



## FEP Medical Policy Manual

### FEP 8.03.05 Outpatient Pulmonary Rehabilitation

**Effective Policy Date: July 1, 2023**

**Original Policy Date: December 2011**

**Related Policies:**

- 7.03.07 - Lung and Lobar Lung Transplant
- 7.03.08 - Heart/Lung Transplant

## Outpatient Pulmonary Rehabilitation

### Description

#### Description

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

#### OBJECTIVE

The objective of this evidence review is to evaluate whether the use of pulmonary rehabilitation improves net health outcomes in individuals with various lung conditions.

## POLICY STATEMENT

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 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 (see evidence review 7.01.71) or for lung transplantation (see evidence review 7.03.07).

Pulmonary rehabilitation programs are considered **medically necessary** following lung transplantation.

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

Multiple courses of pulmonary rehabilitation are considered **investigational**, either 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 **investigational**.

Pulmonary rehabilitation programs are considered **investigational** in all other situations.

## POLICY GUIDELINES

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 the 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 (eg, dementia, organic brain syndrome) and significant or unstable medical conditions (eg, heart failure, acute cor pulmonale, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke).

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

In general, a global fee is submitted for pulmonary rehabilitation that includes all components of the program. If billing is per session, the recommendation is made to adjudicate sessions as a 1 program per lifetime benefit. Programs are usually 6 to 8 weeks in duration. Another alternative for a program not billed as a global fee is to add a dollar or visit maximum.

## FDA REGULATORY STATUS

Not applicable.

## RATIONALE

### 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, 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 (ie, functional ability, quality of life) in patients with moderate-to-severe COPD who underwent a comprehensive pulmonary rehabilitation program in the outpatient setting. Among the many randomized trials, the structure of the pulmonary rehabilitation programs varied, so it is not possible to provide guidance on the optimal components or duration of a pulmonary rehabilitation 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 pulmonary rehabilitation, 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 pulmonary rehabilitation, 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 pulmonary rehabilitation 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 pulmonary rehabilitation 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 pulmonary rehabilitation for chronic pulmonary diseases assesses COPD, observational studies have reported on outcomes from pulmonary rehabilitation 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 pulmonary rehabilitation 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 preoperative outpatient pulmonary rehabilitation, 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 pulmonary rehabilitation with no pulmonary rehabilitation 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 pulmonary rehabilitation programs. Also, the few small RCTs and observational studies have only reported short-term outcomes and there was inconsistent evidence of benefit 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, pulmonary rehabilitation 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 pulmonary rehabilitation, 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 pulmonary rehabilitation program after lung volume reduction surgery in 49 patients who had not received preoperative pulmonary rehabilitation. Health-related quality of life was higher at 3 to 6 months and 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 pulmonary rehabilitation, or patients who had preoperative pulmonary rehabilitation. 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 pulmonary rehabilitation, 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 on 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 postdischarge 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 pulmonary rehabilitation. 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 pulmonary rehabilitation, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One small RCT evaluated a comprehensive pulmonary rehabilitation 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 net health outcome.

## Repeat or Maintenance Pulmonary Rehabilitation

For individuals who have had an initial course of pulmonary rehabilitation who receive repeat or maintenance outpatient pulmonary rehabilitation, 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 pulmonary rehabilitation who receive a single course of home-based pulmonary rehabilitation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Most studies of home-based pulmonary rehabilitation have compared outcomes with standard care. Very few have compared home-based pulmonary rehabilitation with the hospital- or clinic-based pulmonary rehabilitation, 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.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### American College of Physicians

In 2011, joint guidelines on the management of stable chronic obstructive pulmonary disease (COPD) were issued by the American College of Physicians, the American College of Chest Physicians, the American Thoracic Society (ATS), and the European Respiratory Society.<sup>35</sup> The guidelines recommended that "clinicians should prescribe pulmonary rehabilitation for symptomatic patients with an FEV<sub>1</sub> [forced expiratory volume in 1 second] <50% predicted (Grade: strong recommendation, moderate-quality evidence). Clinicians may consider pulmonary rehabilitation for symptomatic or exercise-limited patients with an FEV<sub>1</sub> >50% predicted (Grade: weak recommendation, moderate-quality evidence)."

#### American Thoracic Society and European Respiratory Society

A 2015 joint statement on pulmonary rehabilitation was issued by the ATS and the European Respiratory Society.<sup>36</sup> 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.<sup>37</sup> 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.<sup>38</sup> 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.

## 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.<sup>39</sup> In their 2023 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 1.

**Table 1. 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 ( $\leq 4$ 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).

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

In 2007, the Centers for Medicare & Medicaid Services affirmed its position that a national coverage determination for pulmonary rehabilitation is not appropriate.<sup>40</sup>

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
March 2013	Replace policy	Policy updated with literature review. References 6, 19-23 added; other references renumbered or removed. No change in policy statements.
March 2014	Replace policy	Policy updated with literature review through November 21, 2013. References 1, 5, 9, 12, 20, 23 and 24 added; other references renumbered or removed. Statement added that pulmonary rehabilitation programs are considered investigational in all other situations.
March 2015	Replace policy	Policy updated with literature review through December 15, 2014. References 6, 9-11, and 22-27 added. Statements added the pulmonary rehabilitation is considered medically necessary following lung transplantation and investigational following other types of lung surgery.
September 2016	Policy archived	Policy updated with literature review through January 27, 2016; references 3, 5-9, and 25 added. Policy statements unchanged. Policy Archived.
March 2019	Policy reactivated	Policy reactivated and updated with literature review through January 11, 2018; references 3, 12, 14, 18, 21, 26, 30 and 36 added; reference 26 updated. Policy statements unchanged; statements reordered to align evidence summary.
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; no references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; references added. Policy statements unchanged.

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Date	Action	Description
June 2021	Replace policy	Policy updated with literature review through January 29, 2021; no references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through January 28, 2022; references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through February 1, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.

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