

Subject: Pulmonary Rehabilitation for Chronic Pulmonary Diseases		Original Effective Date: 9/2010
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PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: <http://www.cms.hhs.gov/center/coverage.asp>.

FDA INDICATIONS

Pulmonary Rehabilitation (PR) is not subject to FDA regulation.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

Refer to the following document(s) for Medicare coverage:

In September 2007, the Centers for Medicare and Medicaid Services (CMS), in its final decision memorandum for PR Services, announced there was no basis for a national coverage determination at that time. Specifically, this decision was based on a determination by CMS that the Social Security Act did not expressly define a comprehensive PR program as a Part B benefit, and the evidence was not adequate to draw conclusions on the benefit of the individual components of Pulmonary Rehabilitation. CMS does, however, cover the respiratory services in the Comprehensive Outpatient Rehabilitation Facility regulation (42 CFR 410.100), as well as those services determined covered by local contractors who retain discretion to allow coverage of components of PR.

The Medicare Improvements for Providers and Patients Act of 2008 (MIPPA) added payment and coverage improvements for patients with chronic obstructive pulmonary disease and other conditions, and now provides a covered benefit for a comprehensive PR program under Medicare Part B effective January 1, 2010. This law provides a single PR program, which was codified in the Physician Fee Schedule final rule at 42 CFR 410.47.

Effective January 1, 2010, MIPPA provisions added a physician-supervised, comprehensive PR program which includes mandatory components: (1) physician-prescribed exercise, (2) education or training, (3) psychosocial

assessment, (4) outcomes assessment, and (5) an individualized treatment plan. See the Benefit Policy Manual (BP), Pub. 100-02, chapter 15, § 231, the Claims Processing Manual (CP), Pub. 100-04, chapter 32, § 140, for detailed policy and claims processing instructions. As specified at 42 CFR 410.47(f), pulmonary rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions, with the option for an additional 36 sessions if medically necessary. Contractors shall accept the inclusion of the KX modifier on the claim lines as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond the 36 sessions is medically necessary up to a total of 72 sessions for that beneficiary

Pulmonary Rehabilitation Services NCD (240.8)¹

The CMS National Coverage Determination (NCD) for Pulmonary Rehabilitation Services states that a national coverage determination (NCD) for pulmonary rehabilitation is not appropriate at this time.

Pulmonary Rehabilitation Services LCD

Please access the Medicare Local Coverage Determination (LCD) for coverage criteria that may be available in you specific region at: <http://www.cms.gov/mcd/search.asp?clickon=search>

The above CMS information remains current at the time this policy was last reviewed in June, 2013.

INITIAL COVERAGE CRITERIA

Pulmonary rehabilitation (PR) **may be authorized** when all of the following criteria are met: **[ALL]**

- Prescriber is a Pulmonologist; **and**

- Medically stable and with one of the following diagnosis: **[ONE]**
 - Chronic obstructive pulmonary disease (COPD)^{2,4 50 51}
 - Emphysema^{43,45};
 - Chronic bronchitis;^{12,42}
 - Bronchiectasis^{35 42 56 57}
 - Pre and postoperative recovery from: **[ONE]**
 - Lung transplantation^{60 61 62 63 64}; or
 - Lung volume reduction surgery^{59 65 66}; and

- Documentation of the following:**[BOTH]**
 - Pulmonary function test with an FEV1 less than 50% predicted.^{14 40}; **and**

 - Disabling symptoms following optimal medical management^{10,11} (e.g., medication regimen, pulmonary toilet)⁴⁰ **[ONE]**
 - Dyspnea/fatigue that decrease activity tolerance; **OR**
 - Dyspnea/fatigue causing inability to perform ADL's; **and**

- Documentation of PR program/facility requirements**[ALL]**
 - Facility is a Medicare/Medicaid certified Comprehensive Outpatient Rehabilitation Facility (CORF)
 - Pulmonologist prescribed exercise program
 - Education or training component
 - Psychosocial assessment component

- Outcomes assessment
- An individualized treatment plan
 - Outlines each discipline, goals, type, frequency and duration of the modality, procedure, or activity;
 - An initial evaluation by the PR team may be approved to assess the member’s potential for improvement prior to authorization of the program; **and**
- Smoking Cessation^{2,6,11} for minimally 3 months prior; **and**
- Physically able, willing and motivated to participate;^{10,11} **and**
- Conducted in an outpatient setting; inpatient only if the patient meets inpatient hospitalization criteria; **and**
- Absence of the following medical conditions that may lead to poor outcomes:[**NONE**]
 - Unable to walk⁸
 - Unstable angina or cardiac disease^{7,8,9,10,11}
 - Recent myocardial infarction;^{7,8} member should wait at least 6 months before starting PR
 - Neurologic or orthopedic issues that reduce mobility or cooperation with physical training^{7,9}
 - Poorly controlled coexisting medical condition^{9,10} (e.g., acute cor pulmonale, severe pulmonary hypertension, significant hepatic dysfunction, metastatic cancer, renal failure)⁷
 - Unstable psychiatric conditions^{7,9,10,11}
 - Unresolved substance abuse⁷
 - Severe cognitive deficit¹¹

NOTE: PR is appropriate for patients that meet the outlined indications and who possess the necessary cognitive and physical capabilities.

INITIAL AND CONTINUATION OF THERAPY

Initial Authorization

- An initial evaluation by the PR team may be approved to assess the member’s potential for improvement prior to authorization of the program;
- Initial authorization can be made for 1-2 hour sessions daily for 4 weeks or a total of 12 sessions^{19,20,21} (Please reference the Medicare section for maximum number of allowed sessions for Medicare members)

Continuation of Therapy beyond the initial 12 sessions

- An Additional 8 sessions for a maximum of 20 total sessions may be authorized^{9,23,24,25} [**ALL**]; **and** (Please reference the Medicare section for maximum number of allowed sessions for Medicare members)
- Clinical progress reports/assessments of the following:[**ALL**]
 - Clinical assessments confirming material gains or progress toward goals have been achieved

- Compliance with the plan of care. Therapy should be discontinued and will not be authorized when there is poor adherence to the treatment regimen for any reason.
- None of the following discharge criteria have been met [**NONE**]:
 - Minimal or no potential for material gains or significant progress
 - Member is non-compliant with established plan of care
 - PR goals achieved or patient has reached maximum total of 20 sessions
 - Member of family member/caregiver can assume responsibility for continuing PR at home

Repeat or Maintenance Therapy

Repeat or maintenance PR after completion of the maximum 20 total sessions **may not be authorized** as it is not considered a proven treatment.

(Please reference the Medicare section for maximum number of allowed sessions for Medicare members)

Note: Goal of PR is not to achieve maximum exercise tolerance but to educate and train the patient to maximize endurance through a self-care program at home.³

COVERAGE EXCLUSIONS

All other requests for treatment that do not meet the ‘Coverage Criteria’ section above are considered experimental/investigational or unproven and may not be authorized.

The following requests under the plan of care are considered not medically necessary and will not be authorized: [**NONE**]

- Viewing of films or videotapes, listening to audiotapes, and completing interactive computer programs are not considered an appropriate rehabilitation education program
- Duplication of services between Physical Therapy, Respiratory Care, nursing, or other care modality
- Education or training not related to the member’s illness

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Pulmonary Rehabilitation has been defined by the American Thoracic Society and the European Respiratory Society as “an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities.”³

Pulmonary rehabilitation is a comprehensive planned program designed to decrease symptoms, optimize functional status, increase participation, reverse or stabilize manifestations of the disease, and reduce health-care related costs⁹ (e.g., decreased health care utilization and fewer days of hospitalization).² Integrated into the individualized treatment plan for the patient includes patient assessment, education, exercise training, nutrition and psychosocial support.

The goals for a pulmonary rehabilitation program are to enhance standard therapy in order to control and alleviate symptoms and optimize functional capacity.³ The primary goal is to improve the patient to the highest possible level of independent functioning. This goal is achieved by assisting patients to become more physically active, to learn more about their disease, treatment options, and how to cope with their illness.

Patients are taught to become more actively involved in participating in their own care, more independent in activities of daily living, and less dependent on expensive medical resources and healthcare professionals or caregivers. Pulmonary rehabilitation focuses on reducing symptoms and disease disability rather than attempting to reverse the disease process.

GENERAL INFORMATION

Summary of Medical Evidence

Pulmonary rehabilitation leads to statistically significant and clinically meaningful improvements in health related quality of life (CRQ), functional exercise capacity (WMD 49 meters 95% CI 26 to 72) and maximum exercise capacity (WMD 5.4 watts 95% CI 0.5 to 10.2).^{3,4,14} Pulmonary rehabilitation also reduces dyspnea and health care utilization. One randomized trial identified a decrease in health care utilization following pulmonary rehabilitation: a decrease in hospital days (but not hospitalizations) and primary care physician visits.¹⁵ This study provided evidence that pulmonary rehabilitation can potentially decrease health care costs. Subsequent, non-randomized multi-center studies in California¹⁶ and in the Northeastern states¹⁷ further demonstrated decreased health care utilization. A multicenter, randomized clinical trial was carried out in 7 hospitals provided evidence that an outpatient self-management educational program had positive benefits, including an approximately 40% reduction in hospitalizations for COPD exacerbations and a 59% reduction in unscheduled physician visits.¹⁸ It did demonstrate the importance of the educational component of pulmonary rehabilitation.

Hayes Directory Reports

Hayes does not have a current directory report on the topic of pulmonary rehabilitation. There is an archived report that has not been updated since 2007.²

Cochrane Reviews

A review done in 2006 of 31 randomized controlled trials evaluated pulmonary rehabilitation in patients with COPD measuring functional or maximal exercise capacity and/or quality of life (QOL).⁴ Rehabilitation was defined as minimally four weeks of exercise training with or without psychological support or education. These trials included inpatient, outpatient and home-based programs for COPD patients. COPD patients were defined as best recorded Forced Expiratory Volume after one second FEV1/Forced Vital Capacity (FVC) ratio of individual patients < 0.7; or best recorded FEV1 of individual patients <70% of predicted value. Statistically significant improvements for all outcomes were found. Four domains of quality of life were evaluated (Chronic Respiratory Questionnaire: scores for fatigue, dyspnea, emotional function and mastery), the effect was larger in 12 trials than the minimal clinically important difference of 0.5 units (e.g., dyspnea score: weighted mean differences [WMD] 1.0 units; 95% confidence interval: 0.8 to 1.3 units). Significant improvements were noted in two out of three domains using the St Georges Respiratory Questionnaire. The effect was small and slightly below the threshold of clinical significance for the six-minute walking distance for maximal and functional

exercise capacity (WMD: 48 meters; 95% CI: 32 to 65) in 16 trials. The authors strongly supported that pulmonary rehabilitation is clinically significant and relieves dyspnea and fatigue, improves emotional function and control over COPD patients.

A review done in 2009 of six randomized controlled trials (n=219 patients) was conducted to evaluate the effects of pulmonary rehabilitation after COPD exacerbations receiving conventional care, on future hospital admissions (primary outcome) and health-related quality of life, mortality, and exercise capacity.⁵ The PR program had to include physical exercise. The control groups received community care without rehabilitation. Patients started inpatient rehabilitation within 3 to 8 days of hospital admission in three studies. Outpatient rehabilitation was started after the inpatient treatment in two studies, and in one study outpatient rehabilitation was started after hospital and home treatment of the exacerbation. Statistically significant reductions in hospital admissions over a 34 week period was noted (pooled odds ratio 0.13 [95% CI 0.04 to 0.35], number needed to treat (NNT) 3 [95% CI 2 to 4] and mortality over 107 weeks (pooled odds ratio 0.29 [95% CI 0.10 to 0.84], NNT 6 [95% CI 5 to 30]). Health related quality of life outcomes were well above the minimal important difference (weighted mean differences for fatigue, dyspnea, mastery and emotional function from the Chronic Respiratory Questionnaire. Pulmonary rehabilitation improved exercise capacity (60-215 meters in six minute walk or shuttle tests. There were no reported adverse events. The authors concluded that pulmonary rehabilitation is a highly effective and safe intervention to improve health related quality of care and to reduce hospital admissions and mortality in COPD patients following an exacerbation of their illness.

A more recent Cochrane review (2011) was performed to determine the effects of training intensity (higher versus lower) or type (continuous versus interval training) on primary outcomes in exercise capacity and secondary outcomes in symptoms and HRQoL for people with COPD. The review analysed three RCT's (231 participants) for comparisons between higher and lower-intensity training and eight included studies (367 participants) for comparisons between continuous and interval training. Primary outcomes were outcomes at peak exercise (peak work rate, peak oxygen consumption, peak minute ventilation and lactate threshold), at isowork or isotime, endurance time on a constant work rate test and functional exercise capacity (six-minute walk distance). When comparing higher versus lower-intensity training, the pooled primary outcomes were endurance time and six-minute walk distance. There were no significant differences in endurance time improvement (mean difference (MD) 1.07 minutes; 95% CI -1.53 to 3.67) and six-minute walk distance improvement (MD 2.8 metres; 95% CI -10.1 to 15.6) following higher or lower-intensity training. However, heterogeneity of the endurance time results between studies was significant. When comparing continuous and interval training, there were no significant differences in any of the primary outcomes, except for oxygen consumption at isotime (MD 0.08; 95% CI 0.01 to 0.16) but the treatment effect was not considered clinically important. According to the GRADE system, studies were of low to moderate quality. The authors concluded that comparisons between the higher and lower training intensity were limited due to the small number of included studies and participants. Consequently, there are insufficient data to draw any conclusions on exercise capacity, symptoms and HRQoL for this comparison. For comparisons between continuous and interval training, both appear to be equally effective in improving exercise capacity, symptoms and HRQoL.⁵⁰

Another Cochrane review (2012) was performed to determine whether breathing exercises in people with COPD have beneficial effects on dyspnea, exercise capacity and health-related quality of life compared to no breathing exercises in people with COPD; and to determine whether there are any adverse effects of breathing exercises in people with COPD. Sixteen RCT's involving 1233 participants with mean forced expiratory volume in one second (FEV(1)) 30% to 51% predicted were included. There was a significant improvement in six-minute walk distance after three months of yoga involving pranayama timed breathing techniques (mean difference to control 45 metres, 95% confidence interval 29 to 61 metres; two studies; 74 participants), with similar improvements in single studies of pursed lip breathing (mean 50 metres; 60 participants) and diaphragmatic breathing (mean 35 metres; 30 participants). Effects on dyspnoea and health-related quality of life were inconsistent across trials. Addition of computerised ventilation feedback to exercise training did not provide additional improvement in dyspnea-related quality of life (standardised mean difference -0.03; 95% CI -0.43 to 0.49; two studies; 73 participants) and ventilation feedback alone was less effective than exercise training alone for improving exercise endurance (mean difference -15.4 minutes; 95% CI -28.1 to -2.7 minutes; one study; 32 participants). No significant adverse effects were reported. Few studies reported details of allocation concealment, assessor blinding or intention-to-treat analysis. The authors concluded that breathing exercises over four to 15 weeks improve functional exercise capacity in people with COPD compared to no intervention; however, there are no consistent effects on dyspnea or health-related quality of life. Outcomes were similar across all the breathing exercises examined. Treatment effects for patient-reported outcomes may have been overestimated owing to lack of blinding. Breathing exercises may be useful to improve exercise tolerance in selected individuals with COPD who are unable to undertake exercise training; however, these data do not suggest a widespread role for breathing exercises in the comprehensive management of people with COPD.⁵¹

UpToDate

The evidence indicates that pulmonary rehabilitation performed with smoking cessation, blood gas optimization and medications are considered a part of an optimal treatment program for patients with symptomatic airflow obstruction.⁶ There is limited value in education or psychological support when performed without pulmonary rehabilitation; these domains improve patients' awareness and understanding of their disease. Lower extremity aerobic training has shown to improve patient perception of dyspnea, exercise endurance, and quality of life in COPD patients and should be a part of a pulmonary rehabilitation program. Evidence from small studies suggest that arm training is beneficial for patients that report symptoms when performing upper extremity exercise. The role of breathing training and upper arm exercise training require further study to determine effectiveness. Lower extremity aerobic training enhances exercise endurance, quality of life and perception of dyspnea. Aerobic leg training should be included as a part of all pulmonary rehabilitation programs.

Professional Organizations

The American Thoracic Society (ATS) and the European Respiratory Society (ERS) developed a joint guideline statement (2006) regarding pulmonary rehabilitation that indicates regardless of the type of chronic respiratory disease, patients experience a substantial morbidity from secondary impairments such as cardiac, nutritional and psychosocial dysfunction, as well as suboptimal self-management.⁹ Therefore, PR may be of value for all patients in whom respiratory symptoms are associated with decreased functional capacity or reduced health related quality of living (HRQL). The timing of PR should be based on the clinical status of the individual and should no longer be viewed as a last resort for patients with severe respiratory impairment. PR should be an integral part of the clinical management of all patients with chronic respiratory disease, addressing their functional and/or psychological deficits. At the time this policy was re-reviewed in 2013, this guideline is currently under revision.

An Institute of Clinical Systems Improvements (ICSI) guideline for the diagnosis and management of COPD (updated March 2013) found that Pulmonary Rehabilitation programs are effective in improving exercise capacity, quality of life and perception of symptoms, regardless of age.¹⁰ COPD patients in all stages and at all levels of severity have demonstrated to benefit from exercise training programs with an improvement in exercise tolerance and a reduction in dyspnea and fatigue. The guideline indicates that these benefits wane after the program ends, but if exercise is maintained at home; the patient's health status continues to remain above pre-rehab levels. More information is needed regarding patient selection for pulmonary rehabilitation programs. There currently is insufficient evidence to determine whether repeated courses increase the likelihood a patient will maintain the benefits gained during the initial course. ICSI has outlined recommended indications for referral to a pulmonary rehabilitation program to include the following:

- Symptomatic COPD (characterized by airway obstruction and reduced expiratory airflow)
- Functional limitations that affect quality of life
- Medical regimen that has been maximized, (e.g., bronchodilator, oxygen therapy)
- Mentally capable of learning about their disease (can decrease anxiety and fear)
- Motivated to participate in a pulmonary rehabilitation program

The outlined contraindications include patients with unstable medical conditions (e.g., coronary artery disease, cognitive impairment interfering with learning, severe psychiatric disturbances) or poor commitment to the program. Cardiac and pulmonary stress testing is recommended to be performed to exclude silent cardiac disease and assure safety during exercise training in patients with conditions that might place the patient at risk during exercise training. Many patients are older and have a history of smoking and are at risk for heart disease.

A global evidenced based consensus report (2010) entitled "Global Strategy for the Diagnosis, Management, and Prevention of COPD".¹¹ This report indicates that the evidence shows peak workload increases by 18%, peak oxygen consumption by 11%, and endurance time by 87% from baseline. COPD for all stages of disease appear to benefit from the program. Chair-bound patients do not respond to improvements in functional status even utilizing a home bound program. COPD patients with MRC grade 5 dyspnea do not seem to benefit. Highly motivated patients benefit from the program. Smoking has shown a decreased rate of patients completing the program. A smoking cessation program if enrolled in the program may be a consideration. The length of a program has not been studied in randomized-control trials. The typical treatment range is from 4 to 10 weeks.

The American College of Chest Physicians and the American Association of Cardiovascular and Pulmonary Rehabilitation (ACCP/AACVPR) have issued evidence-based guidelines (2007) for PR for patients with chronic lung disease.³ The ACCP/AACVPR states that PR is appropriate for any stable patient with a chronic lung disease who is disabled by respiratory symptoms (e.g., cystic fibrosis, bronchiectasis, interstitial disease and thoracic cage abnormalities). The goal is to alleviate symptoms, optimize functional capacity, and to restore the patient to the highest possible level of independent function. Exercise training using the muscles of ambulation, lower extremity and upper extremity exercise training, strength training, and low/high intensity exercise training, and education have shown to be effective. The guidelines state there is no consensus of opinion regarding the optimal duration of PR intervention, 6–12 weeks of PR produces benefits in several outcomes (e.g., exercise tolerance, health related quality of life-HRQOL, anxiety, depression). These benefits gradually decline over 12 to 18 months but HRQOL remain above controls at 12 to 18 months. There is weak evidence to suggest that longer pulmonary rehabilitation beyond 12 weeks produce sustained benefits over shorter programs. These guidelines have not been updated since 2007.

The American College of Physicians (ACP) developed an evidence based clinical practice guideline (updated 2011) for stable chronic obstructive pulmonary disease.¹³ The guideline found moderate evidence to support the use of PR programs for symptomatic patients with severe airway obstruction, who have a FEV₁ less than 50% predicted. PR programs have shown to reduce hospitalizations, improve health status and exercise capacity.

The National Institute for Health and Clinical Excellence has developed a guideline (2010) for COPD that include recommendations for pulmonary rehabilitation.⁸ These recommendations state that there is good evidence about the benefits that pulmonary rehabilitation can produce. The evidence for prolonged supervised outpatient programs showed modest benefits and were unrealistic. Based upon current evidence the recommendation for outpatient programs should contain a minimum of 6 weeks and a maximum of 12 weeks of physical exercise, disease education, psychological and social interventions. The benefits of pulmonary rehabilitation appear to wane with time. There is limited evidence concerning the benefits of attendance at further pulmonary rehabilitation programs.

Additionally, pulmonary rehabilitation programs:

- Should be offered to all patients who consider themselves functionally disabled by COPD (usually Medical Research Council Grade 3 and above- Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace) including those who have had a recent hospitalization for an acute exacerbation.
- Are not suitable for patients who are unable to walk, have unstable angina or who have had a recent myocardial infarction.
- Should be held at times that suit patients, and in buildings that are easy for patients to get to and have good access for people with disabilities.
- Should include multidisciplinary interventions tailored to individual patient's needs. The rehabilitation process should incorporate physical training, disease education, nutritional, psychological and behavioral intervention.
- Should make patients aware of the benefits of the program and the commitment required to gain these benefits.

The Agency for Healthcare Research and Quality (AHRQ) conducted a technology assessment (2006) for the Center for Medicare and Medicaid Services (CMS) to address the safety and efficacy of PR primarily for COPD and conditions such as asthma, bronchiectasis, ventilator dependency, and other relevant respiratory illness in patients ≥ 65 years of age.¹² The assessment was based on a re-analysis of 44 RCTs included in three published systematic reviews, and 26 additional RCTs that had not been assessed by these reviews. Little evidence was found on the effects of PR in diseases other than COPD. Overall, exercise-based PR was found to be effective in improving the patients' disease-specific HRQOL, as well as their functional and maximal exercise capacity. Most of the trials were small and many of them had major methodological shortcomings. Analyses of these trials did not identify statistically significant differences between PR protocols that included only exercise training versus protocols that also included additional, non-exercise-based components (e.g., inspiratory muscle training, education, breathing exercises, phone follow-up). The report cautions that absence of statistically significant findings in these comparisons does not imply equivalence of the protocols, and should not be interpreted as such. The report concluded that "based on few small trials with methodological shortcomings, there was insufficient evidence to draw robust conclusions on whether or not exercise training has an incremental impact when added to non-exercise PR components like education or inspiratory muscle training."

Patient Selection Criteria

Evidence regarding the selection of patients has been studied mainly in COPD patients.^{2,9} There are some studies describing pulmonary rehabilitation in other chronic lung diseases. There are prospective and retrospective studies that support the safety and effectiveness of PR in emphysema,^{43,45} and other chronic lung conditions;^{12,42} in stable patients who are disabled by respiratory symptoms of dyspnea, fatigue, sputum production, cough, and obstruction of airflow.^{2,12} There are studies that do not provide convincing data to support pulmonary rehabilitation for restrictive lung diseases.^{38,39} There is insufficient data to support interstitial lung disease and cystic fibrosis for pulmonary rehabilitation programs.^{36,37,44,46,47}

Some evidence was found to support that a period of structured exercise training could improve maximal and functional exercise capacity, skeletal muscle strength, and lumbar bone mineral density in lung transplant recipients and lung volume reduction candidates.^{61 62 63 64 65 66}

Smoking contributes to the loss of FEV1 at an accelerated rate that cannot be prevented by drug therapy and worsening the disability is likely.² Patients that quit smoking will deteriorate more slowly and have a better chance of gaining benefits from PR. Cessation of smoking has been identified as a general rule for the most successful PR programs.^{2,6}

Patient compliance and regular attendance during a rehabilitation program are important factors but do not always occur.⁴⁸ Factors found to decrease attendance include: current smoking, greater breathlessness, higher frequency of hospital admissions, longer duration of the program (e.g., 18 versus 6 weeks), and longer journey time.

Program duration and frequency

Initial Pulmonary Rehabilitation Program

There is no consensus on the optimal duration of pulmonary rehabilitation programs.⁹ There are differences in the types of rehabilitation program content, clinical study designs, patient populations, program content and health systems in various locations making it difficult to draw firm conclusions regarding the optimal duration of a pulmonary rehabilitation program. Studies have shown that short duration programs of 2 weeks or less can result in physical performance improvement.^{19,20} A randomized-control trial of 100 patients with moderate to severe COPD received 4 versus 7 weeks of outpatient rehabilitation.²¹ Participants in both groups had significant improvements in health status and exercise tolerance. A second randomized-control trial demonstrated that an 18-session, 3 times per week for 6 weeks of outpatient pulmonary rehabilitation program, decreased inpatient hospital days and decreased the number of home visits when compared with standard medical management.¹⁵ A single centre RCT has shown that patients with more severe COPD undergoing an 8 week program of pulmonary rehabilitation maintain improvements in exercise capacity and health status for up to 6 months however these were not sustained at one year.²⁵ Several professional organizations including the American College of Chest Physicians, the American Association of Cardiovascular and Pulmonary Rehabilitation (ACCP/AACVPR) and the National Institute for Health and Clinical Excellence recommend 6 to 12 weeks of pulmonary rehabilitation.^{3,8} The American Thoracic Society and European Respiratory Society have identified 20 sessions of comprehensive pulmonary rehabilitation have demonstrated improvements in multiple outcomes.^{9,23,24,25}

Repeat Pulmonary Rehabilitation Program

The benefits of pulmonary rehabilitation appear to wane with time.⁹ Benefits in various outcomes have shown to decline over 6 to 18 months.^{3,9,2,2528,29} but remain improved compared with control subjects after one year. Health related quality of life remains more beneficial than exercise performance. Some of the studies suggest benefits appear to be maintained in the absence of specific maintenance therapy, demonstrating that a change in lifestyle may alter behavior.

There is limited evidence concerning the benefits of attendance at further pulmonary rehabilitation programs.³ There have been conflicting and modest benefits reported following maintenance pulmonary rehabilitation interventions.³⁴ A gradual decline in outcomes are reported following maintenance programs over time.³³ One study failed to show benefit of maintenance program over a patient self-managed, home-based approach.³⁰ Two studies minimal differences or no difference in treatment effect when comparing maintenance training program or unsupervised home training.^{31,32} There is one small study of 61 participants with only 36 patients from the group that were available for evaluation.²⁷ The study suggested that repeated pulmonary rehabilitation led to further temporary improvements in breathlessness and exercise capacity and reduced exacerbations. The methodological limitations of this study included a small sample size with a large proportion of participants that dropped out of the study making it difficult to determine the accuracy of the conclusions. Several professional organizations including the American College of Chest Physicians, the American Association of Cardiovascular and Pulmonary Rehabilitation (ACCP/AACVPR) and the National Institute for Health and Clinical Excellence indicate that the role of maintenance therapy following an initial structured program remains uncertain at this time and a recommendation has not been provided to follow subsequent formal pulmonary rehabilitation.^{3,8}

CODING INFORMATION

CPT	Description
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1019F	Dyspnea assessed, present (COPD) (use in conjunction with 4033F)
4033F	Pulmonary rehabilitation exercise training recommended (COPD)

HCPCS	Description
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face-to-face, one-on-one, each 15 minutes (includes monitoring)
G0238	Therapeutic procedures to improve respiratory function, other than described by G0237, one-on-one, face-to-face, per 15 minutes (includes monitoring)
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, 2 or more individuals (includes monitoring)
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), per hour, per session
S9473	Pulmonary rehabilitation program, nonphysician provider, per diem

ICD-9	Description
491.0	Simple chronic bronchitis
491.1	Mucopurulent chronic bronchitis
491.20	Obstructive chronic bronchitis without exacerbation
491.21	Obstructive chronic bronchitis with exacerbation
491.8	Other chronic bronchitis
491.9	Unspecified chronic bronchitis
492.8	Other emphysema
494.0	Bronchiectasis
496.0	Chronic airway obstruction nec
V42.6	Organ or tissue replaced by transplant, lung

ICD-10 CM	Description –MAY BE COVERED
J41.0	Simple chronic bronchitis
J41.1	Mucopurulent chronic bronchitis
J44.9	Chronic obstructive pulmonary disease unspecified
J44.1	Chronic obstructive pulmonary disease with exacerbation
J41.8	Mixed simple and mucopurulent chronic bronchitis
J42	Unspecified chronic bronchitis
J43.0	Unilateral pulmonary emphysema macleods syndrome
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema

J43.8	Other emphysema
J43.9	Emphysema unspecified
J44.9	Chronic obstructive pulmonary disease unspecified
J47.9	Bronchiectasis, uncomplicated
Z94.2	Lung transplant status

RESOURCE REFERENCES

- Centers for Medicare and Medicaid Services (CMS). National Coverage Determination for Pulmonary Rehabilitation Services (240.8). Accessed at: http://www.cms.gov/mcd/index_list.asp?list_type=ncd#PP
- Hayes, Inc. Hayes Medical Technology Directory. Pulmonary Rehabilitation. Lansdale, PA: Hayes, Inc. April, 2002. Updated April, 2007 and archived Jan 2008.
- Ries AL, Bauldoff G, Carlin BW et al. Pulmonary Rehabilitation: Joint ACCP/AACVPR evidence-based clinical practice guidelines. Chest 2007; 131;4S-42S. Accessed at: <http://www.chestnet.org/Guidelines-and-Resources/Guidelines-and-Consensus-Statements/More-Guidelines>
- Lacasse Y, Goldstein R, Lasseron TJ, Martin S. Pulmonary rehabilitation for chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2006, Issue 4. Art No: CD003793.
- Uhan M, Scharplatz M, Troosters T et al. Pulmonary Rehabilitation following exacerbations of chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2009, Issue 1. Art No: CD005305.
- Celli BR, Stoller JK, Hollingsworth H. Pulmonary rehabilitation in COPD. May, 2013. In: UpToDate, Rose, BD (Ed), UpToDate, Waltham, MA.
- American Association for Respiratory Care (AARC). AARC clinical practice guideline: pulmonary rehabilitation. 2002. Accessed at: <http://www.rcjournal.com/cpgs/pdf/05.02.616.pdf>
- National Institute for Clinical Excellence (NICE). Chronic obstructive pulmonary disease. Management of chronic obstructive pulmonary disease in adults in primary and secondary care. Clinical Guideline 12. June, 2010. Accessed at: <http://www.nice.org.uk/nicemedia/live/13029/49425/49425.pdf>
- Nici L, Donner C, Wouters E, Zuwallack R, Ambrosino N, Bourbeau J, et al. American Thoracic Society/European Respiratory Society statement on pulmonary rehabilitation. Am J Respir Crit Care Med. 2006 Jun 15;173(12):1390-413. Accessed at: <https://www.thoracic.org/statements/>
- Institute of Clinical Systems Improvement (ICSI). Health Care Guideline: Diagnosis and management of Chronic Obstructive Pulmonary Disease (COPD). Seventh Edition. January, 2009. Updated March 2013. Accessed at: <http://www.chestnet.org/Guidelines-and-Resources/Guidelines-and-Consensus-Statements/More-Guidelines>
- Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease. Originally published 1998 Apr. Updated 2010. Accessed at: <http://www.goldcopd.com>
- Agency for Healthcare Research and Quality (AHRQ). Technology Assessment. Pulmonary Rehabilitation for COPD and other lung diseases. November 21, 2006. Accessed at: <http://www.cms.hhs.gov/determinationprocess/downloads/id43TA.pdf>
- Qaseem A, Snow V, Shekelle P, Sherif K, Wilt TJ, Weinberger S, et al. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2007 Nov 6;147(9):633-8. Updated 2011. Accessed at: <http://annals.org/article.aspx?articleid=479627>
- Dynamed. July 2010. Updated June 2013. COPD. Ipswich, MA: EBSCO Publishing.

15. Griffiths TLB. Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomized controlled trial. *Lancet*. 2000; 355(9201):362-368.
16. California Pulmonary Rehabilitation Collaborative Group. Effects of pulmonary rehabilitation on dyspnea, quality of life and health care costs in California. *J. Cardiopulm. Rehabil.* 2004; 24: 52–62.
17. Raskin J., Spiegler P., McCusker C. et al. The effect of pulmonary rehabilitation on healthcare utilization in chronic obstructive pulmonary disease: The Northeast Pulmonary Rehabilitation Consortium. *J. Cardiopulmonary. Rehabilitation*. 2006; 26: 231—236.
18. Bourbeau J., Julien M., Maltais F. et al. Reduction of Hospital Utilization in Patients With Chronic Obstructive Pulmonary Disease. A Disease-Specific Self-management Intervention. *Arch. Intern. Med*. 2003; 163: 585–591.
19. Clini E, Foglio K, Bianchi L, Porta R, Vitacca M, Ambrosino N. Inhospital short-term training program for patients with chronic airway obstruction. *Chest* 2001;120:1500–1505.
20. Votto J, Bowen J, Scalise P, et al. Short-stay comprehensive inpatient pulmonary rehabilitation for advanced chronic obstructive pulmonary disease. *Arch Phys Med Rehabilitation* 1996; 77:1115–1118
21. Sewell L, Singh SJ, Williams JE, et al. How long should outpatient pulmonary rehabilitation be? A randomized controlled trial of four-versus seven weeks. *Thorax* 2006; 61: 767–771
22. Verrill D, Barton C, Beasley W et al. The effects of short-term and long term pulmonary rehabilitation on functional capacity, perceived dyspnea and quality of life. *Chest* 2005;128:673-683.
23. Rossi G, Iorini F, Romagnoli M et al. Length and clinical effectiveness of pulmonary rehabilitation in outpatients with chronic airway obstruction. *Chest* 2005;127:105-109.
24. Fuchs-Climent D, Le Gallais D, Varray A et al. Quality of life and exercise tolerance in chronic obstructive pulmonary disease: effects of a short and intensive inpatient rehabilitation program. *American Journal Physical Medicine and Rehab* 1999;78:330-335.
25. Bestall JC, Paul EA, Garrod R et al. Longitudinal trends in exercise capacity and health status after pulmonary rehabilitation in patients with COPD. *Respir Med*. 2003; 97(2):173-180.
26. Berry MJ, Rejeski WJ, Adair NE et al. A randomized, controlled trial comparing long-term and short-term exercise in patients with chronic obstructive pulmonary disease. *Journal of Cardiopulmonary Rehabilitation*. 2003; 23(1):60-68.
27. Foglio K, Bianchi L, Ambrosino N. Is it really useful to repeat outpatient pulmonary rehabilitation programs in patients with chronic airway obstruction? A 2-year controlled study. *Chest*. 2001; 119(6):1696-1704.
28. Finnerty JP, Keeping I, Bullough I et al. The effectiveness of outpatient pulmonary rehabilitation in chronic lung disease: a randomized controlled trial. *Chest* 2001;119:1705-1710.
29. Hui KP, Hewitt AB. A simple pulmonary rehabilitation program improved health outcomes and reduces hospital utilization in patients with COPD. *Chest* 2003;124:94-97.
30. Brooks D, Krip B, Mangovoski-Alzamora S et al. The effect of post-rehabilitation programs among individuals with chronic obstructive pulmonary disease. *European Resp Journal* 2002;20:20-29.
31. Ringbaek T, Brondum E, Martinez G et al. Long-term effects of 1-year maintenance training on physical functioning and health status in patients with COPD: A randomized controlled study. *Journal of Cardiopulmonary Rehabilitation Prev* Jan-Feb 2010;30 1):47-52.
32. Grosbois J, Lamblin C, Lemaire B et al. Long term benefits of exercise maintenance after outpatient rehabilitation program in patients with chronic obstructive pulmonary disease. *Journal Cardiopulmonary Rehabilitation* 1999; 19:216-225.
33. Ries AL, Kaplan RM, Myers R et al. Maintenance after pulmonary rehabilitation in chronic lung disease a randomized-trial. *American Journal of respiratory Care Med* 2003;167:880-888.

34. Puente-Maestru L, Sanz ML, Sanz P et al. Long-term effects of a maintenance program after supervised or self monitoring training programs in patients with COPD. *Lung* 2003;181:67-78.
35. Newall C, Stockley RA, Hill SL Exercise training and inspiratory muscle training in patients with bronchiectasis. *Thorax* 2005;60:943-948.
36. Ryerson CJ, Garvey C, Collard HR. Pulmonary rehabilitation for interstitial lung disease. *Chest* 2010;138:240-241.
37. Ferreira A, Garvey C, Connors GL et al. Pulmonary rehabilitation in interstitial lung disease: benefits and predictors of response. *Chest* 2009;135:442-447.
38. Salhi B, Troosters T, Behaegel M et al. Effects of pulmonary rehabilitation in patients with restrictive lung diseases. *Chest* 2010; 137;273-279.
39. Naji A, Connor MC, Donnelly SC, McDonnell TJ. Effectiveness of pulmonary rehabilitation in restrictive lung disease. *Journal Cardiopulmonary Rehabilitation* 2006;26(4):237-243.
40. Qaseem A, Snow V, Shekelle P et al. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline from the American College of Physicians. *Annals of Internal Medicine* 2007;147:633-638.
41. Ries AL, Kaplan RM, Limberg TM, Prewitt LM. Effects of pulmonary rehabilitation on physiologic and psychosocial outcomes in patients with chronic obstructive pulmonary disease. *Annals Internal Medicine* 1995 Jun 1;122(11):823-32.
42. Newall C, Stockley, Hill SL. Exercise training and inspiratory muscle training in patients with bronchiectasis. *Thorax* 2005;60:943-948.
43. Ries AL, Make BJ, Lee SM et al. The effects of Pulmonary Rehabilitation in the National Emphysema Treatment Trial. *Chest* 2005;128;3799-3809.
44. Holland AE, Hill C. Physical training for interstitial lung disease. *Cochrane database of Systematic Reviews*. 2008, Issue 4, Art No: CD006322. DOI:10.1002/14651858.CD006322.pub2.
45. Ries AL, Make BJ, Reilly JJ. Pulmonary rehabilitation in emphysema. *Proc American Thoracic Society* 2008, May 1;5(4):524-9.
46. Van Doorn N. Exercise programs for children with cystic fibrosis: a systematic review of randomized controlled trials. *Disability Rehab* 2010;32(1):41-9.
47. Bradley JM, Moran F. Physical training for cystic fibrosis. *Cochrane Database of Systematic Reviews* 2008, Issue 1. Art. No.: CD002768. DOI: 10.1002/14651858.CD002768.pub2.
48. Sabit R; Griffiths TL; Watkins AJ. Predictors of poor attendance at an outpatient pulmonary rehabilitation programme. *Respir Med*. 2008 Jun;102(6):819-24. Epub 2008 Mar 11.
49. Simone RH, Mallory GB, Hoppin AG. Cystic fibrosis: Overview of the treatment of lung disease. May, 2010. In: UpToDate, Rose, BD (Ed), UpToDate, Waltham, MA.

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50. Zainuldin R, Mackey MG, Alison JA. Optimal intensity and type of leg exercise training for people with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2011.
51. Holland AE, Hill CJ, Jones AY, McDonald CF. Breathing exercises for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2012; 10:CD008250.
52. Pan L, Guo YZ, Yan JH, Zhang WX, Sun J, Li BW. Does upper extremity exercise improve dyspnea in patients with COPD? A meta-analysis. *Respir Med*. 2012;106(11):1517.
53. Dolmage TE, Evans RA, Hill K, et al. The effect of pulmonary rehabilitation on critical walk speed in patients with COPD: a comparison with self-paced walks. *Chest* 2012; 141:413.

54. Janaudis-Ferreira T, Hill K, Goldstein RS, et al. Resistance arm training in patients with COPD: A Randomized Controlled Trial. *Chest* 2011; 139:151.
55. Bianchi R, Gigliotti F, Romagnoli I, et al. Impact of a rehabilitation program on dyspnea intensity and quality in patients with chronic obstructive pulmonary disease. *Respiration* 2011; 81:186.
56. UpToDate: Barker A et al. Treatment of bronchiectasis in adults. May, 2013
57. Mandal P, Sidhu MK, Kope L, et al. A pilot study of pulmonary rehabilitation and chest physiotherapy versus chest physiotherapy alone in bronchiectasis. *Respir Med* 2012; 106:1647.
58. Schmidt-Hansen M, Page R, Hasler E. The effect of preoperative smoking cessation or preoperative pulmonary rehabilitation on outcomes after lung cancer surgery: A systematic review. *Clin Lung Cancer*. 2012 Sep 24.
59. UpToDate: Martinez FJ. Lung volume reduction surgery in COPD. May 2013
60. UpToDate: Hashem R. Lung transplantation: General guidelines for recipient selection. May 2013.
61. Li M, Mathur S, Chowdhury NA et al. Pulmonary rehabilitation in lung transplant candidates. *J Heart Lung Transplant*. 2013 Jun;32(6):626-32
62. Wickerson L. Exercise training following lung transplant is now evidence-based practice. *J Physiother*. 2013;59(1):58.
63. Wickerson L, Mathur S, Brooks D. Exercise training after lung transplantation: a systematic review. *J Heart Lung Transplant*. 2010 May;29(5):497-503.
64. Langer D, Burtin C, Schepers L et al. Exercise training after lung transplantation improves participation in daily activity: a randomized controlled trial. *Am J Transplant*. 2012 Jun;12(6):1584-92.
65. Benzo R, Wigle D, Novotny P et al. Preoperative pulmonary rehabilitation before lung cancer resection: results from two randomized studies. *Lung Cancer*. 2011 Dec;74(3):441-5.
66. Morano MT, Araújo AS et al. Preoperative pulmonary rehabilitation versus chest physical therapy in patients undergoing lung cancer resection: a pilot randomized controlled trial. *Arch Phys Med Rehabil*. 2013 Jan;94(1):53-8.
67. Advanced Medical Review (AMR): Policy reviewed by a physician board certified in internal medicine, pulmonary disease, critical care and sleep medicine.