Pulmonary Rehabilitation

Policy Number: MM.09.008  
Original Effective Date: 06/01/2017  
Line(s) of Business: PPO; HMO; QUEST Integration  
Current Effective Date: 06/01/2017

Line(s) of Business Excluded: Fed 87  
Section: Rehabilitative Therapy  
Place(s) of Service: Outpatient

I. Description

Pulmonary rehabilitation (PR) is a multidisciplinary approach to reducing symptoms and improving quality of life in patients with compromised lung function.

The American Thoracic Society (ATS) and the European Respiratory Society (ERS) define 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 the patient’s functioning and quality of life. Most studies have focused on patients with chronic obstructive pulmonary disease (COPD), although there has been some interest in PR in patients with asthma, cystic fibrosis, or bronchiectasis. According to a joint ATS/ERS statement issued in 2013, PR may be of value for conditions other than COPD (e.g., bronchiectasis, asthma, cystic fibrosis) in cases in which respiratory symptoms are associated with diminished functional capacity or reduced health-related quality of life.

PR is also routinely offered to patients awaiting lung transplantation and lung volume reduction surgery. PR before lung surgery may stabilize or improve patients’ exercise tolerance, teach patients techniques that will help them recover after the procedure, and allow health care providers to identify individuals who might be suboptimal surgical candidates due to noncompliance, poor health, or other reasons.

II. Criteria/Guidelines

A single course of pulmonary rehabilitation in the outpatient ambulatory care setting is covered (subject to Limitations and Administrative Guideline) when the following criteria are met:

A. The patient has one of the following conditions:
   1. The patient has moderate to severe chronic pulmonary disease which results in disabling symptoms and significantly diminished quality of life despite optimal medical management.
2. The patient is considered to be an appropriate candidate for lung volume reduction surgery or for lung transplantation and requires preoperative conditioning.
3. The patient has undergone lung transplantation.

B. The patient is medically stable and not limited by another serious or unstable medical condition.

C. The pulmonary rehabilitation outpatient program is a comprehensive, multidisciplinary, goal directed program that generally includes the following:
   1. Team assessment and formulation of an individual treatment plan.
   2. Patient education and training that addresses breathing retraining, bronchial hygiene, medications and proper nutrition.
   3. Psychosocial assessment and/or intervention that addresses support system and dependency issues.
   4. Exercise training that 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.
   5. Formulation and monitoring of an ongoing home exercise program.
   6. Outcomes assessment including initial and periodic evaluations based on patient-centered outcomes and objective clinical measures of effectiveness of the program.

D. The pulmonary rehabilitation program is currently accredited:
   1. For outpatient free standing facilities, the program has been approved by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR).
   2. For hospital-based facilities, the program has been accredited by AACVPR or by the Joint Commission of Accreditation of Healthcare Organizations (JACHO).
   3. At HMSA’s discretion, exceptions can be made for programs that are actively pursuing accreditation.

III. Limitations

A. Multiple courses (with the exception of one course before lung transplant and one course following lung transplant) of pulmonary rehabilitation are not covered, 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.

B. Home-based pulmonary rehabilitation programs are not covered.

C. Pulmonary rehabilitation programs are not covered following other types of lung surgery, included but not limited to lung volume reduction surgery and surgical resection of lung cancer.

D. Pulmonary rehabilitation is limited to 18 sessions. Up to an additional 18 sessions may be covered when medically necessary. Services should be discontinued at any time under the following circumstances:
   1. There is no clear, measurable progress toward the stated rehabilitation goal.
   2. Ability to perform activities of daily living has been restored.
   3. There is no therapeutic benefit or likelihood of improvement beyond what is expected with performance of activities of daily living and prescribed home exercise program and passage of time.
E. Pulmonary rehabilitation is not covered for medically unstable patients and/or patients who are limited by another serious or unstable medical condition. Contraindications to pulmonary rehabilitation include, but are not limited to:
   1. Severe neuropsychiatric disturbance (e.g., dementia, organic brain syndrome; inability to follow directions; inability to remember to perform activities); or
   2. Significant or unstable medical conditions (e.g., heart failure, acute cor pulmonale, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke, coronary artery disease).

F. This policy does not apply to Fed 87.

IV. Administrative Guidelines
   A. Precertification is required for the initial 18 sessions. Documentation supporting that criteria II.A to D are met must be submitted. To precertify, please complete HMSA's Precertification Request and mail or fax the form as indicated.
   B. Precertification is required for continuation beyond 18 sessions. Initial evaluation and outcomes assessments including current re-evaluation must be submitted.
   C. When providing nutritional counseling or smoking cessation services, that are included in the program, indicate by including the ICD-10 codes, as applicable.

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<th>ICD-10 Codes</th>
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<tr>
<td>Z71.6</td>
<td>Tobacco abuse counseling</td>
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<td>Z71.3</td>
<td>Dietary counseling and surveillance</td>
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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>G0239</td>
<td>Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring)</td>
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<tr>
<td>G0424</td>
<td>Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day</td>
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<th>CPT Codes</th>
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<tr>
<td>94664</td>
<td>Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device</td>
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<tr>
<td>94667</td>
<td>Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation</td>
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V. Scientific Background

The policy was based on a TEC Assessment and updated with searches of the MEDLINE database. Most recently, the literature was reviewed through December 15, 2014. Following is a summary of the literature to date.

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

Initial Course of PR Programs for Patients with Chronic Pulmonary Disease

Patients with Chronic Obstructive Pulmonary Disease

Numerous randomized controlled trials (RCTs) and several systematic reviews of RCTs have been published. A 2011 Cochrane review by Puhan and colleagues included studies on the effect of outpatient or inpatient PR following an acute exacerbation of chronic obstructive pulmonary disease (COPD). To be included, the rehabilitation program needed to begin within three weeks of initiating exacerbation treatment and had to include physical exercise. Nine trials with a total of 432 participants met inclusion criteria. Rehabilitation was outpatient in four trials, inpatient in four trials, and the fifth trial included both in- and outpatient rehabilitation. In a pooled analysis of five trials, there was a statistically significant reduction in the primary outcome, rate of hospital admissions, with PR compared with usual care (odds ratio [OR] = 0.22; 95% confidence interval [CI]: 0.08 to 0.58). Secondary outcomes also favored the PR group. For example, there was also a significant reduction in mortality with PR when findings from three studies were pooled (OR = 0.28; 95% CI: 0.10 to 0.84). In addition, in a pooled analysis of six studies, there was a greater change from baseline in the six-minute walk distance (6MWD) with PR (mean difference: 77.7 meters; 95% CI: 12.1 to 143.2).

In 2011, Beauchamp and colleagues conducted a systematic review of trials on PR for COPD, with the aim of determining the optimal duration of rehabilitation programs. Five studies met the inclusion criteria. Studies needed to be randomized and compare different lengths of rehabilitation, and more than 90% of patients in the study needed to be diagnosed with COPD. A pooled analysis of findings was not possible due to heterogeneity of PR program duration and outcome measures. Three of the trials reported a significant difference in quality of life (QOL) in favor of the longer programs. The length of programs was 18 months versus 3 months in 2 studies and 7 weeks versus 4 weeks in the third study. In the other 2 trials, there was not a statistically significant difference between groups.

A 2013 systematic review by Jacome and colleagues searched for studies on PR in patients with mild COPD. They identified only one RCT, which was determined to be insufficient evidence to support PR programs in this population.
In 2014, Wiles and colleagues published a systematic review of RCTs evaluating exercise training combined with psychological interventions for adults with COPD. Twelve trials met inclusion criteria; comparison interventions included usual care, wait listing, or exercise or psychosocial interventions alone. Due to heterogeneity of interventions, comparisons and outcome measures, meta-analyses of the entire group of studies were not conducted. In pooled analyses of subsets of studies, the standardized mean differences consistently favored the combined exercise and psychosocial interventions over usual care/waitlist controls. Compared with exercise or psychosocial interventions alone, the combination intervention was consistently superior to the comparison for some outcomes (e.g., dyspnea, anxiety, exercise capacity) but not for others (e.g., depression, QOL).

Representative RCTs conducted in patients with moderate to severe COPD are described next. Of interest, PR programs differed, both in the individual components of the program and its duration. For example, the programs ranged in length from six weeks to six months. In addition, all the randomized studies were conducted outside the United States, and thus conclusions regarding the structure of a PR program may not be applicable to the U.S. health care system.

In 2000, Guell and colleagues reported on the results of a study that randomly assigned 60 patients with COPD to undergo PR or standard care. The specific focus of the study was to examine the long-term effects (24 months) of the PR program. The patients received breathing retraining in the first three months followed by exercise training in the next three months. The improvement in both symptoms and QOL noted at three months after completion of the program continued with somewhat diminished magnitude in the second year of follow-up.

A 2013 trial by Roman and colleagues in Spain randomized 97 patients to 1 of 3 groups: PR for 3 months followed by 12 months of rehabilitation maintenance, PR for 3 months only, and usual care. Participants had moderate COPD according to GOLD criteria. The PR program was conducted in an ambulatory care setting and included education, respiratory physiotherapy and muscle training. The prespecified primary outcome was change in the Spanish validated version of the Chronic Respiratory Questionnaire (CRQ) at 3 and 12 months. A change of 0.5 point per item was considered to represent a clinically significant change in the score. At 12 months, there was not a statistically significant difference between groups in any of the 4 dimensions of the CRQ (i.e., dyspnea, fatigue, emotional function, mastery). At 3 months, the only statistically significant difference was between the PR only and control group on the dyspnea dimension, and this favored the control group. There were no statistically significant differences between groups on secondary outcomes including the 6MWD and forced expiratory volume in 1 second (FEV1).

A 2014 trial by Deepak and colleagues in Spain included 60 patients who had experienced an acute exacerbation of COPD. They received standard treatment with and without a 12-week PR program that included patient assessment, health education, exercise training and testing, nutrition counseling and psychosocial rehabilitation. At the end of the intervention period, the 6MWD increased significantly in the PR group and decreased significantly in the standard care group (p<0.01 in each group). Moreover, there was significant improvement
in the St. George’s Respiratory Questionnaire (SGRQ) total score and QOL score in the PR group compared with the standard care group.

Section Summary
Multiple RCTs and meta-analyses of RCTs have been published and, for the most part, these have found improved outcomes (i.e., functional ability, QOL) in patients with moderate to severe COPD who undergo a comprehensive PR program in the outpatient setting. There is limited evidence on the efficacy of repeated and/or prolonged PR programs, and the available evidence is mixed on whether these programs lead to additional health outcome benefits.

Patients with Other Chronic Respiratory Diseases
Patients with chronic lung diseases other than COPD have not been studied as extensively as those with COPD, in large part because the lower prevalence of these disorders. No RCTs evaluating comprehensive PR programs in this population were published before 2013. One small RCT that evaluated patients with idiopathic pulmonary fibrosis (IPF) has now been published, but there are still no RCTs in patients with other conditions. Jackson and colleagues conducted a pilot RCT with IPF patients aged 40 through 80 years who had disease onset between 3 and 48 months before screening and had abnormal pulmonary function and a 6MWD between 150 and 500 meters. Patients were assigned to a PR program consisting of twice-weekly two-hour rehabilitation sessions over twelve weeks (n=14) or usual care (n=11). Twenty-one of the 25 patients completed the study. The authors reported a number of outcomes at the end of the three-month intervention period. They did not specify primary outcomes and did not report between-group p values. Follow-up data three months post-intervention were reported by Gaunaurd and colleagues. During the intervention, patients in the PR group had significantly greater self-reported physical activity, but in the subsequent three months, activity levels in the two groups were similar. Pulmonary function measures, e.g., total lung capacity, forced vital capacity (FVC) and spirometry diffusion capacity did not change significantly within either group during the six-month period. 6MWD was not reported.

Only observational studies are available in patients with bronchiectasis. In 2011, Ong and colleagues in Australia retrospectively compared findings in patients with bronchiectasis (n=69) and an age- and sex-matched group of patients with COPD who attended an outpatient PR program. During the twelve-month follow-up period, the two diagnosis groups did not differ significantly on the primary outcome measures, 6MWD (p=0.20), and CRQ score (p=0.7). At the 12-month follow-up, the mean between-group difference in 6MWD was 16.1 meters (95% CI: -15.0 to 47.1), and the mean between-group difference in the CRQ was -1.3 points (95% CI: -10.1 to 8.3). This study was not designed to evaluate whether patients with bronchiectasis benefit from PR programs (e.g., it did not compare PR with usual care).

Section Summary
One small RCT evaluating a comprehensive PR program in patients with IPF provides insufficient evidence that PR is effective in this population. RCTs are not available evaluating
PR in other non-COPD patients. Observational data suggest that outcomes in patients with other respiratory conditions may benefit, but likely not as much as COPD patients.

**Home-Based PR Programs**

Evaluation of home-based PR programs involves searching for evidence that these are at least as effective as programs conducted in the ambulatory care setting. The programs also need to be comprehensive PR programs and be feasible in the context of the U.S. health care system.

Several RCTs and systematic reviews of RCTs have been published on home-based PR programs. Among the systematic reviews, Liu and colleagues in 2013 identified 18 RCTs evaluating home-based PR programs. Most studies compared PR with usual care, and none of the included trials compared home-based and clinic-based programs. Only 2 of the 18 studies were conducted in the United States, and both of those were published in the 1990s. The studies reported different outcomes over different timeframes, and pooled analysis only included data from 2 to 4 studies. For example, a pooled analysis of 3 studies with a total of 112 patients reporting the SGRQ total score found statistically significant improvement in symptoms with home-based PR compared with control (effect size: -11.33; 95% CI: -16.37 to -6.29). A pooled analysis of data from 4 studies (N=167) found a significantly increased 6MWD after 12 weeks in the PR group compared with control (effect size: 35.9; 95% CI: 9.4 to 62.4). The latter analysis had a wide CI, indicating that there is not a precise estimate of effect size.

Previously, a 2010 systematic review by Vieira and colleagues identified twelve RCTs comparing home-based PR with PR in another setting or to standard care in patients with COPD. The comparison intervention in three studies was a hospital-based program, in eight studies was standard care, and one study had both types of comparisons. The methodologic quality of the studies was considered to be average to poor, and most had small sample sizes and relatively short follow-up duration. The authors did not pool study findings and findings of individual studies were mixed. Three studies that compared home-based PR with standard care reported data on between-group differences in QOL; in all three studies, differences were reported as statistically significant. The two studies that reported differences in exercise capacity found home-based PR to result in significantly greater improvement in the 6MWD or constant work rate test than standard care. On the other hand, in the three studies comparing home-based PR and hospital-based programs, there were no statistically significant differences between groups in quality-of-life changes. Moreover, in the two studies that assessed maximal work level and the two studies that assessed the 6MWD, outcomes did not differ significantly after home-based or hospital-based PR programs. The authors commented that the review was limited by the generally low quality of the randomized trials and that most studies had only short-term follow-up.

A study with a relatively large sample size, and that compared home-based PR with outpatient clinic-based PR was published by Maltais and colleagues in 2008. This was a noninferiority trial and was conducted in Canada. Eligibility criteria included stable COPD for at least four weeks before study participation and no previous participation in PR programs; 252 patients were included. All patients initially completed a four-week self-management
educational program. They were then randomized to receive eight weeks of either self-monitored home-based exercise training or outpatient hospital-based exercise training. The exercise program included aerobic and strength exercises conducted three times per week. Patients were followed up for 40 weeks after completion of the exercise program. Both interventions produced similar improvements in the CRQ Dyspnea subscale at one 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 one year was considered clinically unimportant. The study did not evaluate a comprehensive PR program.

**Section Summary**

Most studies of home-based PR compared outcomes with standard care. There are very few studies that compare home-based PR with hospital or clinic-based PR and the available studies are mostly of low quality. Therefore, there is insufficient evidence that comprehensive PR programs conducted in the home setting are at least as effective as comprehensive PR programs in the ambulatory care setting.

**Repeat and Maintenance PR Programs for Patients with COPD**

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 considered to be those that include patients who failed to respond to an initial program or whose response to an initial rehabilitation program has diminished over time. In contrast, maintenance programs tend to be those designed to maintain the effects of the initial PR program, and they are open to all patients who successfully completed an initial program.

One RCT was identified that evaluated a repeat PR program. Carr and colleagues in Canada prospectively identified patients with moderate to severe COPD who experienced an acute exacerbation within 12 months of participating in a PR program. Initially, patients completed either 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, a total of 41 patients developed an exacerbation and 12 did not have an exacerbation. Seven patients withdrew from the study, and the remaining 34 were randomly assigned to receive a repeat PR program within 1 month of the exacerbation (n=17) or 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 of 16 patients (56%) remaining in the intervention group chose an inpatient program and 7 chose an outpatient program. Patients were assessed before the repeat PR program, immediately after the program (3 weeks later), and again 12 weeks after the beginning of the exacerbation (≈5 weeks after completing the repeat rehabilitation program). The primary outcome was change in health-related HRQOL, as measured by the CRQ, a validated measure with 4 domains. There was no statistically significant difference between groups in change in CRQ scores. Among patients in the intervention group, the magnitude of improvement in the domains of dyspnea (0.7±1.5 points) and fatigue (0.5±1.3 points) met
or exceeded the minimum clinically important difference (MCID). In the control group, the magnitude of change in all dimensions did not meet the MCID. Change in the 6MWD, a secondary outcome, was not significantly different between groups at either follow-up time. Outcomes were not reported separately for patients who chose inpatient versus outpatient programs (the policy addresses outpatient programs). The authors 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 a small sample size.

In 2012, an Ontario Health Technology Assessment was published on PR for patients with COPD. The review identified 3 RCTs (total N=284 participants) evaluating maintenance PR programs for individuals with COPD who successfully completed an initial PR program. The studies excluded patients who had experienced a recent acute exacerbation of COPD. The maintenance programs all consisted of supervised exercise sessions; program duration was 3 months in 1 program and 12 months in the other 2 programs. One program also included an unsupervised exercise component, and 1 included educational sessions. The reviewers judged the quality of the studies as generally poor due to methodologic limitations such as inadequate information on randomization, allocation concealment and blinding and lack of clarity around the use of an intention-to-treat analysis. In a pooled analysis of data from 2 of the studies (total N=168), there was a significantly greater 6MWD in patients who participated in the maintenance program compared with those in a control group (mean difference: 22.9 meters; 95% CI: 5.2 to 40.7). The CI was wide, indicating lack of precision in the pooled estimate. In addition, the review authors considered the minimal clinically important difference in meters walked to be 25 to 35 meters, and the meta-analysis of study findings did not meet this threshold of difference between groups.

**Section Summary**

A few small RCTs have been performed that evaluate repeat or maintenance rehabilitation programs. Due to the small number of RCTs, methodologic limitations of available studies, 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.

**PR Programs Before Lung Surgery**

**Lung Volume Reduction Surgery**

PR prior to lung volume reduction surgery (LVRS) represents a distinct subset of patients with COPD, and the National Emphysema Treatment Trial (NETT) requires all candidates to undergo a vigorous course of PR. The final results of the NETT Trial support treatment effectiveness in a subset of patients with COPD.

**Lung Cancer Resection**

Several small RCTs have been published evaluating preoperative PR for patients undergoing lung cancer resection. In 2012, Morano and colleagues published a single-blind study that was conducted in Brazil. Patients with non-small-cell lung cancer eligible for lung resection were randomly assigned to receive 4 weeks of PR (exercise-only, 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 were found to have inoperable disease). Several postoperative outcomes were assessed. Patients in the PR group spent significantly fewer days in the hospital than patients in the chest physical therapy group (mean: 7.8 vs 12.2 days; \( p=0.04 \)). In addition, patients in the PR group spent fewer days with chest tubes than the physical therapy group (mean: 4.5 vs 7.4 days; \( p=0.03 \)). The study did not assess longer term functional outcomes after surgery.

In 2011, Benzo and colleagues published findings of 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 video-assisted thoracoscopic. The first study had poor recruitment and was only able to enroll 9 patients. The second study enrolled 19 patients in either a 10-session preoperative PR program \((n=10)\) or usual care \((n=9)\).

The mean (SD) number of days in the hospital was 6.3 (3.0) in the PR group and 11.0 (6.3) in the control group \((p=0.058)\). A total of 3 patients (33%) in the PR group and 5 patients (63%) in the control group experienced postoperative pulmonary complications \((p=0.23)\). The study likely had too small a sample size to detect statistically and clinically significant differences between groups. The authors recommended that a larger multicenter randomized trial be conducted in this population of patients.

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

**Section Summary**

There is a lack of large RCTs comparing PR with no PR for preoperative candidates undergoing LVRS, lung transplantation, or lung cancer resection. However, NETT required PR before LVRS: PR is standard of care before LVRS and lung transplantation. The few small RCTs and observational studies published to date on PR before lung cancer resection did not find consistent evidence of benefit.

**PR Programs After Lung Surgery**

**Lung Volume Reduction Surgery**

No studies were identified that evaluated comprehensive PR programs in patients after LVRS. A 2008 review article noted that there is a lack of controlled studies and yet PR is typically provided to patients after LVRS to hasten the recovery process.
**Lung Cancer Resection**

One RCT, published by Stigt and colleagues in 2013, evaluated a multicomponent postsurgery PR program in patients with resectable lung cancer. The study was conducted in the Netherlands. Before thoracotomy, 57 patients were randomized to PR (n=23) or usual care (n=26). 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 study was terminated early because the institution started offering video-assisted thorascopic surgery, and few patients were choosing thoracotomy. Data on 49 patients were analyzed. The primary end point was QOL, as measured by the difference between groups in change in the total SGRQ score from baseline to 12 months. This difference (SD) was 2.71 (6.90) points and was not statistically significant (p=0.69). However, the 6MWD, a secondary outcome, improved significantly more in the PR group than the usual care group at 3 months. The between-group difference (SD) in 6MWD was 94 (38) meters (p=0.024). A limitation of this analysis is that only 8 of 23 patients in the PR performed a 6MWD at 3 months; the other 15 patients had dropped out or felt unable to take the test. Eleven of 25 patients in the usual care group performed the 6MWD test.

An exercise-only intervention after lung cancer surgery (not comprehensive PR) was evaluated in an RCT published by Edvardsen and colleagues in 2014. This single-blind study was conducted in Norway and included lung cancer patients 4 to 6 weeks postsurgery. A total of 61 patients were randomized to undergo an exercise program 3 times a week for 20 weeks or usual care. The exercise intervention took place at local fitness centers and was supervised by trained personal trainers and physical therapists. The primary outcome, change in peak oxygen uptake from baseline to the end of the intervention, was significantly greater in the intervention group than 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 FEV1 was 0.6% predicted (95% CI: -4.2 to 5.4; p=0.738) and the difference in stair run was 4.3 steps (95% CI: 1.6 to 7.1; p=0.002). This study did not report other functional outcomes such as 6MWD.

**Lung Transplantation**

No RCTs evaluating comprehensive PR programs post lung transplantation were identified. In 2009, Munro and colleagues published findings of a case series in which patients underwent a comprehensive outpatient PR program 1 month after lung surgery. The 7-week program consisted of 1 hour of supervised exercise 3 times a week and a weekly group education session facilitated by various members of a multidisciplinary team (e.g., nurse, dietician, occupational therapist, social worker). Compared with the beginning of the program, on program completion, both FEV1 and FVC improved significantly (p<0.001). For example, mean FEV1 was 71% 1 month postsurgery and 81% at 3 months. Similarly, 6MWD improved significantly; mean distance was 451 meters at 1 month and 543 at 3 months post-transplant. The study is limited by lack of a control group; the degree of improvement that would have occurred without participation in a PR program is not known.

In addition, there is literature on exercise training after lung transplantation that is not part of a comprehensive PR program. In 2010, Wickerson and colleagues published a systematic review of RCTs and nonrandomized studies that evaluated any type of exercise intervention
in lung transplantation. Seven studies met inclusion criteria; 2 were RCTs, 2 were noncontrolled, and 1 used healthy controls. The authors did not pool study findings. The 2 RCTs both evaluated lumbar extension training and its impact on lumbar bone mineral density; neither reported functional outcomes. The uncontrolled studies reported that there were improvements in functional status following exercise interventions.

More recently, in 2012, an RCT conducted in the U.K. by Langer et al examined activity-related outcomes in lung transplant recipients after exercise training. The study included 40 patients between the ages of 40 and 65 years who underwent single or double lung transplantation and had an uncomplicated postoperative period. All patients underwent a standard mobilization program in the hospital after surgery. Following hospital discharge, patients were randomized to undergo a supervised exercise program 3 times a week for 3 months (n=21) or usual care with instructions to exercise (n=19). Patients in both groups had 6 individual counselling sessions in the 6 months after discharge. A total of 6 patients dropped out of the study, 3 in each group.

The primary outcome was daily walking time assessed by activity monitors. At baseline (time of hospital discharge), mean daily walking time (SD) was 36 (16) minutes in the exercise group and 32 (26) minutes in the control group. At the end of the 3 month intervention and 1 year post discharge, mean walking time was significantly longer in the intervention than control group. At 1 year, the exercise group walked a mean (SD) of 85 (27) minutes per day and the control group walked a mean of 54 (30) 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. The mean (SD) 6MWD at 1 year was 86% (7) of predicted in the exercise group and 74% (11) of predicted in the control group (p=0.002). The study had a relatively small sample size and may have been underpowered to detect clinically meaningful differences between groups on secondary outcomes.

Section Summary
For postsurgical comprehensive PR, only 1 small RCT was identified. The RCT included patients who underwent thoracotomy for lung cancer, was terminated early, and had mixed findings. There were also several small RCTs evaluating exercise training after lung surgery. One of these, conducted in lung transplant recipients, reported physical activity outcomes and found a significant benefit of a 3-month exercise training program compared with usual care on daily walking time and some secondary outcomes.

Summary of Evidence
The literature supports the conclusion that a comprehensive pulmonary rehabilitation (PR) program in the outpatient ambulatory care setting in patients with moderate to severe chronic respiratory disease is associated with improved symptoms and quality of life. Although there have been many randomized trials, the structure of PR programs is variable, so it is not possible to provide further guidance regarding the optimal components of a PR program or its duration. There are insufficient data to conclude whether a comprehensive home-based PR program is at least as effective at improving the net health outcome compared with PR provided in the ambulatory care setting. Thus, a single course of PR may
be considered medically necessary in the ambulatory care setting for patients with moderate to severe chronic pulmonary disease who meet criteria and investigational in the home setting. There are insufficient data focusing on programs designed to maintain the benefits of a PR program or evaluate repeat PR programs. Thus, repeat and maintenance PR programs are considered investigational.

For patients undergoing lung surgery, findings from the National Emphysema Treatment Trial suggest a subset of chronic obstructive pulmonary disease (COPD) patients who are appropriate candidates for PR before lung volume reduction surgery. For patients undergoing lung transplantation, PR is considered standard of care to maximize preoperative pulmonary status. For patients undergoing lung cancer resection, there are a few small randomized controlled trials but these trials have not demonstrated a consistent benefit of PR on health outcomes. Therefore a single course of PR in an outpatient setting is considered medically necessary for patients before lung volume reduction surgery or lung transplantation.

There is a small amount of evidence that supports the use of PR post lung transplantation, and PR is part of standard post-transplantation protocols. Given the evidence and the current standard of care, PR may be considered medically necessary post lung transplantation. For other types of lung surgery, there is insufficient evidence on whether PR programs improve the net health outcome, and therefore PR is considered investigational after lung surgery for other indications.

**Practice Guidelines and Position Statements**

A 2013 joint statement on PR was issued by the American Thoracic Society (ATS) and the European Respiratory Society (ERS). The statement included the following relevant conclusions:

- PR provided to patients with respiratory disease other than COPD has demonstrated improvement in respiratory symptoms, exercise tolerance and quality of life.
- Appropriately designed home-based exercise training has been found to be effective at reducing dyspnea and increasing exercise performance in patients with COPD.
- PR provides an essential role in the management of patients before and after lung transplantation. (This section refers to studies on post-operative exercise training, not dyspnea and increasing exercise performance in patients with COPD.

A 2013 guideline on PR in adults by the British Thoracic Society includes the following recommendations:

- PR should be offered to patients with COPD to improve exercise capacity, dyspnea, health status and psychological wellbeing.
- PR programs of 6 to 12 weeks in duration are recommended. A minimum of 12 supervised sessions are recommended, although some patients may gain benefit from fewer sessions.
- If considering a home-based program, the following factors need careful consideration: patient selection, means of providing remote support and/or supervision and provision of home exercise equipment.
A 2011 joint guideline on management of COPD was issued by the American College of Physicians, the American College of Chest Physicians (ACCP), ATS, and ERS: The guideline recommends that “clinicians should prescribe pulmonary rehabilitation for symptomatic patients with an FEV [forced expiratory volume] <50% predicted (Grade: strong recommendation, moderate-quality evidence). Clinicians may consider pulmonary rehabilitation for symptomatic or exercise-limited patients with an FEV >50% predicted (Grade: weak recommendation, moderate-quality evidence).”

In 2007, a joint guideline on PR for COPD and other chronic respiratory diseases was issued by ACCP and the American Association of Cardiovascular and Pulmonary Rehabilitation. The panel issued a number of recommendations. Following are the strong recommendations based on strong (1A) or moderate (1B) evidence:

**Grade of Recommendation 1A**
- A program of exercise training of the muscles of ambulation is recommended as a mandatory component of pulmonary rehabilitation for patients with COPD.
- Pulmonary rehabilitation improves the symptom of dyspnea and improves health-related quality of life in patients with COPD.
- Six to 12 weeks of pulmonary rehabilitation produces benefits in several outcomes that decline gradually over 12 to 18 months.
- Both low- and high-intensity exercise training produce clinical benefits for patients with COPD. Unsupported endurance training of the upper extremities is beneficial in patients with COPD and should be included in pulmonary rehabilitation programs.

**Grade of Recommendation 1B**
- Lower-extremity exercise training at higher exercise intensity produces greater physiologic benefits than lower-intensity training in patients with COPD. The scientific evidence does not support the routine use of inspiratory muscle training as an essential component of pulmonary rehabilitation.
- Education should be an integral component of pulmonary rehabilitation. Education should include information on collaborative self-management and prevention and treatment of exacerbations.

PR is beneficial for some patients with chronic respiratory diseases other than COPD.

**U.S. Preventive Services Task Force Recommendations**
No U.S. Preventive Services Task Force recommendations related to PR have been identified.

**Medicare National Coverage**
In 2007, the Centers for Medicare and Medicaid Services (CMS) affirmed their position that a national coverage determination for PR is not appropriate.
VII. **Important Reminder**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VIII. **References**

6. Jacome CI, Marques AS. Pulmonary rehabilitation for mild chronic obstructive pulmonary disease: a 1 systematic review. Respir Care. Oct 8 2013. PMID 24106321


