



# Louisiana

## Outpatient Pulmonary Rehabilitation

**Policy #** 00621

**Original Effective Date:** 10/01/2018

**Current Effective Date:** 10/01/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Lung and Lobar Lung Transplant is addressed separately in medical policy 00414.*

### **When Services Are Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider a single course of pulmonary rehabilitation (PR) in the outpatient ambulatory care setting for treatment of chronic pulmonary disease (e.g., moderate-to-severe chronic obstructive pulmonary disease (COPD), bronchiectasis, cystic fibrosis, interstitial lung disease) for patients with moderate-to-severe disease who are experiencing disabling symptoms and significantly diminished quality of life despite optimal medical management to be **eligible for coverage**.

Based on review of available data, the Company may consider a single course of PR in an outpatient ambulatory care setting as a preoperative conditioning component for those considered appropriate candidates for lung volume reduction surgery (LVRS) or for lung transplantation (see medical policy 00414) to be **eligible for coverage**.

Based on review of available data, the Company may consider PR programs following lung transplantation to be **eligible for coverage**.

*Note:*

*When a single course of outpatient PR is considered medically necessary, a maximum of 3 sessions per week for 12 weeks will be approved.*

### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers PR programs following other types of lung surgery, included but not limited to LVRS and surgical resection of lung cancer to be **investigational**.\*

Based on review of available data, the Company considers multiple courses of PR, either as maintenance therapy in patients who initially respond, or in patients who fail to respond, or whose response to an initial rehabilitation program has diminished over time to be **investigational**.\*

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Based on review of available data, the Company considers home-based PR programs to be **investigational**.\*

Based on review of available data, the Company considers PR programs in all other situations to be **investigational**.\*

### **Policy Guidelines**

A PR outpatient program is a comprehensive program that generally includes team assessment, patient 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.

Patient 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 PR. Education in disease management techniques without exercise conditioning does not improve health outcomes of patients who have COPD.

Follow-up to a comprehensive outpatient PR program may include supervised home exercise conditioning.

Candidates for PR should be medically stable and not limited by another serious or unstable medical condition. Contraindications to PR 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).

### **Background/Overview**

In 2013, the American Thoracic Society and the European Respiratory Society defined PR 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.” PR programs are intended to improve patient functioning and quality of life. Most research has focused on patients with COPD, although there has been some interest in patients with asthma, cystic fibrosis, or bronchiectasis.

PR is also routinely offered to patients awaiting lung transplantation and LVRS. PR before lung surgery may stabilize or improve patients’ exercise tolerance, teach patients techniques that will help them recover after

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

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Not applicable.

#### **Centers for Medicare and Medicaid Services (CMS)**

In 2007, the Centers for Medicare & Medicaid Services affirmed its position that a national coverage determination for PR is not appropriate.

### **Rationale/Source**

This review was informed by a 1996 Technology Evaluation Centers (TEC) Assessment.

Evidence reviews 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 evidence review focuses on comprehensive, multidisciplinary programs that include an exercise component plus other modalities. Where there is a lack of evidence on multidisciplinary PR 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 would improve outcomes to the same degree or greater.

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### **CHRONIC OBSTRUCTIVE PULMONARY DISEASE**

Numerous RCTs and several systematic reviews of RCTs have been published. Most recently, Puhan et al (2016) published a Cochrane review that evaluated PR programs for patients who had an exacerbation of COPD. To be included, the rehabilitation program had to begin within 3 weeks of initiating exacerbation treatment and had to include physical exercise. Twenty trials (total 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, 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 meters). Moreover, a pooled analysis of health-related quality of life (HRQOL) found significantly greater improvement after PR vs 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 (odds ratio, 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.

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. PR 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. COPD severity 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 a 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 (CRQ)—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 MCID of 4 watts and the between-group difference in 6MWD—an MD of 43.93 meters—was considered clinically significant.

Rugbjerg et al (2015) published a systematic review that identified 4 RCTs (total N=489 participants). 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) and Gottlieb et al (2011) included patients with moderate COPD, Liu et al (2012) included patients with mild-to-moderate COPD and van Wetering et al (2010) 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.

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### **Section Summary: Chronic Obstructive Pulmonary Disease**

Multiple RCTs and 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**

Jackson et al (2014) evaluated patients with idiopathic pulmonary fibrosis who were 40 to 80 years of age and had disease onset between 3 and 48 months before screening, abnormal pulmonary function, and a 6MWD between 150 and 500 meters. In this pilot RCT, patients were assigned to a PR program consisting of twice-weekly 2-hour rehabilitation sessions over 12 weeks (n=14) or usual care (n=11). Twenty-one of the 25 patients completed the 3-month intervention study. Reviewers did not report between-group statistics. Follow-up data at 3 months postintervention were reported by Gaunaud et al (2014). During the intervention, patients in the PR group had significantly greater self-reported physical activity, but, in the subsequent 3 months, activity levels in the 2 groups were similar. For example, at 6 months, pulmonary function measures (e.g., total lung capacity, forced vital capacity, spirometry diffusion capacity) did not change significantly within either group. 6MWD data were not reported.

### **Section Summary: Idiopathic Pulmonary Fibrosis**

One small RCT has evaluated a comprehensive PR program in patients with idiopathic pulmonary fibrosis; at 3 months postintervention, outcomes did not differ between groups that did and did not receive PR.

### **BRONCHIECTASIS**

Lee et al (2017) published a systematic review of RCTs on PR in patients with non-cystic fibrosis bronchiectasis. 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 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 beyond the immediate postintervention 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 nonexercise control condition immediately postintervention. Limited observational data would suggest that outcomes in patients with other respiratory conditions may benefit, but likely not as much as COPD patients.

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### **PR PROGRAMS BEFORE LUNG SURGERY**

#### **Lung Volume Reduction Surgery**

PR prior to LVRS represents a distinct subset of patients with COPD, and the National Emphysema Treatment Trial requires 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.

#### **Lung Transplantation**

A systematic review of the literature on PR for lung transplant candidates was published by Hoffman et al (2017). 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, one was conducted in the inpatient setting, and the included only 9 patients. Conclusions on the impact of a comprehensive PR program before lung transplantation on health outcomes cannot be drawn from this systematic review.

#### **Lung Cancer Resection**

Several small RCTs have evaluated preoperative PR for patients undergoing lung cancer resection. Morano et al (2013) conducted a single-blind study in Brazil. 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 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;  $p=0.04$ ). Also, 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. 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 ( $n=9$ ). 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.

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. This U.K.-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

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after participation in a 4-session presurgical PR program. In between-group analyses, there were no statistically significant differences between the intervention and comparisons groups in clinical outcomes such as postoperative pulmonary complications, readmissions, and mortality after surgery.

### **Section Summary: PR Programs Before Lung Surgery**

The National Emphysema Treatment Trial has recommended administering PR before LVRS, which is considered the standard of care before LVRS and lung transplantation. However, there is a lack of large RCTs comparing PR with no PR for preoperative candidates undergoing LVRS, 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.

### **PR PROGRAMS AFTER LUNG SURGERY**

#### **Lung Volume Reduction Surgery**

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. Patients underwent LVRS at a single center and had not received PR at that institution presurgery. 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 including with a variety of components, including dietary, physical therapy, physical exercise, psychosocial, occupational therapy, and respiratory therapy. The primary outcome was HRQOL 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 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- vs postsurgery LVRS could not be determined.

#### **Subsection Summary: PR Programs After LVRS**

No comparative studies have evaluated PR programs after LVRS. One case series have evaluated a comprehensive PR program after LVRS in 49 patients who had not received preoperative PR. HRQOL was higher at 3 to 6 months and 12 to 18 months postsurgery. 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**

There is literature on exercise training after lung transplantation (not necessarily provided in comprehensive PR programs). Wickerson et al (2010) published a systematic review of RCTs and nonrandomized studies that have evaluated any exercise intervention in lung transplantation. Seven studies met inclusion criteria; two were RCTs, two were uncontrolled trials, and one used healthy controls. Reviewers did not pool study findings. The 2 RCTs evaluated lumbar extension training and its impact on lumbar bone mineral density; neither reported functional outcomes. The uncontrolled studies reported improvements in functional status following exercise interventions.

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Langer et al (2012) conducted an RCT in the U.K. that examined activity-related outcomes in lung transplant recipients after exercise training. 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 counseling sessions in the 6 months postdischarge. Six patients dropped out of the trial, three in each group. The primary outcome was daily walking time, assessed by activity monitors. At the end of the 3-month intervention and 1-year postdischarge, mean walking times were 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. The primary outcome was change in the 6-minute walking test (6MWT). 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 6MWT (mean improvement in 7-week group, 202 meters vs 14-week group, 149 meters). At 6 months after transplantation, the MD 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.

Munro et al (2009) published a case series that evaluated a comprehensive PR program after lung surgery. The 7-week program, which started 1 month postsurgery, 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 and forced vital capacity had improved significantly (p<0.001). For example, mean forced expiratory volume in 1 second was 71% 1 month, postsurgery and 81% at 3 months. Similarly, 6MWD improved significantly: mean distance was 451 meters at 1 month and 543 meters at 3 months posttransplant. The study lacked a control group. Hence, the degree of improvement that would have occurred without participation in a PR program is unknown.

### **Subsection Summary: PR Programs After Lung Transplantation**

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 did report 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 and had a significantly greater 6MWD.

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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**

Stigt et al (2013) published an RCT evaluating a multicomponent postsurgery PR program in patients with resectable lung cancer. 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 St. George's Respiratory Questionnaire 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 6MWT 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 6MWT.

An exercise-only intervention after lung cancer surgery (not comprehensive PR) was evaluated in an RCT published by Edvardsen et al (2015). This single-blind trial was conducted in Norway and included lung cancer patients at 4 to 6 weeks postsurgery. 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. The 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 forced expiratory volume in 1 second was 0.6% of 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 steps;  $p=0.002$ ). This trial did not report other functional outcomes (e.g., 6MWD).

### **Subsection Summary: Lung Cancer Resection**

A small 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.

### **REPEAT AND MAINTENANCE PR PROGRAMS**

Both repeat and maintenance PR programs provide additional rehabilitation services after initial participation in a PR program. Program categories are not strictly defined, but repeat programs are generally those that include patients who failed to respond to an initial program or whose response to an

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initial rehabilitation program diminished over time. In contrast, maintenance programs tend to be those designed to extend the effects of the initial PR program, and they are open to all patients who successfully completed an initial program.

### **Repeat PR Program**

One RCT was identified that evaluated a repeat PR program. 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. Initially, patients completed a 6-week inpatient program or a 12-week outpatient program. The repeat PR program lasted 3 weeks and consisted of exercise and education; patients could choose inpatient or outpatient versions. Over 6 months, 41 patients developed an exacerbation and 12 did not. 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 HRQOL, 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 MCID. In the control group, the magnitude of change in all domains did not meet the MCID. 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 evidence review 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 PR Program**

In 2012, an Ontario Health Technology Assessment evaluated PR for patients with COPD. Reviewers identified 3 RCTs (total N=284 participants) assessing maintenance PR programs for individuals with COPD who had successfully completed an initial PR 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 two. 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 patients), 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 meters). The CI was wide, indicating lack of precision in the pooled estimate. Also, reviewers considered the MCID to be 25 to 35 meters walked, and meta-analysis of trial findings did not meet this threshold of difference between groups.

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Several RCTs were published after the Ontario assessment. Guell et al (2017) published findings of a 3-year trial of patients with severe COPD. A total of 143 patients attended an initial 8-week outpatient PR 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=0.046). 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=0.119). The CRQ 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=0.617); 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 PR to standard care without maintenance PR in patients who had COPD and had completed at least 60% of an initial PR program. 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 CRQ dyspnea domain. Among trial completers, mean CRQ dyspnea score changed from 2.6 to 3.2 among patients receiving maintenance PR and from 2.5 to 3.3 among controls. The difference between groups was not statistically significant. Secondary outcomes, including other CRQ 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 and Maintenance PR Programs**

A few small RCTs have evaluated repeat or 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 repeat and maintenance PR programs on health outcomes in patients with COPD is insufficient.

### **HOME-BASED PR PROGRAMS**

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 U.S. 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. 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 St. George's Respiratory Questionnaire total score found statistically significant improvements in symptoms with home-based PR

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compared with control (effect size, -11.33; 95% CI, -16.37 to -6.29). A pooled analysis of data from 4 studies (n=167 patients) 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 CI, 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. 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 from 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.

Another systematic review was published by Neves et al (2016). 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.

A study with relatively large sample size and that compared home-based PR with outpatient clinic-based PR was published by Maltais et al (2008). 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 8 weeks of self-monitored home-based exercise training or 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 CRQ 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.

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### **SUMMARY OF EVIDENCE**

#### **Chronic Pulmonary Disease Rehabilitation**

For individuals with moderate-to-severe COPD who receive a single course of outpatient PR, the evidence includes numerous RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and QOL. The published studies found improved outcomes (i.e., functional ability, QOL) 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 a meaningful improvement in the net health outcome.

For individuals with idiopathic pulmonary fibrosis who receive a single course of outpatient PR, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, and QOL. The number of controlled studies is limited. One small RCT evaluated a comprehensive PR program in patients with idiopathic pulmonary fibrosis; at 3 months postintervention, outcomes did not differ between groups that did and did not receive PR. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with bronchiectasis who receive a single course of outpatient PR, the evidence includes RCTs, systematic reviews, and observational data. Relevant outcomes are symptoms, functional outcomes, and QOL. A systematic review of 4 RCTs on PR for patients with bronchiectasis found that some, but not all, outcomes, improved more with PR than with nonexercise control conditions immediately after the intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### **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 QOL. There is a lack of large RCTs comparing PR with no PR for preoperative candidates undergoing LVRS, 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 the effects of the technology on health outcomes.

#### **PR After Lung Surgery**

For individuals who have had LVRS who receive a single course of outpatient PR, the evidence includes a case series. Relevant outcomes are symptoms, functional outcomes, and QOL. No published RCTs were identified. The case series evaluated a comprehensive PR program after LVRS in 49 patients who had not received preoperative PR. HRQOL was higher at 3 to 6 months and 12 to 18 months postsurgery. The series did not provide data on patients who underwent LVRS and did not have postoperative PR, or patients who had preoperative PR. The evidence is insufficient to determine the effects of the technology on health outcomes.

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For individuals who have had lung transplantation who receive a single course of outpatient PR, the evidence includes RCTs, systematic reviews, and observational studies. Relevant outcomes are symptoms, functional outcomes, and QOL. 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 PR. Case series data also support improvements in 6MWD after postoperative PR. The evidence is sufficient to determine that the technology results in a meaningful 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 an RCT. Relevant outcomes are symptoms, functional outcomes, and QOL. One small 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. The evidence is insufficient to determine the effects of the technology on health outcome.

### **Repeat or Maintenance Rehabilitation**

For individuals who have had an initial course of PR who receive repeat or maintenance outpatient PR, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. There are only a few RCTs, and many of them have methodologic limitations and/or did not report clinically significant outcomes. The evidence is insufficient to determine the effects of the technology on health outcome.

### **Home-Based 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 QOL. Most studies of home-based PR have compared outcomes with standard care. Very few have compared home-based PR with the hospital- or clinic-based PR, and the available studies are mostly of low quality. The evidence is insufficient to determine the effects of the technology on health outcome.

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07/05/2018 Medical Policy Committee review

07/11/2018 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 07/2019

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Code Type	Code
CPT	No codes
HCPCS	G0237, G0238, G0239, G0302, G0303, G0304, G0305, G0424, S9473
ICD-10 Diagnosis	C96.6, D38.0-D38.6, D84.1, D86.0-D86.9, E84.0-E84.9, I11.0-I11.9, I27.0, J41.0-J41.8, J43.0-J43.9, J44.0-J44.9, J47.0-J47.9, J84.0-J84.9, J99, M34.0-M34.9, P27.0-P27.9, Q21.0, Z86.711

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