Clinical Review Criteria
Pulmonary Rehabilitation

• COPD
• Chronic Pulmonary Lung Disease
• Emphysema

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Kaiser Permanente’s sole discretion, at any time, with or without notice. Member contracts differ in their benefits. Always consult the patient’s Medical Coverage Agreement or call Kaiser Permanente Customer Service to determine coverage for a specific medical service.

Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
</tr>
<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Pulmonary Rehabilitation Services (240.8)</td>
</tr>
<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
</tr>
<tr>
<td>Local Coverage Article</td>
<td>Pulmonary Rehabilitation Services A52770</td>
</tr>
</tbody>
</table>

For Non-Medicare Members

I. Medically supervised outpatient pulmonary rehabilitation will be considered medically necessary when ONE of the following (either A or B) are met:

A. Pulmonary rehabilitation may be indicated when ALL of the following are present:
   1. Member does not have a recent history of smoking or has quit smoking for at least 3 months; and
   2. Member has a reduction of exercise tolerance that restricts the ability to perform activities of daily living (ADL) and/or work; and
   3. Member has chronic pulmonary disease (including alpha-1 antitrypsin deficiency, asbestosis, chronic obstructive asthma, emphysema/COPD, chronic airflow obstruction, chronic bronchitis, cystic fibrosis, fibrosing alveolitis, pneumoconiosis, pulmonary alveolar proteinosis, pulmonary fibrosis, pulmonary hemosiderosis, radiation pneumonitis), or other conditions that affect pulmonary function such as ankylosing spondylitis, bronchopulmonary dysplasia, Guillain-Barre’s syndrome or other infective polyneuritis, muscular dystrophy, myasthenia gravis, paralysis of diaphragm, sarcoidosis, or scoliosis.
   4. Respiratory dysfunction, as indicated by ONE or more of the following:
      i. FEV1 (forced expiratory volume in 1 second) ≤ 65% of predicted
      ii. DLCO (single breath diffusion capacity of CO2) ≤ 65%
   5. Patient ambulatory able to comply with exercise requirements of the program
   6. Member does not have any concomitant medical condition that would otherwise imminently contribute to deterioration of pulmonary status or undermine the expected benefits of the program to include ALL of the following:
      a. No dementia or disabling stroke
      b. No symptomatic coronary artery disease,
      c. No ejection Fraction < 20%
      d. No untreated or unstable dysrhythmias
      e. No active joint disease
      f. No claudication
      g. No metastatic cancer
      h. No active pulmonary infection
      i. No unstable pulmonary hypertension
      j. No severe psychiatric disease
k. No significant neurologic disease that prevents participation in the exercise component of the program

B. Patient has been referred to or is enrolled in a lung transplant program or is status-post operative for a lung transplant or lung volume reduction surgery

Background

The American Thoracic Society and the European Respiratory Society define pulmonary rehabilitation as “an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease. Comprehensive pulmonary rehabilitation programs include patient assessment, exercise training, and psychosocial support”.

Individuals with chronic obstructive pulmonary disease (COPD) constitute the largest population of those referred for pulmonary rehabilitation. COPD is defined as a slowly progressive disease of the airways characterized by airflow limitation and loss of lung function that is not fully reversible. Pulmonary rehabilitation may also be of value for other patients who have respiratory symptoms associated with reduced functional capacity or health-related quality of life (Celli 2008; Nici 2006).

The American Academy of Chest Physicians and the American Association of Cardiovascular and Pulmonary Rehabilitation updated their guideline on pulmonary rehabilitation in 2007. The new guideline accepts the above definition of pulmonary rehabilitation. This guideline considers the three most important features of a successful pulmonary rehabilitation program to be: a multidisciplinary approach, individual assessment and goal-setting, and paying attention to physical functioning and social functioning. The guideline recommends at least 6 weeks of pulmonary rehabilitation; however, no specific combination of program components is recommended (Ries 2007).

Medical Technology Assessment Committee (MTAC)

Pulmonary Rehabilitation
05/01/2000: MTAC REVIEW

Evidence Conclusion: Although there is some evidence that specific pulmonary rehabilitation programs have lasting benefits for selected patients (Guell et al., Griffiths et al.), conclusions cannot be drawn about the effectiveness of pulmonary rehabilitation in general for the following reasons: Each pulmonary rehabilitation program has different components (see attached table); study methodologies do not permit conclusions about which component or components affect outcomes. Each pulmonary rehabilitation program is a different length and has a different intensity (see attached table): it is not possible to draw conclusions about what length or intensity is necessary to improve outcomes. Study methodologies do not permit conclusions about whether the pulmonary rehabilitation program itself or other factors such as the social support provided by program participation affects outcomes. Most programs have small sample sizes and results may be unreliable. Replications of individual programs are not available. The results of programs are not necessarily generalizable to other populations. For example, the Guell et al. study was conducted only with men and results may not be generalizable to women. Most of the early studies examining the effectiveness of PR were of poor quality (as reported in the meta-analysis by Cambach et al.) The ideal evidence, which does not currently exist, would be well conducted RCTs that examine different combinations of PR program components (e.g. education alone, education+exercise, exercise alone, etc.). In addition, there needs to be sufficient numbers of participants and data for the entire population of interest (i.e. both men and women).

Articles: The literature search yielded 73 articles. There were 8 randomized controlled trials (RCTs) and 2 meta-analyses. Five RCTs were excluded because of one of the following reasons: The groups compared were not directly relevant to this review (in-patient vs. out-patient PR, PR vs. lung surgery); had a small sample size (total n <50); or were included in the meta-analysis that was selected for review.

Articles selected for critical appraisal include: The more recent meta-analysis: Cambach, W, Wagenaar, RC, Koelman, TW, van Keimpema, T, Kemper, HCG. The long-term effects of pulmonary rehabilitation in patients with asthma and chronic obstructive pulmonary disease: A research synthesis. Arch Phys Med Rehabil 1999; 80: 103-
Pulmonary Rehabilitation

12/01/2008: MTAC REVIEW

Evidence Conclusion: The best evidence on the efficacy of pulmonary rehabilitation for COPD is a Cochrane review of randomized controlled trials (Lacasse et al., 2006). PR was defined as a program of at least 4 weeks’ duration that included exercise therapy, with the optional addition or education or psychosocial support. The meta-analysis did not specify whether programs included individualized assessment or a multidisciplinary team, so it is not clear how many programs met the criteria defined for this review. Pooled analyses in the Cochrane report found significantly better functional exercise capacity, maximal exercise capacity and quality of life in patients randomized to PR compared to usual care. Limitations of the evidence included in the Cochrane review include: Most of the published RCTs were small, and of low-quality. None were rated by the Cochrane reviewers as high-quality. No data were reported on long-term effectiveness of PR. Most studies reported findings at the end of the active intervention. The outcomes reported were exercise capacity and quality of life. There are insufficient data on the impact of PR on the rate of exacerbations and hospitalizations. The comparison intervention in the Cochrane review was usual care, the content of which varied from study to study. Thus, we cannot draw conclusion on which components of PR might be effective. Another limitation of the body of evidence is that RCTs comparing PR to sham programs are not available. Therefore, we cannot determine whether PR programs per se are effective or whether there is a ‘placebo effect’ of participating in a program believed by patients to be beneficial. One RCT (Sewell et al., 2005) suggests that an individually tailored exercise program, a key feature of pulmonary rehabilitation, may not be any more effective than a general exercise program in which all participants perform the same exercise. The Sewell study did not find statistically significant differences in functional ability or exercise performance in patients with COPD randomly assigned to receive a 7-week PR program of education plus a general or individualized exercise program. The Sewell study is not conclusive—sample size calculations were not reported and it may have been underpowered. In conclusion: The evidence on pulmonary rehabilitation for COPD has important limitations. RCTs were small and of low quality, outcome data are short-term and are only available for exercise capacity and quality of life, and a placebo effect of participating in a PR program cannot be ruled out. There are no RCTs comparing a PR program meeting criteria established for this review and a less-intensive intervention. It is important to know whether a comprehensive PR program that includes individualized assessment and involves a multi-disciplinary team is more effective than a less resource-intensive intervention such as an exercise program. There is insufficient evidence on the effectiveness of pulmonary rehabilitation for conditions other than COPD.

Articles: The ideal study is a double-blind randomized controlled trial comparing pulmonary rehabilitation to a sham rehabilitation program (i.e. a program of similar intensity without the therapeutic content under evaluation). No studies meeting these criteria were identified. However, there was one relatively large RCT (Sewell et al., 2005) that compared an individualized exercise program to a general exercise program for COPD. The general exercise program could be considered a type of sham and could allow for blinding of participants. Other than a sham-controlled trial, the next best design is a study comparing two PR programs with a different combination of components, especially if one of the PR programs met the definition for this review. One small RCT was identified that compared exercise only, exercise plus activity training and exercise plus didactic education (Norweg et al., 2005). This study, however, was excluded due to the small number of participants. A third type of comparison intervention is “usual care”. Since the previous MTAC review, a Cochrane review of randomized controlled trials comparing pulmonary rehabilitation to usual care for patients with COPD has been published (Lacasse et al., 2006). No large, well-conducted RCT on PR versus any comparison intervention published after the Cochrane review was identified. The search did not yield any randomized controlled trials or meta-analyses that evaluated pulmonary rehabilitation for any lung condition other than COPD. The Cochrane review and one RCT were critically appraised: Lacasse Y, Goldstein R, Lasserson TJ, Martin S. Pulmonary rehabilitation for chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2006. Issue 4. See Evidence Table. Sewell L, Singh SJ, Williams JEA et al. Can individualized rehabilitation improve functional independence in elderly patients with COPD? Chest 2005; 128: 1194-1200. See Evidence Table.
The use of pulmonary rehabilitation in the treatment of COPD, chronic pulmonary lung disease and emphysema does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

**Pulmonary Rehabilitation**

**12/20/2010: MTAC REVIEW**

**Evidence Conclusion:** A recent meta-analysis that evaluated the effectiveness of pulmonary rehabilitation after an acute exacerbation of COPD found that compared to usual care, subjects in the pulmonary rehabilitation intervention had fewer hospital admissions. However, only 3 studies with a total of 93 subjects were included in the meta-analysis (Puhan 2009).

### Pulmonary Rehabilitation vs. Usual Care

<table>
<thead>
<tr>
<th>Outcome</th>
<th># of studies</th>
<th># of subjects</th>
<th>Odds Ratio (95% CI)</th>
<th>NNT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital admission</td>
<td>3</td>
<td>93</td>
<td>0.13 (0.04 to 0.35)</td>
<td>3* (2 to 4)</td>
</tr>
</tbody>
</table>

*NNT over 34 weeks

Conclusion: Evidence from a meta-analysis that included small studies of moderate quality suggests that pulmonary rehabilitation is effective at reducing hospital admissions in patients with an acute exacerbation of COPD.

**Articles:** Only randomized controlled trials, meta-analyses, and clinical trials were included in the review. Studies were excluded if they were: community based; if they did not have sufficient statistical power to detect a difference in one of the main outcomes; or if they did address one of the main outcome measures (hospitalizations or emergency department visits). The following study was critically appraised: Puhan M, Scharplatz M, Troosters T, Walters ED and Steurer J. Pulmonary rehabilitation following exacerbation of chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2009, Issue 1. Art No.: CD005305. DOI: 10.1002/14651858.CD005305.pub2. See Evidence Table.

The use of pulmonary rehabilitation in the treatment of COPD, chronic pulmonary lung disease and emphysema does not meet the Kaiser Permanente Medical Technology Assessment Criteria.