients with chronic obstructive pulmonary disease (COPD), but relatively limited evidence on its effectiveness for patients with bronchiectasis and interstitial lung disease (ILD).</p> <p>The effectiveness of PR for bronchiectasis and ILD patient populations was deemed to be at least non-inferior relative to usual care.</p> <p>Separating the COPD, bronchiectasis and ILD populations may not be practicable or clinically desirable.</p> <p>Although evidence is scant, it is likely that PR benefits COPD patients regardless of whether they have stable disease or a recent exacerbation.</p> <p>Based on evidence, 8 weeks is likely to be an appropriate duration of PR for COPD.</p>
Safety	It is highly unlikely that safety will be an issue if proper clinical governance is in place.
MBS item descriptor	The proposed structure is an appropriate template for the further development of MBS PR items for people with chronic lung disease.
Uptake	It is unclear whether uptake will increase with increased capacity following MBS listing.
Leakage	The potential for leakage is low due to capacity restraints.
Retreatment	It is unclear whether retreatment is accounted for in eligible patients (this should be clarified by the applicant before the MSAC meeting).
Cost savings	Cost savings due to reduced emergency department and hospital admissions may be lower than estimated in the long term due to retreatment.

ESC Discussion

ESC noted that Application 1405.1 is a resubmission that proposes Medicare Benefits Schedule (MBS) listing of a PR program for patients with chronic lung disease, including COPD, bronchiectasis and ILD.

Application 1405 requested public funding for PR for the management of lung cancer, and PME for the management of COPD, bronchiectasis, ILD and lung cancer. MSAC did not support the application due to limited evidence to support the clinical effectiveness of the services in these populations and uncertain cost-effectiveness. In addition, the assessment report only considered the impact of these services in patients with stable disease and excluded those who had had a recent exacerbation (the population with potentially the

greatest benefit from the proposed services). MSAC requested additional information for the resubmission.

ESC noted that the resubmission is for patients with COPD, bronchiectasis or ILD (not lung cancer). It includes PR only, not PME, and also includes patients who have had a recent exacerbation. Group sessions would be run with up to eight patients; ESC noted a lack of clinical evidence to support this group size but accepted that it was based on efficiencies of staff to patient ratios.

ESC reviewed the patient population, intervention and proposed MBS item descriptors, as per the original application (with the exclusion of lung cancer patients). ESC noted the significant unmet need for these populations, and the importance of including GP referral rather than specialist-only referral to avoid issues of access and inequity. ESC recalled that there was limited evidence to support the comparative safety of the proposed services, but the risk of harm is low given the nature of the interventions. ESC noted that the services should be delivered by accredited and clinically competent practitioners to maintain patient safety. The resubmission included 12 additional studies on COPD and 3 additional studies on ILD. No additional studies were available for bronchiectasis.

ESC noted the data on comparative effectiveness for patients with COPD. ESC noted that the level of evidence using GRADE methodology was very low in the assessment, but the applicant had stated that the same body of evidence referred to in published guidelines was assessed as moderate quality. ESC considered that GRADE assessments can vary depending on their purpose, and that the actual quality of evidence was likely to be somewhere between very low and moderate.

ESC noted that the point estimates of PR effectiveness were clinically relevant and indicated that PR had a beneficial effect, although there was substantial heterogeneity between studies. There was also substantial heterogeneity between studies in the subgroup analyses, leading to wide effect estimates, particularly for program duration and disease severity. However, ESC considered that the effect was consistent regardless of COPD severity. ESC concluded that program duration of 8 weeks would be appropriate. Studies on patients with ILD and bronchiectasis showed improvements in functional status but not quality of life. ESC noted several translation issues but acknowledged that the applicant had included studies to adequately address these.

In the economic evaluation, revisions to the model for the resubmission included changing the base case to reflect changes to the PICO, considering transitions for severity after 2 years, and including cost savings due to reduced emergency department and hospital admissions. ESC considered these changes to be appropriate. When cost savings are included, PR becomes dominant for both stable disease and recent exacerbations. ESC discussed whether the proportion of patients with severe disease may be more likely to be treated in a hospital outpatient program, but this was not considered likely (estimated to be 1-2 in 12 patients), so the severe group should remain in the model. ESC noted that effectiveness data do not support a long-term model, and a 2-year model should be considered. ESC noted that it was unclear how the applicant had incorporated retreatment rates and effectiveness over time – this should be clarified with the applicant before proceeding to MSAC, as it may affect the costs.

ESC noted that the resubmission provided an updated financial analysis, which also included large cost savings due to reduced hospital and emergency department admissions. However, it is unclear how this was calculated and whether the inputs were consistent with the economic model. Specifically, rates of retreatment need to be clarified with the applicant for the financial estimates as well as the economic model. Cost savings may be lower than

estimated in the long term due to retreatment. It was noted that retreatment is an important consideration, given that the effects of PR wane after 2 years due to deconditioning of skeletal muscle, but chronic lung disease is a long-term condition so retreatment is likely. ESC noted that existing MBS items for chronic care do not include group treatment, so retreatment would require its own MBS item.

ESC noted that the potential for leakage is low due to capacity constraints. It is unclear whether current services would be able to quickly scale up to meet demand, and whether uptake will increase following increased capacity after listing.

ESC noted that consumer input had been provided in the resubmission. ESC also noted that many patients with COPD have comorbidities that may make it difficult for them to follow the PR program diligently in order to avoid exacerbations. However, ESC also noted that PR is tailored to the individual patient, which was considered to be advantageous.

ESC concluded that, although the majority of evidence relates to patients with COPD, this could be generalised to patients with ILD or bronchiectasis, and it may be impractical to separate these groups. ESC noted the consistency of the effect of PR regardless of disease severity, but that issues relating to retreatment need to be addressed. A 2-year time horizon was considered to be helpful for decision making.

Finally, ESC noted the uncertainty around financial estimates and the potentially high cost to the MBS, and questioned whether a different funding mechanism may be more appropriate.

In summary, ESC considered that the reduced scope of the resubmission addressed many of the concerns expressed by MSAC following the original submission. ESC considered that there was evidence of effectiveness of PR for the COPD population, and that it may be impractical and undesirable to separate this from the bronchiectasis and ILD populations (for which there are fewer studies). Uncertainties remained regarding uptake and retreatment.

15. Other significant factors

Nil

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

We note the discrepancy in conclusions reached by ESC and MSAC. ESC concluded that on the basis of the evidence profile 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, functional exercise capacity, and healthcare utilisation (ED presentations, hospital admissions and hospital length of stay). In contrast, MSAC stated that PR did not have clinically relevant benefits for healthcare utilisation for COPD patients. Reduction in hospitalisations in the 12 months following PR is evidenced by a Cochrane Review (Puhan et al 2016) and also Australian data (Australian and New Zealand Pulmonary Rehabilitation Guidelines, Alison et al 2017) which is inclusive of studies of PR delivered in community-based facilities.

As requested by ESC, we proposed an evidence-based model of re-treatment to support the small number (approx 10%) of patients who may require repeat PR within 2 years (Heng et al, 2014). We feel our Application has been disadvantaged by the focus and importance placed by ESC on a retreatment model and we intend to correspond further with MSAC in relation to this.

MSAC proposed existing MBS items for chronic disease management (CDM) as being a suitable pathway for patients to access PR in the community. The CDM items are not appropriate for PR as they are intended to support patient access to a variety of individual allied health services, for chronic conditions requiring multidisciplinary care, and only provide 5 sessions per calendar year. PR requires 2-3 sessions/week for 8 weeks in a supervised group setting. Utilising CDM items (all 5 sessions) would not only be inadequate for PR but would also prohibit patients accessing other allied health services for the remainder of the calendar year.

Given the above, Lung Foundation Australia intends to submit a proposal for consideration at the June MSAC Executive Meeting. This proposal will aim to seek MSAC advice on re-submission or a fast-tracked application for MBS item numbers for one PR program (with no retreatment) specifically for patients with COPD.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website:
[visit the MSAC website](#)