MEDICAL POLICY

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POLICY TITLE	OUTPATIENT PULMONARY REHABILITATION
POLICY NUMBER	MP-8.008

Original Issue Date (Created):	**March 28, 2005**
Most Recent Review Date (Revised):	**March 25, 2014**
Effective Date:	**June 1, 2014**

I. POLICY

A single course of pulmonary rehabilitation in the outpatient setting may be considered **medically necessary** for outpatient treatment of chronic pulmonary disease for patients with moderate-to-very severe disease.

Candidates for pulmonary rehabilitation should be medically stable and not limited by another serious or unstable medical condition.

Contraindications to pulmonary rehabilitation include

- severe psychiatric disturbance (e.g., dementia),
- significant or unstable medical conditions (e.g., congestive heart failure, acute cor pulmonale, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke).

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

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

Home-based pulmonary rehabilitation programs are considered **investigational**.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with multiple courses of pulmonary rehabilitation and home-based pulmonary rehabilitation services.

Pulmonary rehabilitation programs are considered **investigational** in all other situations. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with other situations.

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Policy Guidelines

A pulmonary rehabilitation 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 pulmonary rehabilitation. Education in disease management techniques without exercise conditioning does not improve health outcomes of patients who have chronic obstructive pulmonary disease.

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

Candidates for pulmonary rehabilitation should be medically stable and not limited by another serious or unstable medical condition.

Cross-reference:

MP-1.025 Lung Volume Reduction Surgery for Severe Emphysema
MP-9.015 Lung and Lobar Lung Transplant
MP-9.014 Heart/Lung Transplant

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II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[Y] SeniorBlue HMO*
[Y] SeniorBlue PPO*
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO**

*Pulmonary rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions, with the option for an additional 36 sessions if medically necessary. Refer to Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual Chapter 15, section 231, revised by CR 6823, and the Medicare Claims Processing Manual, Chapter 32, Section 140. These revised documents are attached to CR 6823, which is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R124BP.pdf* (Benefit Policy Manual) and *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1966CP.pdf* (Claims Processing Manual) on the CMS website.

** Refer to FEP Medical Policy Manual MP-8.03.05 Outpatient Pulmonary Rehabilitation. The FEP Medical Policy manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND

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Pulmonary rehabilitation is a multidisciplinary approach to reducing symptoms and improving quality of life in patients with compromised lung function. The approach can be used in patients with chronic pulmonary disease and as preoperative conditioning before lung surgery.

The American Thoracic Society (ATS) and the European Respiratory Society (ERS) define pulmonary rehabilitation (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." (1) Pulmonary rehabilitation programs are intended to improve the patient's functioning and quality of life. The vast majority of study has 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 (American Thoracic Society/European Respiratory Society) statement issued in

2013, pulmonary rehabilitation may be of value for conditions other than COPD e.g. bronchiectasis, asthma and cystic fibrosis in cases in which respiratory symptoms are associated with diminished functional capacity or reduced health-related quality of life.

Pulmonary rehabilitation is also routinely offered to patients awaiting lung transplantation and lung volume reduction surgery (LVRS). PR before lung surgery may stabilize or improve patients' exercise tolerance, teach patients techniques that will help them recover after the procedure, and allow healthcare providers to identify individuals who might be suboptimal surgical candidates due to non-compliance, poor health, or other reasons.

IV. RATIONALE

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This policy is updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period November 2012 through November 21, 2013. Following is a summary of the literature to date.

Initial course of pulmonary rehabilitation programs for patients with chronic pulmonary disease

Patients with Chronic Obstructive Pulmonary Disease (COPD)

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 COPD. (3) To be included, the rehabilitation program needed to begin within 3 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 4 trials, inpatient in 4 trials, and the fifth trial included both in- and out-patient rehabilitation. In a pooled analysis of 5 trials, there was a statistically significant reduction in the primary outcome, rate of hospital admissions, with PR compared to 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 3 studies were pooled (OR: 0.28, 95% CI: 0.10 to 0.84). In addition, in a pooled analysis of 6 studies, there was a greater change from baseline in the 6 minute walk distance (6MWD) with PR (mean difference=77.7 meters, 95% CI: 12.1 to 143.2 meters).

In 2011, Beauchamp and colleagues conducted a systematic review of trials on pulmonary rehabilitation for COPD, with the aim of determining the optimal duration of rehabilitation programs. (4) 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 in favor of the longer programs. The length of programs was 18 month 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. (5) They identified only 1 RCT which was determined to be insufficient evidence to support PR programs in this population.

Representative RCTs conducted in patients with moderate to severe COPD are described below. Of interest, PR programs differed, both in the individual components of the program and its duration. For example, the programs ranged in length from 6 weeks to 6 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. healthcare system.

Guell and colleagues reported on the results of a study that randomly assigned 60 patients with COPD to undergo PR or standard care. (6) 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 3 months followed by exercise training in the next 3 months. The improvement in both symptoms and QOL noted at 3 months after completion of the program continued with somewhat diminished magnitude in the second year of follow-up.

Wedzicha and colleagues examined the effects of a PR program in patients with moderately severe and severe COPD who were randomly assigned to receive an 8-week program of PR or standard care. (7) Patients with severe COPD were treated at home. While significant improvement was noted in exercise performance and QOL among those with moderately severe COPD assigned to the PR program, no improvement was found in those with severe COPD.

A trial van Wetering and colleagues focused on patients with less advanced COPD. (8) They randomly assigned 199 patients with average moderate airflow obstruction but impaired exercise capacity (peak work load <70% predicted normal) to a 4-month PR program or usual care. At the end of the intervention, the PR group had significantly greater improvement in the St. George's Respiratory Questionnaire (SGRQ) total score, a mean reduction of 3.9 points in the PR group, and an increase of 0.3 point in the usual care group. At 12 months, the SGRQ score had almost returned to baseline in the PR group; it remained stable in the usual care group. A total of 156 of 199 (79%) participants completed the 24-month follow-up. After 24 months, the total SGRQ score was slightly higher than baseline in the usual care group and lower than baseline in the PR group, a statistically significant 2.6 unit mean difference (p=0.045).

A 2013 trial by Roman and colleagues in Spain randomized 97 patients to 1 of 3 groups: pulmonary rehabilitation for 3 months followed by 12 months of rehabilitation maintenance, PR for 3 months only and usual care. (9) 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 pre-specified 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 points 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, or 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 6MWT and FEV1.

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 and quality of life) 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 shows mixed results on 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 identified. There are several published case series and comparative observational studies.

For example, in a prospective study published in 2010, Kozu and colleagues compared outcomes in 2 cohorts of patients that participated in an identical 8-week outpatient PR program in Japan. (10) The study included 45 patients with idiopathic pulmonary fibrosis (IPF), and these were matched by age and disease severity to 45 COPD patients. A total of 36 of 45 (80%) IPF patients and 40 of 45 (89%) completed the program. At the end of the program, each group experienced statistically significant increases in exercise capacity (distance walked in 6 minutes), improvement in dyspnea (lower dyspnea grade), and an increase in the activities of daily living (ADL) score compared to baseline. The COPD group, but not the IPF group, also had statistically significant increases in health status as measured by the short form-36 (SF-36). Six-month follow-up data were available for 30 of 45 (67%) of IPF patients and 37 of 45 (82%) of COPD patients. Comparing the 2 groups at 6 months, patients in the COPD group had significantly greater exercise capacity, greater improvement in dyspnea, and higher ADL scores compared to the IPF group.

In 2011, Ong and colleagues in Australia retrospectively compared findings in patients with bronchiectasis (n=69) and an age- and gender-matched group of patients with COPD who attended an outpatient PR program. (11) During the 12-month follow-up period, the 2 diagnosis groups did not differ significantly on the primary outcome measures, 6MWD (p=0.20) and score on the Chronic Respiratory Questionnaire (p=0.7). At the 12-month follow-up, the mean between-group difference in the 6MWD was 16.1m (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 or not patients with bronchiectasis benefit from PR programs (e.g., it did not compare PR to usual care).

Section summary: No published RCTs were identified that evaluated pulmonary rehabilitation programs in patients with chronic respiratory diseases other than COPD. Observational data suggest that outcomes patients with other respiratory conditions may benefit, but likely not as much as COPD patients.

Home-based pulmonary rehabilitation 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. (12) Most studies compared PR to 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 time frames, 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 St. George's Respiratory Questionnaire total score found statistically significant improvement in symptoms with home-based PR compared to control (effect size: -11.33, 95% CI: -16.37 to -6.29). A pooled analysis of data from 4 studies (total n=167) found a significantly increased 6-minute walk distance (6MWD after 12 weeks in the PR group compared to control (effect size: 35.9, 95% CI: 9.4 to 62.4). The latter analysis had a wide confidence interval, indicating that there is not a precise estimate of effect size.

Previously, a 2010 systematic review by Vieira and colleagues identified 12 RCTs comparing home-based PR to PR in another setting or to standard care in patients with COPD. (13) The comparison intervention in 3 studies was a hospital-based program, in 8 studies was standard care, and 1 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 to standard care reported data on between-group differences in QOL; in all 3 studies, differences were reported as statistically significant. The 2 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 3 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 2 studies that assessed maximal work level and the 2 studies that assessed the 6-minute walk test (6MWT), 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 to outpatient clinic-based PR was published by Maltais and colleagues in 2008. (14) This was a non-inferiority trial and was conducted in Canada. Eligibility criteria included stable COPD for at least 4 weeks before study participation and no previous participation in PR programs 252 patients were included. All patients initially completed a 4-week self-management educational program. They were then randomized to receive 8 weeks of either self-monitored home-based exercise training or outpatient hospital-based exercise training. The exercise program included aerobic and strength exercises conducted 3 times per week. Patients were followed up for 40 weeks after completion of the exercise program. Both interventions produced similar improvements in the Chronic Respiratory Questionnaire dyspnea subscale 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 (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 study did not evaluate a comprehensive pulmonary rehabilitation program.

Section summary: Most studies of home-based PR compared outcomes to standard care. There are very few studies that compare home-based PR to 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 pulmonary rehabilitation programs for patients with chronic pulmonary disease

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. (15) 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 (approximately 5 weeks after completing the repeat rehabilitation program). The primary outcome was change in HRQOL as measured by the Chronic Respiratory Questionnaire, 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 one study with a small sample size.

In 2012, an Ontario Health Technology Assessment was published on pulmonary rehabilitation for patients with COPD. (16) The review identified 3 RCTs (total of 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 (ITT) analysis. In a pooled analysis of data from 2 of the studies (total n=168), there was a significantly greater 6 minute walk distance in patients who participated in the maintenance program compared to those in a control group (mean difference: 22.9 meters [95% CI: 5.2 to 40.7]). The confidence interval 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 25-35 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.

Pulmonary rehabilitation programs prior to lung surgery

Pulmonary rehabilitation 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. (17)

Several small RCTs have been published evaluating preoperative pulmonary rehabilitation for patients undergoing lung cancer resection. In 2012, Morano and colleagues published a single-blind study that was conducted in Brazil. (18) Patients were randomly assigned to receive 4 weeks of pulmonary rehabilitation (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 of 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 of 4.5 vs. 7.4 days, p=0.03). There was not a significant difference between groups in the length of hospital stay. The study did not assess longer-term functional outcomes after surgery.

In 2011, Benzo and colleagues published findings of 2 small exploratory RCTs evaluating pulmonary rehabilitation prior to lung cancer resection. (19) Eligibility criteria included having moderate to severe COPD and being scheduled for lung cancer resection either by open thoracotomy or video-assisted thoracoscopy. 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 pre-operative PR program (n=10) or usual care (n=9).
The mean number of days in the hospital was 6.3 (standard deviation [SD] =3.0) in the PR group and 11.0 (SD=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 post-operative 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-randomized controlled study on PR for patients undergoing lung cancer surgery was identified. The study, by Bradley and colleagues in the U.K., evaluated an outpatient-based PR intervention in 58 lung cancer patients who were candidates for surgery. (20) 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 6MWT of 20 meters in the intervention group before and after participation in a 4-session pre-surgical PR program. In between-group analyses, there were not statistically significant differences between the intervention and comparisons groups in clinical outcomes such as post-operative pulmonary complications, readmissions and mortality following surgery.

Section summary: There is a lack of large RCTs comparing PR to no PR for preoperative candidates undergoing LVRS, lung transplantation, or lung cancer resection. However, the National Emphysema Trial (NETT) required PR prior to lung volume reduction surgery: PR is standard of care prior to LVRS and lung transplantation. The few small RCTs and observational studies published to date on PR prior to lung cancer resection did not find consistent evidence of benefit.

Ongoing Clinical Trials

Pulmonary Rehabilitation in Interstitial Lung Diseases (NCT01198288: (21) This trial from Belgium is randomizing patients with interstitial lung disease to receive 6 months of pulmonary rehabilitation or usual care. The primary study outcome is change in the six minute walk distance after 6 months. The expected sample size is 60 patients.

Effects of Home-based Pulmonary Rehabilitation in Patients With Severe or Very Severe Chronic Obstructive Pulmonary Disease (COPD) (NCT01198288) (22): The study, conducted in Italy, is randomizing patients with COPD to receive standard care only (medication, information about exercise, and monthly check-in calls) or standard care plus 10 in-home supervised pulmonary rehabilitation sessions. The primary outcome is the distance walked test, and secondary outcomes include quality of life, dyspnea, and COPD relapse rate. Estimated enrollment is 182 patients.

Benefits and Costs of Home-based Pulmonary Rehabilitation in Chronic Obstructive Pulmonary Disease (HomeBase) (NCT01423227): (23) This study, conducted in Australia, is randomizing 144 patients with COPD to a hospital-based pulmonary rehabilitation program or a home-based PR program. The primary outcome is change in the 6 minute walk distance at 8 weeks and at 12 months. The expected completion date is October 2014.

Summary

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 to 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.

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For patients undergoing lung surgery, findings from the National Emphysema Treatment Trial suggest a subset of COPD patients who are appropriate candidates for PR prior to 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 RCTs 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 prior to lung resection surgery or lung transplantation

Practice Guidelines and Position Statements
A 2013 joint statement on pulmonary rehabilitation was issued by the American Thoracic Society (ATS) and the European Respiratory Society (ERS). (1) The statement included the following relevant conclusions:

- Pulmonary rehabilitation 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.

A 2013 guideline on pulmonary rehabilitation in adults by the British Thoracic Society includes the following recommendations: (24)

- Pulmonary rehabilitation should be offered to patients with COPD to improve exercise capacity, dyspnea, health status and psychological wellbeing.
- PR programs of 6-12 weeks' 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 (ACP), the American College of Chest Physicians (ACCP), the ATS, and the ERS (25): The guideline recommends that "clinicians should prescribe pulmonary rehabilitation for symptomatic patients with an [forced expiratory volume] FEV <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 pulmonary rehabilitation was issued by the American College of Chest Physicians (ACCP) and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) (26): 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 chronic obstructive pulmonary disease.

- Pulmonary rehabilitation improves the symptom of dyspnea and improves HRQOL 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.
- Pulmonary rehabilitation is beneficial for some patients with chronic respiratory diseases other than COPD.

V. DEFINITIONS

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

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Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

HCPCS Code	Description
G0237	MUSCLES FACE TO FACE ONE ON ONE EACH 15 MINUTES
G0238	TX PROC IMPRV RESP FUNCT NOT G0237 FCE-FCE 15MIN
G0239	TX PROC IMPRV RESP FUNCT/INCR RESP MUSC 2/> IND
G0424	PULMONARY REHAB W EXER
S9473	PULMONARY REHABILITATION PROGRAM, NON-PHYSICIAN PROVIDER, PER DIEM

ICD-9 Procedure Codes	Description
93.18	Breathing exercise
93.19	Exercise, not elsewhere classified
94.49	Other counseling

ICD-9-CM Diagnosis Code*	Description
135.	SARCOIDOSIS
235.7	NEOPLASM OF UNCERTAIN BEHAVIOR OF TRACHEA, BRONCHUS, AND LUNG
277.00-277.01	CYSTIC FIBROSIS WITHOUT MENTION OF MECONIUM ILEUS
277.6	OTHER DEFICIENCIES OF CIRCULATING ENZYMES
277.8	OTHER SPECIFIED DISORDERS OF METABOLISM
402.10	BENIGN HYPERTENSIVE HEART DISEASE WITHOUT HEART FAILURE
415.1	PULMONARY EMBOLISM AND INFARCTION
416.0	PRIMARY PULMONARY HYPERTENSION
491.20	OBSTRUCTIVE CHRONIC BRONCHITIS, WITHOUT EXACERBATION
491.8	OTHER CHRONIC BRONCHITIS
492.0	EMPHYSEMATOUS BLEB
492.8	OTHER EMPHYSEMA
494.	BRONCHIECTASIS

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ICD-9-CM Diagnosis Code*	Description
496.	CHRONIC AIRWAY OBSTRUCTION, NOT ELSEWHERE CLASSIFIED
515.	POSTINFLAMMATORY PULMONARY FIBROSIS
516.3	IDIOPATHIC FIBROSING ALVEOLITIS
517.8	LUNG INVOLVEMENT IN OTHER DISEASES CLASSIFIED ELSEWHERE
710.1	SYSTEMIC SCLEROSIS
745.4	VENTRICULAR SEPTAL DEFECT
748.61	CONGENITAL BRONCHIECTASIS
770.7	CHRONIC RESPIRATORY DISEASE ARISING IN THE PERINATAL PERIOD

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
J99	Respiratory disorders in diseases classified elsewhere
D86.0 – D86.9	Sarcoidosis; code range
D38.0 – D38.6	Neoplasm of uncertain behavior of middle ear and respiratory and intrathoracic organs; code range
E84.0 – E84.9	Cystic fibrosis; code range
D84.1	Defects in the complements system
C96.6	Unifocal Langerhans-cell histiocytosis
I11.0 – I11.9	Hypertensive heart disease; code range
I27.0	Primary pulmonary hypertension
Z86.71	Personal history of pulmonary embolism ``
J44.0 – J44.9	Other Chronic obstructive pulmonary disease; code range
J41.0 – J41.8	Simple and mucopurulent chronic bronchitis; code range
J43.0 – J43.9	Emphysema; code range
J47.0 – J47.9	Bronchiectasis; code range
J84.0 – J84.9	Other interstitial pulmonary diseases
M34.0 – M34.9	Systemic sclerosis (scleroderma); code range
Q21.0	Ventricular septal defect (Eisenmenger's syndrome)
P27.0 – P27.9	Chronic respiratory disease originating in the perinatal period; code range

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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X. POLICY HISTORY

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MP 8.008	**CAC 11/30/04**
	CAC 9/27/05
	CAC 11/29/05
	CAC 11/28/06
	CAC 1/29/08
	CAC 5/26/09
	CAC 5/25/10 Consensus
	CAC 7/26/11 Adopting BCBSA. Changed title to match BCBSA- Outpatient Pulmonary Rehabilitation (formerly Outpatient Pulmonary Rehabilitation and Pulmonary Function Tests). Changed disease severity range indication from moderate-to-severe disease to moderate-to-very severe disease. Changed policy statement for multiple courses of pulmonary rehab from "not medically necessary" to "investigational". Deleted the limit of 18 sessions. Deleted statement indicating this therapy is not medically necessary for other diagnosis. Deleted information related to pulmonary functions testing, patient initiated spirometry, transtelephonic or home PFTs. Deleted benefits information indicating noncoverage for maintenance programs including health club fees and exercise equipment. Deleted statement indicating ST, PT, OT and cardiac rehab is not covered in conjunction with pulmonary rehab unless for an unrelated condition. Added statement indicating home-based pulmonary rehabilitation programs are considered investigational. Deleted paragraph indicating patients with severe pulmonary impairment are not appropriate candidates.
	Administrative posting 3/22/12. Policy revised for clarification eliminating some restrictive clinical verbiage that is not found in the GOLD document.
	Administrative change 6/14/12.Deleted Medicare variation. LCD L31483 retired.
	Administrative change 7/23/12 Added Medicare variation referencing Claims Processing Manual. Added FEP variation referencing FEP policy manual.
	CAC 6/4/13 Consensus list review. Administrative code review complete.
	CAC 3-25-14 Consensus. Added statement "Pulmonary rehabilitation programs are considered **investigational** in all other situations". Policy guideline section created and guideline statements moved into that section. Added rationale section. Updated references. Coding reviewed.

POLICY TITLE	OUTPATIENT PULMONARY REHABILITATION
POLICY NUMBER	MP-8.008

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