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Outpatient Pulmonary Rehabilitation

I Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

A single course of pulmonary rehabilitation in the outpatient ambulatory care setting **may be considered medically necessary** for the treatment of chronic pulmonary disease for individuals with moderate-to-severe disease (See Policy Guidelines) who are experiencing disabling symptoms and significantly diminished quality of life despite optimal medical management.

A single course of pulmonary rehabilitation **may be considered medically necessary** in an outpatient ambulatory care setting as a preoperative conditioning component for those considered appropriate candidates for lung volume reduction surgery or for lung transplantation.

Pulmonary rehabilitation programs **may be considered medically necessary** following lung transplantation.

Pulmonary rehabilitation programs **are considered experimental, investigational and/or unproven** following other types of lung surgery, including but not limited to lung volume reduction surgery and surgical resection of lung cancer.

Pulmonary rehabilitation programs in the outpatient ambulatory care setting **are considered experimental, investigational and/or unproven** for the treatment of post-acute sequelae of SARS-CoV-2 infection.

Multiple courses of pulmonary rehabilitation **are considered not medically necessary**:

- As maintenance therapy in individuals who initially respond, or
- In individuals who fail to respond, or
- Whose response to an initial rehabilitation program has diminished over time.

Home-based pulmonary rehabilitation programs **are considered experimental, investigational and/or unproven.**

Pulmonary rehabilitation programs **are considered experimental, investigational and/or unproven** in all other situations.

Policy Guidelines

Moderate to severe chronic obstructive pulmonary disease may be suggested by Stage 2 or worse on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. (42) A significantly diminished quality of life may be suggested by clinical symptoms equivalent to a Grade 2 or higher on the Modified Medical Research Council (mMRC) Dyspnea Scale as outlined below or a clinically equivalent assessment utilizing another instrument (COPD Assessment Test, Baseline Dyspnea Index, modified Borg Scale, etc.):

- Grade 2: Walks slower than people of the same age because of dyspnea or has to stop for breath when walking at own pace;
- Grade 3: Stops for breath after walking 100 yards (91 m) or after a few minutes;
- Grade 4: Too dyspneic to leave house or breathless when dressing.

Pulmonary rehabilitation is typically provided for 4-6 hours per week for up to 6-8 weeks.

A pulmonary rehabilitation outpatient program is a comprehensive program that generally includes team assessment, individual training, psychosocial intervention, exercise training, and follow-up. The overall length of the program and the total number of visits for each component may vary from program to program.

- Team assessment includes input from a physician, respiratory care practitioner, nurse, and psychologist, among others.
- Individual training includes breathing retraining, bronchial hygiene, medications, and proper nutrition.
- Psychosocial intervention addresses support system and dependency issues.
- Exercise training includes strengthening and conditioning, and may include stair climbing, inspiratory muscle training, treadmill walking, cycle training (with or without ergometer), and supported and unsupported arm exercise training. Exercise conditioning is an essential component of pulmonary rehabilitation. Education in disease management techniques without exercise conditioning does not improve health outcomes of individuals who have chronic obstructive pulmonary disease.
- Follow-up to a comprehensive outpatient pulmonary rehabilitation program may include supervised home exercise conditioning.

Candidates for pulmonary rehabilitation should be medically stable and not limited by another serious or unstable medical condition. Contraindications to pulmonary rehabilitation include severe psychiatric disturbance (e.g., dementia, organic brain syndrome) and significant or unstable medical conditions (e.g., heart failure, acute cor pulmonale, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke).

Description

Pulmonary rehabilitation is a multidisciplinary approach to reducing symptoms and improving quality of life in individuals with compromised lung function. Pulmonary rehabilitation programs generally include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Pulmonary Rehabilitation

In 2013, the American Thoracic Society and the European Respiratory Society defined pulmonary rehabilitation as a "comprehensive intervention based on a thorough patient assessment followed by patient-tailored therapies that include, but are not limited to exercise training, education, and behavior change." (1) Pulmonary rehabilitation programs are intended to improve patient functioning and quality of life. Most research has focused on patients with chronic obstructive pulmonary disease, although there has been some interest in patients with asthma, cystic fibrosis, or bronchiectasis.

Pulmonary rehabilitation is also routinely offered to patients awaiting lung transplantation and lung volume reduction surgery. Pulmonary rehabilitation before lung surgery may stabilize or improve patients' exercise tolerance, teach patients techniques that will help them recover

after the procedure, and allow health care providers to identify individuals who might be suboptimal surgical candidates due to noncompliance, poor health, or other reasons.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

This medical policy focuses on comprehensive, multidisciplinary programs that include an exercise component plus other modalities. Where there is a lack of evidence on multidisciplinary pulmonary rehabilitation programs, interventions that are strictly exercise will be considered. In this regard, exercise constitutes the primary intervention that improves outcomes and that if exercise alone improves outcomes, then it would be expected that exercise plus other modalities will improve outcomes to the same degree or greater.

Chronic Obstructive Pulmonary Disease

Clinical Context and Therapy Purpose

The purpose of a single course of outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without outpatient pulmonary rehabilitation, in individuals with moderate-to-severe chronic obstructive pulmonary disease (COPD).

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with moderate-to-severe COPD.

Interventions
The therapy being considered is a single course of outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators
Comparators of interest include usual care without outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, bronchodilators, and steroid regimens.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of outpatient pulmonary rehabilitation as a treatment for moderate-to-severe COPD has varying lengths of follow up. While studies described below all reported at least one outcome of interest, at least 6 months duration of follow-up is desirable to fully assess outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Numerous RCTs and several systematic reviews of RCTs have been published. Most recently, Puhan et al. (2016) published a Cochrane review that evaluated pulmonary rehabilitation (PR) programs for patients who had an exacerbation of COPD. (2) To be included, the rehabilitation program had to begin within 3 weeks of initiating exacerbation treatment and had to include physical exercise. Twenty trials (N=1477 participants) met inclusion criteria. Rehabilitation was outpatient in 6 trials, inpatient in 12 trials, both inpatient and outpatient in 1 trial, and home-based in 1 trial. In a pooled analysis of 8 trials, there was a statistically significant reduction in the primary outcome (rate of hospital admissions) for PR compared with usual care (odds ratio [OR], 0.44; 95% confidence interval [CI], 0.21 to 0.91). Several secondary outcomes also favored the PR group. In a pooled analysis of 13 trials, there was a significantly greater improvement from baseline in the 6-minute walk distance (6MWD) in the PR groups (mean difference [MD], 62.4 meters; 95% CI, 38.5 to 86.3). Moreover, a pooled analysis of health-related quality of life found significantly greater improvement after PR versus control (MD=-7.80; 95% CI, -12.1 to -

3.5). However, in a pooled analysis of 6 trials, there was no statistically significant difference between groups in mortality rate (OR=0.68; 95% CI, 0.28 to 1.67). Trials had a mean duration of only 12 months which may not be long enough to ascertain a difference in mortality rates. Participants in all the studies included in this analysis could not be blinded and this may have introduced bias for outcomes to some degree. Also, some studies did not assess the outcomes of those participants who dropped out of the PR or were lost to follow-up.

McCarthy et al. (2015) published a Cochrane review that included RCTs assessing the effect of outpatient or inpatient PR on functional outcomes and/or disease-specific quality of life (QOL) in patients with COPD. (3) Pulmonary rehabilitation programs had to be at least 4 weeks in duration and include exercise therapy with or without education and/or psychological support. Sixty-five RCTs (total N=3822 participants) met inclusion criteria. Severity of COPD was not specifically addressed by Cochrane reviewers, but article titles suggest a focus on patients with moderate-to-severe COPD. In pooled analyses, there was statistically significantly greater improvement in all outcomes in PR groups than in usual care groups. Also, between-group differences on key outcomes were clinically significant. For example, on all 4 important domains of the validated Chronic Respiratory Questionnaire (dyspnea, fatigue, emotional function, and mastery) the effect was larger than the accepted minimal clinically important difference (MCID) of 0.5 units. Also, the between-group difference in maximal exercise capacity exceeded the minimal clinically important difference of 4 watts, and the between-group difference in 6MWD (a mean difference of 43.93 meters) was considered clinically significant.

Rugbjerg et al. (2015) published a systematic review that identified 4 RCTs (N=489). (4) Inspection of the trial designs for the 4 RCTs indicated that none evaluated a comprehensive PR program in patients who met criteria for mild COPD. Rather than being comprehensive PR programs, all interventions were exercise-based. One intervention included an educational component, and another used a qigong intervention, which included breathing and meditation in addition to exercise. Also, none of the RCTs enrolled a patient population with only mild COPD. Roman et al. (2013) (5) and Gottlieb et al. (2011) (6) included patients with moderate COPD, Liu et al. (2012) (7) included patients with mild-to-moderate COPD, and van Wetering et al. (2010) (8) included patients with moderate-to-severe COPD. Conclusions cannot be drawn about the efficacy of PR in patients with mild COPD from this systematic review.

Tables 1 and 2 summarize the characteristics and results of Puhan et al. (2016) (2) and McCarthy et al. (2015) studies. (3) The study by Rugbjerg et al. (2015) (4) is not included in Tables 1 and 2 because of study overlap.

Table 1. Systematic Review Characteristics

Study	Dates	Trials	Participants	Intervention	N (Range)	Design	Duration
Puhan et al. (2016) (2)	Up to Mar 2010*; March	20	PR patients (N=1477) that met inclusion criteria and	Inpatient and outpatient PR	1477 (26-389)	RCT	3-18 mo

	2010 to Oct 2015		had an exacerbation of COPD				
McCarthy et al. (2015) (3)	Up to Jul 2004; Jul 2004 to Mar 2014	65	Patients (N=3822) with mean ages ranging from 31.3 to 74.1 years; in-patient, out-patient, community-based or home-based rehabilitation program of ≥4 weeks on continuous oxygen; those with clinical diagnosis of moderate-to-severe COPD and best recorded FEV_1 <0.7; exercise therapy/ intervention (rehabilitation) vs. standard care (control)	Outpatient or inpatient PR ≥4 wk that includes exercise therapy +/- education and psychological support (range of PR exercise program=7 wk to 6 mo)	3822 (12-350)	RCT	≥24 mo

COPD: chronic obstructive pulmonary disease; FEV_1: forced expiratory volume in 1 second; PR: pulmonary rehabilitation; RCT: randomized controlled trial; mo: month; wk: week.
* A previous review included information from studies up to this date.

Table 2. Systematic Review Results

Study	Rate of Hospital Readmission	6-minute Walk Distance
Puhan et al. (2016) (2)	N=810; 8 trials	N=819; 13 trials
N=1477		
PR compared with usual care	Relative effect (95% CI) OR=0.44 (0.21 to 0.91)	Change from baseline, random effects (95% CI) MD=62.38 meters (38.45 to 86.31)
McCarthy et al. (2015) (3)	NR	N=1879; 38 studies
N=3822		
PR compared with usual care	NR	Random, effect size (95% CI) MD=43.93 (32.64 to 55.21)

CI: confidence interval; MD: mean difference; NR: not reported; OR: odds ratio; PR: pulmonary rehabilitation.

Section Summary: Chronic Obstructive Pulmonary Disease

Multiple meta-analyses of RCTs have, for the most part, found improved outcomes (i.e., functional ability, QOL) in patients with moderate-to-severe COPD who have had a

comprehensive PR program in the outpatient setting. There is limited evidence on the efficacy of repeated and/or prolonged PR programs, and that evidence is mixed on whether these programs improve additional health outcome benefits.

Idiopathic Pulmonary Fibrosis

Clinical Context and Therapy Purpose

The purpose of a single course of outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without outpatient PR, in individuals with idiopathic pulmonary fibrosis.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with idiopathic pulmonary fibrosis.

Interventions

The therapy being considered is a single course of outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators

Comparators of interest include usual care without outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medication therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of outpatient pulmonary rehabilitation as a treatment for idiopathic pulmonary fibrosis has varying lengths of follow up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least 3 months of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Three systematic reviews with meta-analyses have evaluated the use of pulmonary rehabilitation in patients with idiopathic pulmonary fibrosis. Tables 3 and 4 summarize the characteristics and results of the systematic reviews, respectively.

A Cochrane review by Downman et al. (2021) evaluated the efficacy and safety of pulmonary rehabilitation in patients with interstitial lung disease in terms of short-term (≤6 months) and long-term (6-11 months) outcomes; a priori subgroup analyses were performed for participants with idiopathic pulmonary fibrosis. (9) In patients with idiopathic pulmonary fibrosis, there were significant improvements in 6MWD and Saint George's Respiratory Questionnaire results with pulmonary rehabilitation versus standard treatment in the short-term, but the benefits did not last in the long term (see Table 4). Additionally, pulmonary rehabilitation improved dyspnea scores based on the modified Medical Research Dyspnea Scale (0–4 point scale; 0 indicates no dyspnea) in studies with a follow-up duration of 8 to 12 weeks (MD=-0.41; 95% CI, -0.74 to 0.09). Long-term survival was not improved with pulmonary rehabilitation versus standard treatment in studies with a follow-up of 6 to 11 months (OR=0.32; 95% CI, 0.08 to 1.19).

The meta-analysis by Yu et al. (2019) evaluated pulmonary rehabilitation for exercise tolerance and quality of life for patients with idiopathic pulmonary fibrosis. (10) They analyzed results of 5 RCTs (N=190). In addition to better 6MWD and Saint George's Respiratory Questionnaire results with pulmonary rehabilitation than with standard treatment (see Table 4), forced vital capacity was significantly higher for the pulmonary rehabilitation group (MD=3.69; 95% CI, 0.16 to 7.23; p=.04). However, pulmonary rehabilitation had no significant effect on lung diffusing capacity determined by the single-breath technique (MD=3.02; 95% CI, -0.38 to 6.42; p=.08). The results of this study suggest the benefits of pulmonary rehabilitation lie in its effect on quality of life, and it may slow the decline of lung function in patients with idiopathic pulmonary fibrosis.

Cheng et al. (2018) looked at 4 RCTs and evaluated results in terms of short-term (9-12 weeks) and long-term (6-12 months) outcomes. (11) They found significant benefits in the short term as measured by 6MWD and Saint George's Respiratory Questionnaire, but the benefits did not last in the long term.

Table 3. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Downman et al. (2021) (9)	Through April 2020	21	n=10 studies of patients with mixed ILD etiologies, including IPF; n=9 studies of patients with IPF only; n=5 studies of other ILD etiologies	NR	RCTs	3 wk-4 years

Yu (2019) et al. (10)	2008-2016	5 (7 articles)	Patients with diagnosed IPF	190 (21-32)	RCTs	10 wk-11 mo
Cheng et al. (2018) (11)	2008-2017	4 (5 articles)	Patients with diagnosed IPF	142 (21-61)	RCTs	9 wk-11 mo

ILD: interstitial lung disease; IPF: idiopathic pulmonary fibrosis; RCT: randomized controlled trial; mo: month; NR: not reported; wk: week.

Table 4. Systematic Review Results

Study	**6-minute Walk Distance**		**SGRQ**	
Downman et al. (2021) (9)	8 trials	3 trials	6 trials	2 trials
	Short-term (3-12 weeks)	**Long-term studies (6-11 months)**	**Short-term (8 wk-6 months)**	**Long-term (6-11 months)**
MD, fixed effects	37.25	1.64	-7.91	-3.45
95% CI	26.16 to 48.33	-24.89 to 28.17	-10.55 to -5.26	-7.43 to 0.52
P-value	<.00001	.9	<.00001	.09
Yu et al. (2019) (10)	5 trials		3 trials	
MD, fixed effects	48.60		-7.87	
95% CI	29.03 to 68.18		-11.44 to -4.30	
P-value	<0.001		0.031	
Cheng et al. (2018) (11)	4 trials	2 trials	3 trials	2 trials
	Short-term (9-12 weeks)	**Long-term (6-12 months)**	**Short-term (9-12 weeks)**	**Long-term (6-12 months)**
WMD, random effects	38.38	17.02	-8.4	-3.45
95% CI	4.64 to 72.12	-26.87 to 60.81	-11.4 to -5.36	-8.55 to 1.64
P-value	<0.05	0.43	<0.001	0.088

CI: confidence interval; MD: mean difference; SGRQ: Saint George's Respiratory Questionnaire (lower score is better); WMD: weighted mean difference.

Section Summary: Idiopathic Pulmonary Fibrosis

Three systematic reviews of RCTs have evaluated PR programs for patients with idiopathic pulmonary fibrosis. Significant differences favoring pulmonary rehabilitation over standard care were seen in 6MWD in the short term. Starting at 3 months post-intervention, outcomes did not differ between groups.

Bronchiectasis

Clinical Context and Therapy Purpose

The purpose of a single course of outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without outpatient pulmonary rehabilitation, in individuals with bronchiectasis.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with bronchiectasis.

Interventions

The therapy being considered is a single course of outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators

Comparators of interest include usual care without outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medication therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of outpatient pulmonary rehabilitation as a treatment for bronchiectasis has varying lengths of follow up. While studies described below all reported at least one outcome of interest, 3 to 6 months duration of follow-up is desirable to fully assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Review

Lee et al. (2017) published a systematic review of RCTs on PR in patients with non-cystic fibrosis bronchiectasis. (12) Reviewers identified 4 RCTs. They selected studies of exercise-only interventions as well as exercise combined with education and/or another intervention. The control intervention had to be something other than exercise based. A pooled analysis of 3

RCTs immediately after an 8-week intervention found significantly greater incremental shuttle walk distance in the intervention compared with the control group (MD=66.6; 95% CI, 51.8 to 81.7). A pooled analysis of 2 trials found significantly greater improvement in the St. George's Respiratory Questionnaire (SGRQ) score postintervention (MD=-4.65; 95% CI, -6.70 to -2.60). There was no significant difference postintervention on the Leicester Cough Questionnaire (total) scores. Reviewers did not conduct meta-analyses of data beyond the immediate postintervention period.

Randomized Controlled Trials

Araújo et al. (2022) conducted an RCT in Brazil on the effects of pulmonary rehabilitation in individuals with bronchiectasis. (13) Adults with bronchiectasis confirmed with high-resolution computer tomography were randomized to receive outpatient pulmonary rehabilitation (3 weekly sessions; n=20) or a control intervention consisting of usual care, airway clearance therapy, and breathing exercises (n=21) for 3 months. Physical capacity (measured by 6MWD), dyspnea, quality of life (measured by the SGRQ), fatigue, respiratory muscle strength, and fibrinogen levels were measured before and after treatment. At the end of the 3-month period, the 6MWD increased by a mean of 54 meters in the rehabilitation group versus 12 meters in the control group ($p<.01$). Additionally, fibrinogen showed a significant reduction in the rehabilitation group compared to control (-92.8 vs. -47.1 mg/dl; $p<.01$) at 3 months from baseline; quality of life improved at a greater magnitude in the rehabilitation group (-7.5 vs. 3.2; $p<.01$), which exceeded the minimal clinically important difference of 4 points. This study was limited by its small sample size and short follow-up period.

Section Summary: Bronchiectasis

A systematic review of RCTs on PR for patients with bronchiectasis found that some, but not all, outcomes improved more with PR than with a non-exercise control condition immediately post-intervention. Similarly, an RCT published after the systematic review found that 6MWD and quality of life scores increased with pulmonary rehabilitation compared to a non-exercise control group. Limited observational data would suggest that outcomes in patients with other respiratory conditions may benefit, but likely not as much as COPD patients.

Preoperative Pulmonary Rehabilitation Programs

Clinical Context and Therapy Purpose

The purpose of a single course of preoperative outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without outpatient pulmonary rehabilitation, in individuals with scheduled lung surgery for volume reduction, transplantation, or resection.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with scheduled lung surgery for volume reduction, transplantation, or resection.

Interventions
The therapy being considered is a single course of preoperative outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators
Comparators of interest include usual care without outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medication therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of preoperative outpatient pulmonary rehabilitation as a treatment for scheduled lung surgery for volume reduction, transplantation, or resection has varying lengths of follow up. While studies described below all reported at least one outcome of interest, 3 to 6 months duration follow-up are desirable to assess outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Lung Volume Reduction Surgery (LVRS)
Pulmonary rehabilitation prior to LVRS represents a distinct subset of patients with COPD, and the National Emphysema Treatment Trial required all candidates to undergo a vigorous course of PR. The final National Emphysema Treatment Trial results supported the treatment effectiveness in a subset of patients with COPD. (14)

Lung Transplantation
A systematic review of the literature on PR for lung transplant candidates was published by Hoffman et al. (2017). (15) Interventions had to include exercise training but did not have to be part of a comprehensive PR program and could have taken place in the inpatient or outpatient setting. Reviewers identified 6 studies (2 RCTs and 4 case series). Both RCTs evaluated the impact of exercise (not comprehensive PR) on outcomes; additionally, 1 was conducted in the inpatient setting and included only 9 patients. Conclusions on the impact of a comprehensive PR program prior to lung transplantation on health outcomes cannot be drawn from this systematic review.

Lung Cancer Resection

Randomized Controlled Trials

Several small RCTs have evaluated preoperative PR for patients undergoing lung cancer resection. Morano et al. (2013) conducted a single-blind study in Brazil. (16) Patients with non-small-cell lung cancer eligible for lung resection were randomized to 4 weeks of an exercise-only PR program (5 sessions per week) or to chest physical therapy; there were 12 patients in each group. All patients in the PR group and 9 of 12 in the chest physical therapy group subsequently underwent surgery (the other 3 patients had inoperable disease). Several short-term postoperative outcomes were assessed. Patients in the PR group spent significantly fewer days in the hospital (mean, 7.8 days) than patients in the chest physical therapy group (mean, 12.2 days; p=0.04). In addition, patients in the PR group spent fewer days with chest tubes (mean, 4.5 days) than the physical therapy group (mean, 7.4 days; p=0.03). The trial did not assess longer-term functional outcomes after surgery.

Benzo et al. (2011) conducted 2 small exploratory RCTs evaluating PR before lung cancer resection. (17) Eligibility criteria included having moderate-to-severe COPD and being scheduled for lung cancer resection either by open thoracotomy or by video-assisted thoracoscopy. The first trial had poor recruitment, enrolling only 9 patients. The second study enrolled 19 patients into a 10-session, preoperative PR program (n=10) or usual care (n=9). The mean number of days in the hospital was 6.3 in the PR group and 11.0 in the control group (p=0.058). Three (33%) patients in the PR group and 5 (63%) patients in the control group experienced postoperative pulmonary complications (p=0.23). The trial sample size was likely too small to detect statistically or clinically significant differences between groups. Trialists recommended conducting a larger multicenter randomized trial in this population.

Tables 5 and 6 summarize the characteristics and results of the RCTs, respectively.

Table 5. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Morano et al. (2013) (16)	Brazil	1	March 2008 to Mar 2011	Patients undergoing lung cancer resection and who have non-small cell lung cancer resection by open thoracotomy (or video-assisted); and previous pulmonary disease, interstitial lung disease, or	PR: Strength/ endurance training + education; 5 sessions/wk for 4 wk (20 sessions; n=12)	CPT breathing exercises + education; 5 sessions/ wk for 4 wk (20 sessions; n=12)

				obstructive airway disease, with impaired respiratory function by spirometry (N=24)		
Benzo et al. (2011) (17)	United States	2	NR	Patients who require lung cancer resection by open thoracotomy (or video-assisted); moderate-to-severe COPD (N=19)	PR: 10 preoperative PR sessions involving customized protocol with nonstandard components (exercise prescription based on self-efficacy, inspiratory muscle training; slow breathing) (n=10)	Usual care (n=9)

COPD: chronic obstructive pulmonary disease; CPT: chest physical therapy; NR: not reported; PR: pulmonary rehabilitation; RCT: randomized controlled trial; wk: week.

Table 6. Summary of Key RCT Results

Study	Hospital Stay at 4 Weeks, mean (SD)	ICU Stay (days) at 4 Weeks	Postoperative Hospitalizations
Morano et al. (2013) (16)	N=31 patients at t=0; 24 in analysis; 21 in final analysis	N=31 patients at t=0; 24 in analysis; 21 in final analysis	NR
PR (exercise) n=12	7.8 (4.8)	2 (2-3)[a]	NR
CPT (control) n=9	12.2 (3.6)	2 (2-4.5)[a]	NR
P-value	0.04	0.20	NR
Benzo et al. (2011) (17)	N=17	N=17	NR
PR arm	6.3 (3.0)	0.6 (1.9)[b]	NR
Usual care	11.0 (6.3)	1.7 (3.1)[b]	NR
P-value	0.06	0.39	NR

CPT: chest physical therapy; ICU: intensive care unit; NR: not reported; PR: pulmonary rehabilitation; RCT: randomized controlled trial; SD: standard deviation.

[a] Median (25th-75th percentile).

[b] Mean (SD).

The purpose of Tables 7 and 8 is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Morano et al. (2013) (16)				3. No CONSORT reporting of harms was addressed	1. Short duration of follow-up (4-weeks)
Benzo et al. (2011) (17)	4. Recruitment not met				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 8. Study Design and Conduct Limitations

Study	Allocations[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Morano et al. (2013) (16)	4. Inadequate control for selection bias: the participants were not evenly randomized			1. High loss to follow-up or missing data	1. Power is not reported	
Benzo et al. (2011) (17)						

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Study

Bradley et al. (2013), in a nonrandomized comparative study, evaluated an outpatient-based PR intervention in 58 lung cancer patients who were candidates for surgery. (18) This United Kingdom-based study also evaluated a comparison group of 305 patients, also surgical candidates, who received usual care. Patients in the 2 groups were matched by age, lung function, comorbidities, and type of surgery. In a within-group analysis, there was a statistically significant 20-meter improvement in 6MWD in the intervention group before and after participation in a 4-session presurgical PR program. In between-group analyses, there were not statistically significant differences between the intervention and comparisons groups in clinical outcomes such as postoperative pulmonary complications, readmissions, and mortality after surgery.

Section Summary: Preoperative Pulmonary Rehabilitation Programs

The National Emphysema Treatment Trial has recommended administering PR before lung volume reduction surgery, which is considered the stanxdard of care before lung volume reduction surgery and lung transplantation. However, there is a lack of large RCTs comparing PR with no PR for preoperative candidates undergoing lung volume reduction surgery, lung transplantation, or lung cancer resection. The available studies evaluated exercise programs and comprehensive PR. Also, the few small RCTs and observational studies have reported on short-term outcomes and have found inconsistent evidence of benefit even on these outcomes.

Lung Volume Reduction Surgery Postoperative Pulmonary Rehabilitation Programs

Clinical Context and Therapy Purpose

The purpose of a single course of outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without outpatient pulmonary rehabilitation, in individuals who have had lung volume reduction surgery.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who have had lung volume reduction surgery.

Interventions
The therapy being considered is a single course of outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators
Comparators of interest include usual care without outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medication therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of outpatient pulmonary rehabilitation as a treatment for individuals who have had lung volume reduction surgery has varying lengths of follow up. While studies described below all reported at least one outcome of interest, 3 to 6 months duration of follow-up is desirable to assess outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

No RCTs evaluating comprehensive PR programs after LVRS were identified. Bering et al. (2009) reported on a case series involving 49 patients with severe emphysema who participated in a PR program after LVRS. (19) Patients underwent LVRS at a single center and had not received PR at that institution pre-surgery. After hospital discharge, patients underwent an outpatient comprehensive PR program for 4 hours a day, 5 days a week for 2 weeks. The program included a multidisciplinary team with a variety of components, including dietary, physical therapy, physical exercise, psychosocial, occupational therapy, and respiratory therapy. The primary outcome was health-related quality of life measured by the 36-Item Short-Form Health Survey. Compared with pre-LVRS scores, significantly better scores were achieved on the Physical Component Summary and Mental Component Summary at both time 2 (3-6 months post-LVRS) and time 3 (12-18 months post-LVRS). Study limitations included no comparison with patients who had LVRS and no PR and the difficulty disentangling the impact of LVRS from that of PR on outcomes. Moreover, patients had not received PR before LVRS, so the treatment effects of pre-versus post-surgery LVRS could not be determined.

Section Summary: Lung Volume Reduction Surgery Postoperative Pulmonary Rehabilitation Programs

No comparative studies have evaluated PR programs after LVRS. One case series evaluated a comprehensive PR program after LVRS in 49 patients who had not received preoperative PR. Health-related QOL was higher at 3 to 6 months and 12 to 18 months post-surgery. The study did not provide data on patients who underwent LVRS and did not have postoperative PR or on patients who had preoperative PR.

Lung Transplantation Postoperative Pulmonary Rehabilitation Programs

Clinical Context and Therapy Purpose

The purpose of a single course of outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without outpatient pulmonary rehabilitation, in individuals who have had lung transplantation.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest are individuals with who have had lung transplantation.

Interventions

The therapy being considered is a single course of outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators

Comparators of interest include usual care without outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medical therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of outpatient pulmonary rehabilitation as a treatment for individuals who have had lung transplantation has varying lengths of follow up. While studies described below all reported at least one outcome of interest, 3 to 6 months duration of follow-up is desirable to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Exercise training after lung transplantation is reported in the literature but not necessarily provided in comprehensive PR programs. Wickerson et al. (2010) published a systematic review of the available literature in which the researcher had evaluated any exercise intervention in conjunction with lung transplantation. Seven studies (RCTs, controlled trials, and prospective cohorts) met the inclusion criteria, including two RCTs targeting lumbar bone mineral density. Also included in the review were uncontrolled studies reported improvement in functional status as a byproduct of an exercise-program intervention. (20)

Randomized Controlled Trials

Langer et al. (2012) conducted an RCT in the United Kingdom that examined activity-related outcomes in lung transplant recipients after exercise training. (21) The trial included 40 patients who underwent single-or double-lung transplantation and had an uncomplicated postoperative period. Following hospital discharge, patients were randomized to a supervised exercise program 3 times a week for 3 months (n=21) or to usual care with instructions to exercise (n=19). Patients in both groups had 6 individual counselling sessions in the 6 months post discharge. Six patients dropped out of the trial, 3 in each group. The primary outcome was daily walking time, assessed by activity monitors. At the end of the 3-month intervention and at 1-year post discharge, mean walking time was significantly longer in the intervention group. At 1 year, the exercise group walked a mean of 85 minutes per day while the control group walked a mean of 54 minutes per day (p=0.006). Other outcomes related to daily physical activity were reported as secondary outcomes and some, but not all, significantly favored the intervention group. Mean 6MWD at 1 year was 86% of predicted in the exercise group and 74% of predicted in the control group (p=0.002). The trial had a relatively small sample size and may have been underpowered to detect clinically meaningful differences between groups on secondary outcomes.

Fuller et al. (2017) published an RCT reporting on the impact of short (7-week) vs long (14-week) rehabilitation programs for patients who underwent lung transplantation. (22) The primary outcome was change in the 6MWD. Secondary outcomes included the strength of the quadriceps and hamstring muscles (as measured by an isokinetic dynamometer), and QOL (as measured by the 36-Item Short-Form Health Survey). In both the 7- and 14-week rehabilitation groups, participants increased their 6MWD (mean improvement in 7-week group, 202 meters vs 14-week group, 149 meters). At 6 months after transplantation, the mean difference between groups was 59.3 meters, favoring the 7-week group (95% CI, 12.9 to 131.6 meters). The increases in strength in quadriceps and hamstring muscles in both groups did not differ statistically. The 36-Item Short-Form Health Survey summary scores of the domains of physical health and mental health both increased over time with no significant difference between groups at any time point.

Tables 9 and 10 summarize the characteristics and results of the RCTs, respectively.

Table 9. Summary of Key RCT Characteristics

Trial	Countries	Sites	Participants	Interventions	
				Active	***Comparator***
Langer et al. (2012) (21)	United Kingdom	1	Patients aged 40-65 years old who had undergone a single or bilateral LTX with no postoperative complications (N=40)	Exercise program (3 x/week for 3 months) (n=21)	Usual care with added instruction to exercise (n=19)
Fuller et al. (2017) (22)	United States	1	Post-LTX patients aged ≥18 years (N=66; 33 women; mean age=51+/-13 years) who had undergone either single LTX or bilateral LTX	Longer-duration (14-week) rehabilitation program after LTX	Shorter (7-week) rehabilitation program after LTX

LTX: lung transplantation; RCT: randomized controlled trial.

Table 10. Summary of Key RCT Results

Study	Daily Walking Time	Mean Improvement in 6MWD from Baseline (SD)	6MWD Difference Between Groups
Langer et al. (2012) (21)			
N=40	N=34 (final)	NR	NR
3-mo exercise program (baseline/final)=21/18	Mean=85 min/day at 1 year (SD=27 min)	NR	NR
Usual care (baseline/final)=19/16	Mean=54 min/day at 1 year (SD=30 min)	NR	NR
Mean difference	26 min (adjusted)	NR	NR
95% CI	8 to 45	NR	NR
P-value	0.0006	NR	NR
Fuller et al. (2017) (22)			
N=66	NR	N=64 at 6 mo	N=64 at 6 mo
Longer-duration (14 wk) PR program	NR	+149 m (169 m)	NR
Shorter-duration (7 wk) PR program	NR	+202 m (72 m)	NR
P-value	NR	0.5	NR
Mean difference	NR	NA	59.3 m favoring 7-wk group
95% CI	NR	NR	12.9 to 131.6

6MWD: 6-minute walk distance; CI: confidence interval; NR: not reported; NA: not applicable; OR: odds ratio; PR: pulmonary rehabilitation; RCT: randomized controlled trial; SD: standard deviation; min: minutes; m: meters; wk: week; mo: months.

The purpose of Tables 11 and 12 is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 11. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Langer et al. (2012) (21)					
Fuller et al. (2017) (22)	1. Selection criteria not clear		2. Fitness activity monitor not validated as comparator for this clinical scenario		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 12. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Langer et al. (2012) (21)		1. Patients not blinded. Blinding not feasible. Outcome assessment				

		not blinded.				
Fuller et al. (2017) (22)		1. Patients not blinded. Blinding not feasible. Outcome assessment not blinded.			1, 2. Power is affected by small sample size, underpowered to detect meaningful differences.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Case Series

Munro et al. (2009) published a case series that evaluated a comprehensive PR program after lung surgery. (23) The 7-week program, which started 1-month post-surgery, consisted of 1 hour of supervised exercise 3 times a week and a weekly group education session facilitated by a multidisciplinary team (e.g., nurse, dietician, occupational therapist, social worker). Compared with baseline, on program completion, both forced expiratory volume in 1 second (FEV_1) and forced vital capacity (FVC) had improved significantly ($p<0.001$). For example, mean FEV_1 was 71% at 1-month post-surgery and 81% at 3 months. Similarly, 6MWD improved significantly: mean distance was 451 meters at 1 month and 543 meters at 3 months post-transplant. The study lacked a control group, hence, the degree of improvement that would have occurred without participation in a PR program is unknown.

Section Summary: Lung Transplantation Postoperative PR Programs

A systematic review of exercise training after lung transplantation (not necessarily provided in a comprehensive PR program) identified 7 controlled and uncontrolled studies but did not pool study findings. Neither RCT identified reported functional outcomes, but the uncontrolled

studies reported improvements in functional outcomes. An RCT, published after the systematic review, found that patients who had a postsurgical exercise intervention walked more 1-year post discharge and had a significantly greater 6MWD. The most recent RCT (2017) did not identify a difference in outcomes with longer duration of PR. Findings on other outcomes were mixed. Case series data also support improvement in the 6MWD after postoperative PR.

Lung Cancer Resection Postoperative Pulmonary Rehabilitation Programs

Clinical Context and Therapy Purpose

The purpose of a single course of outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without outpatient pulmonary rehabilitation, in individuals who have had lung cancer resection.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who have had lung cancer resection.

Interventions

The therapy being considered is a single course of outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators

Comparators of interest include usual care without outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medical therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of outpatient pulmonary rehabilitation as a treatment for individuals who have had lung cancer resection has varying lengths of follow up. While studies described below all reported at least one outcome of interest, 3 to 6 months duration of follow-up is desirable to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials

Stigt et al. (2013) published an RCT evaluating a multicomponent post-surgery PR program in patients with resectable lung cancer. (24) The trial was conducted in the Netherlands. Before thoracotomy, 57 patients were randomized to PR or usual care. The 12-week PR program started 4 weeks after surgery and consisted of exercise training, pain management, and visits with a medical social worker. The trial was terminated early because the institution started offering video-assisted thoracoscopic surgery, at which point few patients chose thoracotomy. Data on 49 patients (PR=23, usual care=26) were analyzed. The primary end point was QOL, as measured by the difference between groups in change in the total SGRQ score from baseline to 12 months. This difference was 2.71 points, which was not statistically significant (p=0.69). However, 6MWD (a secondary outcome) improved significantly more in the PR group than in the usual care group at 3 months. The between-group difference in 6MWD was 94 meters (p=0.024). A limitation of this analysis is that only 8 of 23 patients in the PR performed a 6MWD at 3 months; the other 15 patients had dropped out or did not take the test. Eleven of 25 patients in the usual care group performed the 6MWD.

An exercise-only intervention after lung cancer surgery (not comprehensive PR) was evaluated in an RCT published by Edvardsen et al. in 2015. (25) This single-blind trial was conducted in Norway and included lung cancer patients at 4 to 6 weeks post-surgery. Sixty-one patients were randomized to an exercise program 3 times a week for 20 weeks or to usual care. The exercise intervention took place at local fitness centers and was supervised by trained personal trainers and physical therapists. A significantly greater improvement was reported for the primary outcome (change in peak oxygen uptake from baseline to the end of the intervention) in the intervention group than in the control group (between-group difference, 0.26 L/min; p=0.005). Findings on secondary outcomes were mixed. For example, the between-group difference in FEV_1 was 0.6% predicted (95% CI, -4.2% to 5.4%; p=0.738) and the difference in stair run was 4.3 steps (95% CI, 1.6 to 7.1; p=0.002). This trial did not report other functional outcomes (e.g., 6MWD).

Section Summary: Lung Cancer Resection Postoperative Pulmonary Rehabilitation Programs

A single RCT has evaluated a comprehensive PR program in patients who underwent thoracotomy for lung cancer. The trial was terminated early, had a high dropout rate, and reported mixed findings. An exercise-only intervention in patients who had lung cancer surgery had mixed findings and did not evaluate functional outcomes. Current evidence is not sufficiently robust to draw conclusions on the utility of PR programs to those who have had lung resection.

Post-Acute Sequelae of SARS-CoV-2 Infection

Clinical Context and Therapy Purpose

The purpose of a single course of outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without outpatient pulmonary rehabilitation, in individuals who have sequelae of SARS-CoV-2 infection.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who have sequelae of SARS-CoV-2 infection.

Interventions
The therapy being considered is a single course of outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators
Comparators of interest include usual care without outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medical therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of outpatient pulmonary rehabilitation as a treatment for individuals who have sequelae of SARS-CoV-2 infection has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, 3 to 6 months duration of follow-up is desirable to assess outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Numerous systematic reviews and meta-analyses have evaluated pulmonary rehabilitation programs in patients who have sequelae of SARS-CoV-2 infection (COVID-19), but few have specifically evaluated pulmonary rehabilitation in the ambulatory setting. Table 13 describes characteristics of 3 systematic reviews and Table 14 includes results for the single pooled analysis.

Dillen et al. (2023) evaluated ambulatory rehabilitation in patients with persistent symptoms after COVID-19. (26) The systematic review was not specific to pulmonary rehabilitation; however, 5 RCTs and 5 cohort studies evaluated breathing exercises alone or physical training

with breathing exercises as part of rehabilitation and found benefit for several outcomes including dyspnea, pulmonary function, quality of life, and functional capacity.

Two systematic reviews focused on telehealth interventions in patients with post-acute COVID-19. Calvache-Mateo et al. (2023) compared telerehabilitation to no intervention, usual care, placebo, or face-to-face intervention (Tables 13 and 14). (27) Pulmonary rehabilitation methods varied amongst the studies, but the majority of studies included respiratory training or breathing exercises. Telerehabilitation sessions were conducted 3 to 7 times weekly and varied in duration from 20 to 60 minutes. The study found improved QOL, dyspnea, and functional capacity; however, there was high heterogeneity with a limited number of small studies. Pescaru et al. (2023) conducted a systematic review of 3 RCTs and 4 cohort studies evaluating telerehabilitation in patients with post-acute COVID-19 (Table 13). The programs were diverse, and the data were not pooled. (28) There was great variability in findings with some improvements in dyspnea, quality of life, physical health, and mental health. However, the observational nature of many of the studies along with small sample sizes prohibit any conclusions regarding the benefit of telerehabilitation for these patients.

Table 13. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Dillen et al. (2023)	Through May 2022	10	Patients with persistent COVID-19 symptoms	718 (20-150)	RCT/cohort	NR
Calvache-Mateo et al. (2023)	Through July 2023	10	Patients with long COVID-19 undergoing pulmonary rehabilitation	866 (17-150)	RCT	4 to 17 weeks
Pescaru et al. (2023)	Through April 2023	7	Patients with post-acute COVID-19 undergoing pulmonary rehabilitation	412 (67-622)	RCT/cohort	4 to 10 weeks

NR: not reported; RCT: randomized controlled trial.

Table 14. Systematic Review Results

Study	Dyspnea	FVC	QOL	Functional capacity	Adverse events
Calvache-Mateo et al. (2023)					
Total N	489	247	699	450	575
Pooled effect (95% CI)	MD: 4.95 (2.81-7.08)[a]	MD: 0.21 (-0.17-0.60)	MD: 0.59 (0.09-1.09)[b]	MD: 0.75 (0.39-1.11)[c]	OR: 0.53 (0.27 to 1.02)
I^2 (p)	*98%* (<.00001)	*66%* (.03)	*90%* (<.00001)	*66%* (.01)	*0%* (.78)
Range of N	48-148	44-107	44-129	44-148	44-129

Range of effect sizes	0.18-28.5	-0.10-0.78	-0.51-2.75	0.31-1.37	0.30-2.50

CI: confidence interval; FVC: forced vital capacity; MD: mean difference; OR: odds ratio; QOL: quality of life.

[a] As measured by the Modified Medical Research Council Scale, the Multideminsional Dyspnea-12 Scale, or the Transition Dyspnea Index.

[b] As measured y the EuroQOL 5-Dimension, Short Form 12 or 36 Health Survey, Kansas City Pulmonary-Behavioral Inventory of Lung Disease, St. George's Respiratory Questionnaire, or Short Health-related Quality of Life Questionnaire.

[c] As measured by the 6 minute walk test or Ruffier test.

Section Summary: Post-Acute Sequelae of SARS-CoV-2 Infection

Systematic reviews of RCTs and cohort studies have found improved dyspnea, functional outcomes, and quality of life in patients who receive ambulatory pulmonary rehabilitation compared with no therapy, sham therapy, or usual care. The evidence is limited by the heterogeneity of the intervention, heterogeneity of the scales for outcome measures, and small sample sizes of the included trials.

Repeat or Maintenance Outpatient Pulmonary Rehabilitation Programs

Clinical Context and Therapy Purpose

The purpose of repeat or maintenance outpatient pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as usual care without repeat or maintenance outpatient pulmonary rehabilitation, in individuals who have had an initial course of pulmonary rehabilitation.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with who have had an initial course of pulmonary rehabilitation.

Interventions

The therapy being considered is repeat or maintenance outpatient pulmonary rehabilitation. Pulmonary rehabilitation programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change. Repeat or maintenance pulmonary rehabilitation programs provide additional rehabilitation services after initial participation in a pulmonary rehabilitation program. Maintenance programs tend to be designed to extend the effects of the initial pulmonary rehabilitation program, and they are open to all patients who successfully completed an initial program.

Comparators

Comparators of interest include usual care without repeat or maintenance outpatient pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medical therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating repeat or maintenance outpatient pulmonary rehabilitation as a treatment for individuals who have had an initial course of pulmonary rehabilitation has varying lengths of follow up. While studies described below all reported at least one outcome of interest, 3 to 6 months duration follow-up is desirable to assess outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Repeat Outpatient Pulmonary Rehabilitation Programs
Repeat PR programs provide additional rehabilitation services after initial participation in a PR program. Repeat programs are generally those that include patients who failed to respond to an initial program or whose response to an initial rehabilitation program diminished over time.

Carr et al. (2009) prospectively identified Canadian patients with moderate-to-severe COPD who experienced an acute exacerbation within 12 months of participating in a PR program. (29) All patients had initially completed a 6-week inpatient program or a 12-week outpatient program. Patients were then randomized to receive 3 weeks of pulmonary rehabilitation therapy or usual care. The repeat PR program lasted 3 weeks and consisted of exercise and education; patients could choose inpatient or outpatient versions. Over a mean of 14 ± 11 weeks, 41 patients developed an exacerbation. Seven patients withdrew from the trial, and the remaining 34 were randomized to a repeat PR program within 1 month of the exacerbation (n=17) or to no repeat PR program (n=17). One patient in the intervention group dropped out; of the remaining 33 patients, 25 (76%) experienced an exacerbation of moderate severity; the remaining 8 had severe exacerbations. Nine (56%) of 16 patients in the intervention group chose an inpatient program and 7 chose an outpatient program. Patients were assessed before the repeat PR program, immediately after (3 weeks later), and again 12 weeks after the beginning of the exacerbation (5 weeks after completing the repeat rehabilitation program). The primary outcome was change in health-related QOL, as measured on the 4 domains of the CRQ score. There was no statistically significant difference between groups in mean change in CRQ scores. Among patients in the intervention group, the magnitude of improvement in the domains of dyspnea (0.7 points) and fatigue (0.5 points) met or exceeded the minimal clinically important difference. In the control group, the magnitude of change in all domains did not meet the minimal clinically important difference. Change in the 6MWD (a secondary outcome)

did not differ significantly between groups at either follow-up. Outcomes were not reported separately for the inpatient or outpatient programs (this medical policy addresses outpatient programs). Trialists recommended that future evaluations of repeat PR programs include patients with more serious exacerbations, last longer than 3 weeks, and start as close in time as possible to the exacerbation. Conclusions about repeat PR programs cannot be drawn from 1 study with 33 subjects.

Maintenance Outpatient Pulmonary Rehabilitation Programs

Randomized Controlled Trials

In 2012, an Ontario Health Technology Assessment evaluated pulmonary rehabilitation for patients with COPD. (30) Reviewers identified 3 RCTs (N=284) assessing maintenance pulmonary rehabilitation programs for individuals with COPD who had successfully completed an initial pulmonary rehabilitation program. The trials excluded patients who had experienced a recent acute exacerbation of COPD. All maintenance programs consisted of supervised exercise sessions; program duration was 3 months in 1 program and 12 months in the other 2. One program also included an unsupervised exercise component, and another included educational sessions. Reviewers judged study quality as generally poor due to methodologic limitations (e.g., inadequate information on randomization, allocation concealment, blinding, and lack of clarity around the use of an intention-to-treat analysis). In a pooled analysis of data from 2 trials (n=168), there was a significantly greater improvement in 6MWD in patients who participated in the maintenance program than in those in a control group (MD=22.9 meters; 95% CI, 5.2 to 40.7). The confidence interval was wide, indicating lack of precision in the pooled estimate. Also, reviewers considered the minimal clinically important difference to be 25 to 35 meters walked, and meta-analysis of trial findings did not meet this threshold of difference between groups.

Several RCTs were published after the Ontario assessment. Güell et al. (2017) published findings of a 3-year trial of patients with severe COPD. (31) A total of 143 patients attended an initial 8-week outpatient pulmonary rehabilitation program, and 138 were then randomized to a 3-year maintenance program (n=68) or a control group (n=70). The maintenance intervention consisted of home-based exercises, calls from a physical therapist every 2 weeks, and supervised training sessions every 2 weeks. The control group was advised to exercise at home without supervision. Some outcomes, but not others, favored the intervention group at 2 years, but outcomes did not differ significantly between groups at 3 years. For example, compared with baseline, at 2 years the 6MWD increased by 2 meters in the intervention group and decreased by 32 meters in the control group (p=.046). At 3 years, compared with baseline, the 6MWD decreased by 4 meters in the intervention group and decreased by 33 meters in the control group (p=.119). The chronic respiratory questionnaire dyspnea score, at 2 years compared with baseline, decreased by 0.4 points in the intervention group and by 0.3 points in the control group (p=.617); findings were similar at 3 years. The trial also had a high dropout rate.

Wilson et al. (2015) published a single-blind RCT comparing maintenance pulmonary rehabilitation to standard care without maintenance pulmonary rehabilitation in patients who

had COPD and had completed at least 60% of an initial pulmonary rehabilitation program. (32) One hundred forty-eight patients were randomized; 110 (74%) completed the trial and were included in the analysis. The maintenance program consisted of a 2-hour session every 3 months for 1 year. The session included an hour of education and an hour of supervised individualized exercise training. The primary efficacy outcome was change from baseline (post PR) in the chronic respiratory questionnaire dyspnea domain. Among trial completers, mean chronic respiratory questionnaire dyspnea score changed from 2.6 to 3.2 among patients receiving maintenance pulmonary rehabilitation and from 2.5 to 3.3 among controls. The difference between groups was not statistically significant. Secondary outcomes, including other chronic respiratory questionnaire domains, scores on the endurance shuttle walk test, and a number of exacerbations or hospitalizations, also did not differ significantly between groups.

Section Summary: Repeat or Maintenance Outpatient Pulmonary Rehabilitation Programs
Evidence for repeat pulmonary rehabilitation programs includes 1 small, randomized study. Additional larger RCTs are needed before conclusions can be made about the effectiveness of repeat pulmonary rehabilitation. A limited number of RCTs are available to evaluate maintenance rehabilitation programs. Due to the paucity of RCTs, methodologic limitations of available trials, and lack of clinically significant findings, the evidence to determine the effect of maintenance pulmonary rehabilitation programs on health outcomes in patients with COPD is insufficient.

Home-Based Pulmonary Rehabilitation Programs
Clinical Context and Therapy Purpose
The purpose of a single course of home-based pulmonary rehabilitation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as a single course of ambulatory care-based pulmonary rehabilitation, in individuals with an indication for outpatient pulmonary rehabilitation.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with an indication for outpatient pulmonary rehabilitation.

Interventions
The therapy being considered is a single course of home-based pulmonary rehabilitation. PR programs include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

Comparators
Comparators of interest include a single course of ambulatory care based pulmonary rehabilitation. Treatment includes physical exercise, diaphragmatic breathing, oxygen therapy, and medical therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life.

The existing literature evaluating a single course of home-based pulmonary rehabilitation indicates that 3 to 6 months duration of follow-up is desirable to assess outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Evaluation of home-based PR programs requires evidence that these programs are at least as effective as programs conducted in the ambulatory care setting. The programs also need to be comprehensive and be feasible in the United States health care system.

Several RCTs and systematic reviews of RCTs have assessed home-based PR programs. Among the systematic reviews, Liu et al. (2014) identified 18 RCTs evaluating home-based PR programs. (33) Most trials compared PR with usual care, and none of the selected trials compared home-based with clinic-based programs. Only 2 trials were conducted in the United States, and both were published in the 1990s. All trials reported different outcomes over different timeframes, and pooled analyses only included data from 2 to 4 studies. For example, a pooled analysis of 3 studies (n=112 patients) reporting the SGRQ total score found statistically significant improvements in symptoms with home-based PR compared with control (effect size, -11.33; 95% CI, -16.37 to -6.29). A pooled analysis of data from 4 studies (n=167) found a significantly increased 6MWD after 12 weeks in the PR group compared with control (effect size, 35.9; 95% CI, 9.4 to 62.4). The latter analysis had a wide confidence interval, indicating an imprecise estimate of effect.

Vieira et al. (2010), in a systematic review, identified 12 RCTs comparing home-based PR with PR in another setting or with standard care in patients who had COPD. (34) The comparison intervention in 3 trials was a hospital-based program; in 8 trials, it was standard care; and in 1 trial, both comparisons were made. The methodologic quality of the trials was considered average to poor, and most had small sample sizes and relatively short follow-up durations. Reviewers did not pool trial findings, and findings of individual studies were mixed. Three trials that compared home-based PR with standard care reported on between-group differences in QOL; in all 3 studies, differences were reported as statistically significant. The 2 trials that reported differences in exercise capacity found home-based PR to result in significantly greater

improvements in the 6MWD or constant work rate test than standard care. On the other hand, in the 3 trials comparing home-based PR and hospital-based programs, there were no statistically significant differences between groups in QOL changes. Moreover, in the 2 trials that assessed maximal work level and the 2 trials that assessed the 6MWD, outcomes did not differ significantly after home-based or hospital-based PR programs. Reviewers commented that their analysis was limited by the generally low quality of the randomized trials and short-term length of follow-up.

Stafinski et al. (2022) identified 12 RCTs and 2 comparative observational studies (N=2293) to include in their systematic review evaluating home-based pulmonary rehabilitation programs in individuals with COPD. (35) Nine studies compared home-based pulmonary rehabilitation to usual care, 4 compared to outpatient-pulmonary rehabilitation, and 1 compared home-based to outpatient pulmonary rehabilitation or usual care. The overall quality for most outcomes was considered low to very low, based on the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) tool. Health-related QOL was measured across studies using the COPD assessment test, chronic respiratory disease questionnaire (CRQ), and the Saint George's respiratory questionnaire. In a meta-analysis comparing home-based to outpatient pulmonary rehabilitation in RCTs (n=2 studies) immediately after treatment, there were no differences between groups in changes in the dyspnea domain of the CRQ (MD=0.36; 95% CI, -1.34 to 2.06; p=.68), the emotional function domain of the CRQ (MD= -0.35; 95% CI, -0.83 to 0.14; p=.16), or the fatigue domain of the CRQ (MD=0.06; 95% CI, -1.16 to 1.27; p=.93). In all 4 studies comparing home-based to outpatient pulmonary rehabilitation, the 6MWD statistically significantly increased after both interventions, and the gains were similar between programs. This study demonstrated that there were no appreciable differences between home-based and outpatient pulmonary rehabilitation programs in short-term outcomes. A meta-analysis was not able to be performed on most outcomes due to a high level of heterogeneity and limited data. Additionally, long-term outcomes were not evaluated in included studies.

Another systematic review was published by Neves et al. (2016). (36) However, this review combined home and community-based PR programs in analyses so no conclusions can be drawn on the impact of home-based programs compared with programs based in the ambulatory care setting.

Randomized Controlled Trial

A study with a relatively large sample size and that compared home-based PR with outpatient clinic-based PR was published by Maltais et al. in 2008. (37) This noninferiority trial was conducted in Canada. Eligibility criteria included stable COPD for at least 4 weeks before study participation and no previous participation in PR programs; 252 patients were included. All patients initially completed a 4-week self-management educational program. They were then randomized to receive 8 weeks of self-monitored home-based exercise training or to outpatient hospital-based exercise training. The exercise program included aerobic and strength exercises conducted 3 times a week. Patients were followed for 40 weeks after completion of the exercise program. Both interventions produced similar improvements in the chronic respiratory questionnaire dyspnea domain scores at 1 year: improvement in dyspnea of 0.62 (95% CI, 0.43

to 0.80) units in the home intervention (n=107) and 0.46 (95% CI, 0.28 to 0.64) units in the outpatient intervention (n=109). The difference between treatments at 1 year was considered clinically unimportant. The trial did not evaluate a comprehensive PR program.

Section Summary: Home-Based PR Programs

Most studies of home-based PR have compared it with standard care. Very few studies have compared home-based PR with a hospital or clinic-based PR, and those available are mostly of low quality. Therefore, there is insufficient evidence to determine whether comprehensive PR programs conducted in the home setting are at least as effective as comprehensive PR programs in the ambulatory care setting.

Summary of Evidence

Chronic Pulmonary Disease Rehabilitation

For individuals with moderate-to-severe chronic obstructive pulmonary disease (COPD) who receive a single course of outpatient pulmonary rehabilitation (PR), the evidence includes numerous systematic reviews of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, and quality of life. The published studies found improved outcomes (i.e., functional ability, quality of life) in patients with moderate-to-severe COPD who underwent a comprehensive PR program in the outpatient setting. Among the many randomized trials, the structure of the PR programs varied, so it is not possible to provide guidance on the optimal components or duration of a PR program. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with idiopathic pulmonary fibrosis who receive a single course of outpatient PR, the evidence includes 3 systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Significant differences favoring pulmonary rehabilitation over usual care were seen in 6-minute walk distance (6MWD) in the short term. Starting at 3 months post-intervention, outcomes did not differ between groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with bronchiectasis who receive a single course of outpatient PR, the evidence includes a systematic review of RCTs and an RCT published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review included 4 RCTs on PR for patients with bronchiectasis found that some, but not all, outcomes, improved more with pulmonary rehabilitation than with nonexercise control conditions immediately after the intervention. An RCT published after the systematic review found that 6MWD and quality of life scores increased with PR compared to a non-exercise control group in the short-term. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Although most published evidence on outpatient PR for chronic pulmonary diseases assesses COPD, observational studies have reported on outcomes from PR for other chronic pulmonary diseases. Clinical guidelines from pulmonary organizations have supported the use of

outpatient pulmonary rehabilitation for individuals who are experiencing disabling symptoms and have significantly diminished quality of life despite optimal medical management. Therefore, outpatient PR may be considered medically necessary for this population.

Preparation for Lung Surgery

For individuals with scheduled lung surgery for volume reduction, transplantation, or resection who receive a single course of outpatient PR, the evidence includes RCTs and observational studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. There is a lack of large RCTs comparing PR with no PR for preoperative candidates undergoing lung volume reduction surgery, lung transplantation, or lung cancer resection. Moreover, the available studies have evaluated exercise programs, but not necessarily comprehensive PR programs. Also, the few small RCTs and observational studies have only reported short-term outcomes and inconsistent evidence of benefit even on these outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Findings from the National Emphysema Treatment Trial have suggested that pulmonary rehabilitation is an appropriate component of care for patients with COPD before undergoing lung volume reduction surgery. Also, pulmonary rehabilitation is considered the standard of care in individuals undergoing lung transplantation to maximize preoperative pulmonary status. Thus, PR may be considered medically necessary for individuals considered appropriate candidates for lung volume reduction surgery or lung transplantation.

Pulmonary Rehabilitation After Lung Surgery

For individuals who have had lung volume reduction surgery who receive a single course of outpatient PR, the evidence includes a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. No published RCTs were identified. The case series evaluated a comprehensive PR program after LVRS in 49 patients who had not received preoperative PR. Health-related quality of life was higher at 3 to 6 months and at 12 to 18 months post-surgery. The series did not provide data on patients who underwent lung volume reduction surgery and did not have postoperative PR, or patients who had preoperative PR. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had lung transplantation who receive a single course of outpatient PR, the evidence includes RCTs, a systematic review, and a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. Neither of the 2 RCTs identified in a 2010 systematic review reported functional outcomes, but uncontrolled studies have reported improvements in functional outcomes. An RCT, published after the systematic review, found that patients who had a postsurgical exercise intervention walked more 1-year post discharge than before and had a significantly greater 6MWD. Findings on other outcomes were mixed. The most recent RCT (2017) did not identify a difference in outcomes with longer duration of pulmonary rehabilitation. Case series data also support improvements in 6MWD after

postoperative PR. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had lung cancer resection who receive a single course of outpatient PR, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One small RCT have evaluated a comprehensive PR program in patients who underwent thoracotomy for lung cancer. The trial was terminated early, had a high dropout rate, and reported mixed findings. An exercise-only intervention in patients who had lung cancer surgery had mixed findings and did not evaluate functional outcomes. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

Post-Acute Sequelae of SARS-CoV-2 Infection

For individuals who have post-acute sequalae of SARS-CoV-2 infection, the evidence includes systematic reviews of RCTs and cohort studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. One systematic review pooled data from 10 RCTs and found significant improvement in quality of life, dyspnea scores, and functional capacity with telerehabilitation compared with sham intervention, no intervention, or usual care including face-to-face intervention. Lung function and adverse events were not different between groups. Other systematic reviews also found benefit with ambulatory pulmonary rehabilitation in these patients, but the data were not pooled, and the evidence is limited by a small number of studies most of which are observational in nature. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Repeat or Maintenance Pulmonary Rehabilitation

For individuals who have had an initial course of PR who receive repeat or maintenance outpatient PR, the evidence includes a limited number of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One small RCT evaluating repeat pulmonary rehabilitation programs had methodologic limitations and did not report inpatient and outpatient outcomes separately; it also lasted only 3 weeks. In the evaluation of maintenance pulmonary rehabilitation programs, evidence was mixed. Due to the paucity of RCTs, methodologic limitations of available trials, and lack of clinically significant findings, the evidence to determine the effect of maintenance pulmonary rehabilitation programs on health outcomes in patients with COPD is insufficient. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Home-Based Pulmonary Rehabilitation

For individuals who have an indication for outpatient PR who receive a single course of home-based PR, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Most studies of home-based PR have compared outcomes with standard care. Very few have compared home-based PR with hospital- or clinic-based PR, and the available studies are mostly of low quality. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Thoracic Society and European Respiratory Society

A 2015 joint statement on pulmonary rehabilitation was issued by the American Thoracic Society (ATS) and the European Respiratory Society (ERS). (38) The statement included the following relevant conclusions:

- "Pulmonary rehabilitation (PR) has demonstrated physiological, symptom-reducing, psychosocial, and health economic benefits in multiple outcome areas for patients with chronic respiratory diseases."
- "The evidence indicates that patients who benefit from PR include not only persons with moderate to severe airflow limitation but also those with mild to moderate airflow limitation with symptom-limited exercise tolerance, those after hospitalization for COPD exacerbation, and those with symptomatic non-COPD respiratory conditions."
- "Patients graduating from a PR program stand to benefit from a home, community-based, or program-based maintenance exercise program to support the continuation of positive exercise behavior."

In 2017, the Society issued a joint statement on the management of COPD exacerbation. (39) For patients hospitalized with a COPD exacerbation, they suggest "the initiation of pulmonary rehabilitation within 3 weeks after hospital discharge" (strength: conditional; quality of evidence: very low). In addition, "[they] suggest not initiating pulmonary rehabilitation during hospitalization" (strength: conditional; quality of evidence: very low).

In 2021, the ATS published a report from a workshop that was convened to achieve consensus on the essential components of pulmonary rehabilitation and to identify requirements for successful implementation of emerging program models. (40) A Delphi process involving experts from across the world identified 13 "essential" components of pulmonary rehabilitation that must be delivered in any program model, encompassing patient assessment, program content, method of delivery, and quality assurance; an additional 27 "desirable" components were also identified. See the full text of this publication for further details.

In 2023, the ATS published a clinical practice guideline on pulmonary rehabilitation for adults with chronic respiratory disease. (41) Several recommendations regarding pulmonary rehabilitation were reported, which are summarized in Table 15.

Table 15. American Thoracic Society Recommendations for Pulmonary Rehabilitation in Adults with Chronic Respiratory Disease

Recommendation Statement	Strength and Quality of Evidence
For adults with stable chronic obstructive pulmonary disease (COPD), we recommend participation in pulmonary rehabilitation	strong recommendation, moderate-quality evidence
For adults with COPD, we recommend participation in pulmonary rehabilitation after hospitalization for an exacerbation of COPD	strong recommendation, moderate-quality evidence

For adults with interstitial lung disease, we recommend participation in pulmonary rehabilitation	strong recommendation, moderate-quality evidence
For adults with pulmonary hypertension, we suggest participation in pulmonary rehabilitation	conditional recommendation, low-quality evidence
For adults with stable chronic respiratory disease, we recommend offering the choice of center-based pulmonary rehabilitation or telerehabilitation	strong recommendation, moderate-quality evidence
For adults with COPD, we suggest either supervised maintenance pulmonary rehabilitation or usual care after initial pulmonary rehabilitation	conditional recommendation, low-quality evidence

Global Initiative for Chronic Obstructive Lung Disease

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) updates their guidelines annually on the diagnosis, management, and prevention of COPD. (42) In their 2025 guidance, GOLD notes that:

"Pulmonary rehabilitation should be considered as part of integrated patient management... Optimum benefits are achieved from programs lasting 6 to 8 weeks. Available evidence indicates that there are no additional benefits from extending pulmonary rehabilitation to 12 weeks. Supervised exercise training at least twice weekly is recommended, and this can include any regimen from endurance training, interval training, resistance/strength training; upper and lower limbs ideally should be included as well as walking exercise; flexibility, inspiratory muscle training and neuromuscular electrical stimulation can also be incorporated. In all cases the rehabilitation intervention (content, scope, frequency, and intensity) should be individualized to maximize personal functional gains."

The benefits to patients with COPD from pulmonary rehabilitation cited in the guidelines are listed in Table 16.

Table 16. Benefits of Pulmonary Rehabilitation in Patients with COPD (GOLD guidelines)

Pulmonary Rehabilitation Benefit	**LOE**
Pulmonary rehabilitation improves dyspnea, health status, and exercise tolerance in stable patients.	A
Pulmonary rehabilitation reduces hospitalization among patients who have had a recent exacerbation (≤4 weeks from prior hospitalization).	B
Pulmonary rehabilitation leads to a reduction in symptoms of anxiety and depression.	A

COPD: chronic obstructive pulmonary disease; GOLD: Global Initiative for Chronic Obstructive Lung Disease; LOE: level of evidence.

Related to the setting of pulmonary rehabilitation, the GOLD guidelines state that "community-based and home-based programs have been shown to be as effective as hospital-based programs in randomized controlled trials, as long as the frequency and intensity are equivalent." This statement cites studies described alone or included in systematic reviews in the Rationale Section (Maltais et al. 2008 and Holland et al. 2017).

National Institute for Health and Care Excellence (NICE)

In 2020, NICE issued a rapid guideline on managing the long-term effects of COVID-19. (43) The guideline was most recently updated in January 2024. The guideline recommends using a "multidisciplinary approach to guide rehabilitation, including physical, psychological and psychiatric aspects of management...The evidence showed that breathlessness, fatigue and 'brain fog' are among the most commonly reported long-term symptoms, so support for these should be part of the person's rehabilitation plan."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 17.

Table 17. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05990946	A Prospective, Randomized, Controlled Study to Evaluate the Impact of Remote Symptom Management Via Smartphone App Based on Electronic Patient-Reported Outcomes on Rehabilitation Exercise Adherence After Minimally Invasive Surgery in Lung Cancer Patients	736	June 2025
NCT06085261	Chronic Obstructive Pulmonary Disease: A Multi-center Supervised Tele-rehabilitation Study	360	Dec 2024
NCT06077994	The Enhanced Pulmonary Rehabilitation Program With Digital Remote Patient Monitoring: A Feasibility Randomized Clinical Trial	78	Aug 2024
NCT04820257	Home-based Pulmonary Rehabilitation for COPD Patients	80	Dec 2028
Unpublished			
NCT03326089	Short and Long-term Effects of Oxygen Supplemented Pulmonary	20	Aug 2023

	Rehabilitation in Idiopathic Pulmonary Fibrosis.		
NCT03244137	Effects of Pulmonary Rehabilitation on Cognitive Function in Patients With Severe to Very Severe Chronic Obstructive Pulmonary Disease.	56	Dec 2019
NCT02426437	How Does Early Rehabilitation Affect Patient-centered Health Outcomes and Cardiovascular Risk in COPD Patients	87	Dec 2019
NCT02842463	Use of the 6-minute Stepper Test to Individualize Pulmonary Rehabilitation in Patients With Mild to Moderate Chronic Obstructive Pulmonary Disease.	105	Dec 2023
NCT06077994	The Enhanced Pulmonary Rehabilitation Program With Digital Remote Patient Monitoring: A Feasibility Randomized Clinical Trial	78	Aug 2024

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	94625, 94626, 94799, 97799
HCPCS Codes	G0237, G0238, G0239, G0302, G0303, G0304, G0305, S9473

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
08/01/2025	Document updated with literature review. Coverage reorganized with movement of Notes to Policy Guidelines; no change to policy intent. Reference 41 added; others updated. Title changed from Pulmonary Rehabilitation.
04/15/2025	Document updated with literature review. The following change was made to Coverage: Added "Pulmonary rehabilitation programs in the outpatient ambulatory care setting are considered experimental, investigational and/or unproven for the treatment of post-acute sequelae of SARS-CoV-2 infection." References 26-28, 40, and 42 added; others updated, and one removed.
05/15/2024	Document updated with literature review. The following change was made to Coverage: Typical length of pulmonary rehabilitation program changed from 12 weeks to 6-8 weeks. References 9, 13, 32, 38 and 39 added.
07/15/2022	Reviewed. No changes.
05/15/2021	Document updated with literature review. Coverage unchanged. References 9, 10, and 33 added; others removed.
06/15/2020	Reviewed. No changes.
12/15/2019	Document updated with literature review. The following change was made to Coverage: Added NOTE 1. The following references were added/updated: 21, 33, 36 and 38.
06/15/2018	Reviewed. No changes.
07/15/2017	Document updated with literature review. Coverage unchanged.
07/15/2016	Reviewed. No changes.
07/01/2015	Document updated with literature review. The following statements were added to the coverage section: 1) Pulmonary rehabilitation programs may be considered medically necessary following lung transplantation. 2) The following was added to the experimental, investigational and/or unproven statement pulmonary rehabilitation programs are considered experimental, investigational and/or unproven for all other indications including but not limited to programs following other types of lung surgery (e.g., lung volume reduction surgery and surgical resection of lung cancer).
09/01/2014	Document updated with literature review. The following was added to coverage: Pulmonary rehabilitation programs are considered experimental, investigational and/or unproven in all other situations. A NOTE was added to the coverage section: Pulmonary Rehabilitation is typically provided for 4-6 hours per week for up to 12 wks. The following coverage change was made:

	Multiple courses of pulmonary rehabilitation are considered not medically necessary.
02/01/2014	Document updated with literature review. Coverage changed to include Home-based pulmonary rehabilitation programs are considered experimental, investigational and unproven.
12/15/2010	Document updated with literature review. Coverage changed to include conditional coverage of pulmonary rehabilitation for lung transplantation. Description revised, rationale replaced. CPT/HCPCS code(s) updated.
02/01/2008	Codes Revised/Added/Deleted