



Louisiana

Outpatient Pulmonary Rehabilitation

Policy # 00621

Original Effective Date: 10/01/2018

Current Effective Date: 08/10/2020

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

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

When Services Are Eligible for Coverage

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

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

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

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

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

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

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When Services Are Considered Investigational

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

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

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

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

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

Policy Guidelines

A 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

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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. Contraindications to pulmonary rehabilitation include severe psychiatric disturbance (eg, dementia, organic brain syndrome) and significant or unstable medical conditions (eg, heart failure, acute cor pulmonale, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke).

Background/Overview

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

Pulmonary rehabilitation is also routinely offered to patients awaiting lung transplantation and lung volume reduction surgery. Pulmonary rehabilitation 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.

Rationale/Source

Pulmonary rehabilitation is a multidisciplinary approach to reducing symptoms and improving quality of life in patients with compromised lung function. Pulmonary rehabilitation programs generally include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

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Chronic Pulmonary Disease Rehabilitation

For individuals with moderate-to-severe chronic obstructive pulmonary disease (COPD) who receive a single course of outpatient pulmonary rehabilitation, the evidence includes numerous systematic reviews of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, and quality of life. The published studies found improved outcomes (ie, functional ability, quality of life) in patients with moderate-to-severe COPD who underwent a comprehensive pulmonary rehabilitation program in the outpatient setting. Among the many randomized trials, the structure of the pulmonary rehabilitation programs varied, so it is not possible to provide guidance on the optimal components or duration of a pulmonary rehabilitation program. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with idiopathic pulmonary fibrosis who receive a single course of outpatient pulmonary rehabilitation, the evidence includes 2 systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. The number of controlled studies is limited. One small RCT evaluated a comprehensive pulmonary rehabilitation program in patients with idiopathic pulmonary fibrosis; at 3 months postintervention, outcomes did not differ between groups that did and did not receive pulmonary rehabilitation. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Although most published evidence on outpatient pulmonary rehabilitation for chronic pulmonary diseases assesses COPD, observational studies have reported on outcomes from pulmonary rehabilitation for other chronic pulmonary diseases. Clinical guidelines from pulmonary organizations have supported the use of outpatient pulmonary rehabilitation for individuals who are experiencing disabling symptoms and have significantly diminished quality of life despite optimal

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medical management. Therefore, outpatient pulmonary rehabilitation may be considered medically necessary for this population.

Preparation for Lung Surgery

For individuals with scheduled lung surgery for volume reduction, transplantation, or resection who receive a single course of outpatient pulmonary rehabilitation, the evidence includes RCTs and observational studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. There is a lack of large RCTs comparing pulmonary rehabilitation with no pulmonary rehabilitation for preoperative candidates undergoing lung volume reduction surgery, lung transplantation, or lung cancer resection. Moreover, the available studies have evaluated exercise programs, but not necessarily comprehensive pulmonary rehabilitation programs. Also, the few small RCTs, and observational studies have only reported short-term outcomes and inconsistent evidence of benefit even on these outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Findings from the National Emphysema Treatment Trial have suggested that pulmonary rehabilitation is an appropriate component of care for patients with COPD before undergoing lung volume reduction surgery. Also, pulmonary rehabilitation is considered standard of care in patients undergoing lung transplantation to maximize preoperative pulmonary status. Thus, pulmonary rehabilitation may be considered medically necessary for patients considered appropriate candidates for lung volume reduction surgery or lung transplantation.

Pulmonary Rehabilitation After Lung Surgery

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

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For individuals who have had lung transplantation who receive a single course of outpatient pulmonary rehabilitation, the evidence includes RCTs, a systematic review, and a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. Neither of the 2 RCTs identified in a 2010 systematic review reported on functional outcomes, but uncontrolled studies have reported improvements in functional outcomes. An RCT, published after the systematic review, found that patients who had a postsurgical exercise intervention walked more 1 year post discharge than before and had a significantly greater 6-minute walk distance. Findings on other outcomes were mixed. The most recent RCT (2017) did not identify a difference in outcomes with longer duration of pulmonary rehabilitation. Case series data also support improvements in 6-minute walk distance after postoperative pulmonary rehabilitation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had lung cancer resection who receive a single course of outpatient pulmonary rehabilitation, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One small RCT evaluated a comprehensive pulmonary rehabilitation program in patients who underwent thoracotomy for lung cancer. The trial was terminated early, had a high dropout rate, and reported mixed findings. An exercise-only intervention in patients who had lung cancer surgery had mixed findings and did not evaluate functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcome.

Repeat or Maintenance Pulmonary Rehabilitation

For individuals who have had an initial course of pulmonary rehabilitation who receive repeat or maintenance outpatient pulmonary rehabilitation, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, and quality of life. This small RCT had methodologic limitations and did not report inpatient and outpatient outcomes separately; it also lasted only 3 weeks. The evidence is insufficient to determine the effects of the technology on health outcome.

Home-Based Pulmonary Rehabilitation

For individuals who have an indication for outpatient pulmonary rehabilitation who receive a single course of home-based pulmonary rehabilitation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Most studies of home-based pulmonary rehabilitation have compared outcomes with standard care. Very few have compared home-based pulmonary rehabilitation with the hospital- or clinic-based pulmonary

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rehabilitation, and the available studies are mostly of low quality. The evidence is insufficient to determine the effects of the technology on health outcome.

Supplemental Information

Practice Guidelines and Position Statements

American Thoracic Society and European Respiratory Society

A 2015 joint statement on pulmonary rehabilitation was issued by the American Thoracic Society and the European Respiratory Society. The statement included the following relevant conclusions:

- “Pulmonary rehabilitation (PR) has demonstrated physiological, symptom-reducing, psychosocial, and health economic benefits in multiple outcome areas for patients with chronic respiratory diseases.”
- “The evidence indicates that patients who benefit from PR include not only persons with moderate to severe airflow limitation but also those with mild to moderate airflow limitation with symptom-limited exercise tolerance, those after hospitalization for COPD [chronic obstructive pulmonary disease] exacerbation, and those with symptomatic non-COPD respiratory conditions.”
- “Patients graduating from a PR program stand to benefit from a home, community-based, or program-based maintenance exercise program to support the continuation of positive exercise behavior.”

In 2017, the Society issued a joint statement on the management of COPD exacerbation. For patients hospitalized with a COPD exacerbation, they suggest “the initiation of pulmonary rehabilitation within 3 weeks after hospital discharge” (strength: conditional; quality of evidence: very low). In addition, “[they] suggest not initiating pulmonary rehabilitation during hospitalisation” (strength: conditional; quality of evidence: very low).

American College of Physicians

In 2011, Joint guidelines on the management of stable COPD were issued by the American College of Physicians, the American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. The guidelines recommended 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

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rehabilitation for symptomatic or exercise-limited patients with an FEV₁ >50% predicted (Grade: weak recommendation, moderate-quality evidence).”

United States Preventive Services Task Force Recommendations

Not applicable

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|----------------|--|--------------------|-----------------|
| <i>Ongoing</i> | | | |
| NCT02823587 | Effects of Pulmonary Rehabilitation on Secretion Transport, Inflammation and Respiratory System Strength and Quality of Life in Patients With Bronchiectasis | 60 | Dec 2019 |
| NCT02426437 | Examining Pulmonary Rehabilitation on Discharged COPD Patients | 150 | Dec 2019 |
| NCT03095859 | Post-operative, Inpatient Rehabilitation After Lung Transplant Evaluation: A Feasibility Study | 40 | Mar 2020 |
| NCT03326089 | Short and Long-term Effects of Oxygen Supplemented Pulmonary Rehabilitation in Idiopathic Pulmonary Fibrosis | 20 | Jun 2020 |
| NCT02842463 | Use of the 6-minute Stepper Test to | 80 | June 2020 |

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| | | | |
|--------------------|---|-----|---|
| | Individualise Pulmonary Rehabilitation in Patients With Mild to Moderate Chronic Obstructive Pulmonary Disease | | |
| NCT03244137 | Effects of Pulmonary Rehabilitation on Cognitive Function in Patients With Severe to Very Severe Chronic Obstructive Pulmonary Disease | 100 | Sep 2020 |
| NCT02887521 | Pulmonary Rehabilitation Before Lung Cancer Resection | 194 | Dec 2020 |
| <i>Unpublished</i> | | | |
| NCT03299504 | Factors Predicting Success in Lung Transplant Recipients Who Have Participated in the COLTT Program (Daily Intensive Post-hospitalization Rehabilitation): A Retrospective Review | 105 | Apr 2018 (last updated 08/24/18) |
| NCT02887521 | Pulmonary Rehabilitation Before Lung Cancer Resection | 194 | Oct 2019 (terminated ^a ; updated 10/08/19) |
| NCT03244137 | Effects of Pulmonary Rehabilitation on Cognitive Function in Patients With Severe to Very Severe Chronic Obstructive Pulmonary Disease | 100 | Dec 2019 (last updated 01/07/20) |

NCT: national clinical trial.

^a Terminated due to poor accrual.

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07/05/2018 Medical Policy Committee review

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

07/03/2019 Medical Policy Committee review

07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/02/2020 Medical Policy Committee review

07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/16/2020 Coding update

Next Scheduled Review Date: 07/2021

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|------------------|--|
| CPT | No codes |
| HCPCS | G0237, G0238, G0239, G0302, G0303, G0304, G0305, G0424, S9473 |
| ICD-10 Diagnosis | C96.6, D38.0-D38.6, D84.1, D86.0-D86.9, E84.0-E84.9, I11.0-I11.9, I27.0, J41.0-J41.8, J43.0-J43.9, J44.0-J44.9, J47.0-J47.9, J84.0-J84.9, J99, M34.0-M34.9, P27.0-P27.9, Q21.0, Z86.711 Added codes eff 10/1/2020: J84.170, J84.178 |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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