CLINICAL MEDICAL POLICY	
Policy Name:	Pulmonary Rehabilitation
Policy Number:	MP-058-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	08/15/2019; 07/15/2018; 10/01/2017
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 10

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary pulmonary rehabilitation.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Pulmonary Rehabilitation (PR) – A multi-disciplinary program of care for patients with chronic respiratory impairment who are symptomatic and often have decreased daily life activities.

Chronic Obstructive Pulmonary Disease (COPD) – A common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases. The chronic airflow limitation that is characteristic of COPD is caused by a mixture of small airways disease (e.g., obstructive bronchiolitis) and parenchymal destruction (emphysema), the relative contributions of which vary from person to person.

Forced vital capacity (FVC) – The volume of air that can forcibly be blown out after full inspiration, measured in liters. FVC is the most basic maneuver in spirometry tests.

Forced Expiratory Volume (FEV_1) – The amount of air that can be exhaled in the first second after taking the deepest breath as possible. An important measurement in lung function, it can be used to measure the presence of lung disease or disease progression—the lower the value, the worse the disease.

Restrictive Pulmonary Disease – A disorder characterized by reduced lung volume, either because of an alteration in the lung itself or because of a condition that affects the mechanics of breathing (chest wall, muscles, etc.).

ADL – Activities of daily living.

Lung Volume Reduction Surgery (LVRS) or Reduction Pneumoplasty – A procedure that is performed on patients with severe emphysema in order to allow the remaining compressed lung to expand and thus improve respiratory function.

PROCEDURES

1. This medical policy addresses the pulmonary rehabilitation services that are provided on an outpatient basis. One course of outpatient pulmonary rehabilitation may be medically necessary for patients that meet the following criteria:
   A. PR is ordered by the PCP, in consultation with a pulmonologist or cardiothoracic surgeon actively involved in the patient's respiratory care; OR
   B. PR is ordered by the pulmonologist or cardiothoracic surgeon; AND
   C. The patient is diagnosed with moderate to very severe COPD defined as Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification II, III, and IV (*Attachment D*); OR
   D. If the patient does not have a GOLD classification documented, then the patient must have a FEV_1 or FVC of less than 80% of predicted value with one of the following other chronic pulmonary diseases:
      1) Idiopathic pulmonary cystic fibrosis; OR
      2) Bronchiectasis; OR
      3) Chronic obstructive asthma; OR
      4) Chronic bronchitis; OR
      5) Emphysema; OR
      6) Interstitial lung disease; OR
      7) Pneumoconiosis (Coalworker's Pneumoconiosis, asbestos-induced Pneumoconiosis, silica dust-induced Pneumoconiosis, talc dust-induced Pneumoconiosis, Aluminosis, Bauxite fibrosis, Berylliosis, Graphite fibrosis, Siderosis, and Stannosis); OR
      8) Organic dust airway disease (Byssinosis, Flax-dressers' disease, Cannabinosis); AND

E. The patient is experiencing chronic functional disability limiting the ability to complete age-appropriate ADLs (e.g., increased exertional dyspnea, decreased endurance, increased fatigue, and increased anxiety); AND
F. The patient agrees to program participation; AND
G. The pulmonary rehabilitation program must include all of the following:
    1) Physician-prescribed exercise each day PR items and services are furnished; AND
    2) Education and training tailored to the patient's needs; AND
    3) Psychosocial assessment; AND
    4) Outcomes Assessment; AND
    5) An individualized treatment plan; AND
H. The patient must not have any significant orthopedic or neurologic problems that reduce mobility or cooperation with physical training; AND
I. The patient is a non-smoker OR agrees to stop smoking during the duration of the program OR will enroll in a smoking cessation program while on the PR.

2. Health Options may consider a pulmonary rehabilitation course to be medically necessary for preoperative conditioning or postoperative recovery for one of the following extensive surgical interventions:
    A. Preoperative LVRS; OR
    B. Preoperative lung transplantation; OR
    C. Postoperative LVRS; OR
    D. Postoperative lung transplantation

3. Contraindications
    A. Severe psychiatric disturbances (e.g., dementia, organic brain syndrome)
    B. Significant or unstable medical conditions (e.g., congestive heart failure, acute cor pulmonale, substance abuse, significant liver disease, metastatic cancer, disabling stroke)

4. When pulmonary rehabilitation services are not covered
    Pulmonary Rehabilitation services are not covered for conditions other than those listed above because the scientific evidence has not been established and are considered not medically necessary. Home-based pulmonary rehabilitation programs are not covered and are considered not medically necessary.

    Home exercise equipment, physiotherapy, or personal comfort and convenience items are excluded from pulmonary rehabilitation coverage. These services are not covered benefits and are considered not medically necessary.

    Multiple courses of pulmonary rehabilitation are considered experimental and 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. Multiple courses of PR program services and long-term rehabilitative services are not covered and considered not medically necessary.

5. Post-payment Audit Statement
    The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

6. Place of Service
   Pulmonary Rehabilitation is an outpatient program based in a hospital or clinic setting.

7. Length of Coverage
   PR program sessions are limited to a maximum of two 1-hour sessions per day for up to 36 sessions in one course, with the option for an additional 36 sessions (not to exceed 72 sessions) if medically necessary. Rehabilitation treatment that is greater than 36 sessions will require medical director review.

CODING REQUIREMENTS

Procedure Codes

HCPCS Codes	Description
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring).
G0238	Therapeutic procedures to improve respiratory function other than described by G2037, one on one, face to face, per 15 minutes (includes monitoring).
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring).
G0302	Pre-operative pulmonary surgery services for preparation for LVRS, complete course of services, to include a minimum of 16 days of services.
G0303	Pre-operative pulmonary surgery services for preparation for LVRS, 1 to 9 days of services.
G0304	Pre-operative pulmonary surgery services for preparation for LVRS, 1 to 9 days of services.
G0305	Post-discharge, pulmonary surgery services after LVRS, minimum of 6 days of services.
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day.
CPT Code	**Description**
94799	Unlisted pulmonary service or procedure

Diagnosis Codes

ICD-10 Codes	Description
E84.0	Cystic fibrosis with pulmonary manifestations
J41.0	Simple chronic bronchitis
J41.1	Mucopurulent chronic bronchitis
J41.8	Mixed simple and mucopurulent
J42	Unspecified chronic bronchitis
J43.0	Unilateral pulmonary emphysema [MacLeod's syndrome]
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation

J44.9	Chronic obstructive pulmonary disease, unspecified (asthma with chronic obstructive pulmonary disease, chronic asthmatic (obstructive) bronchitis, chronic obstructive asthma)
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
J60	Coalworker's pneumoconiosis
J61	Pneumoconiosis due to asbestos and other mineral fibers
J62.0	Pneumoconiosis due to dust containing silica
J62.8	Pneumoconiosis due to talc dust
J63.0	Pneumoconiosis due to other dust containing silica
J63.1	Pneumoconiosis due to other inorganic dusts
J63.2	Aluminosis
J63.3	Bauxite fibrosis
J63.4	Siderosis
J63.5	Stannosis
J63.6	Pneumoconiosis due to other specified inorganic dusts
J64	Unspecified Pneumoconiosis
J65	Pneumoconiosis associated with tuberculosis
J66.0	Byssinosis
J66.1	Flax-dressers' disease
J66.2	Cannabinosis
J66.8	Airway disease due to other specific organic dusts
J84.10	Pulmonary fibrosis, unspecified
J84.112	Idiopathic pulmonary fibrosis
J84.17	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere
J84.89	Other specified interstitial pulmonary diseases
J95.1	Acute pulmonary insufficiency following thoracic surgery
J95.2	Acute pulmonary insufficiency following nonthoracic surgery
J95.3	Chronic pulmonary insufficiency following surgery
J95.821	Acute post-procedural respiratory failure
J95.822	Acute and chronic post-procedural respiratory failure
J96.00	Acute respiratory failure, unspecified whether with hypoxia or hypercapnia
J96.20	Acute and chronic respiratory failure, unspecified whether hypoxia or hypercapnia
J96.21	Acute and chronic respiratory failure with hypoxia
J96.22	Acute and chronic respiratory failure with hypercapnia
Q21.0	Ventricular septal defect
Q33.4	Congenital bronchiectasis
Z48.24	Encounter for aftercare following lung transplant
Z48.280	Encounter for aftercare following heart-lung transplant
Z76.82	Awaiting organ transplant
Z87.09	Personal history of other diseases of the respiratory system
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Pulmonary disease is a major cause of morbidity and mortality. Currently, pulmonary disease is the world's fourth leading cause of death and is projected to become the third leading cause of death by 2020 (Global Initiative for Chronic Obstructive Lung Disease, 2017). Cigarette smoking is the lead environmental risk factor of pulmonary disease. Other important risk factors include occupational and environmental exposures, age, gender, genetic and hereditary linking, lung development and growth, socioeconomic status, asthma, bronchitis, and infections (Global Initiative for Chronic Obstructive Lung Disease, 2017).

Treatment of pulmonary disease works to capture the underlying pathophysiology, such as removing the offending agent (e.g., smoking cessation), preventing complications, and treating complications related to the lung disease (e.g., suppression of bacterial infection). There are other interventions that positively impact disability associated with pulmonary disease which lead treatment through pulmonary rehabilitation (PR). The majority of chronic lung diseases are under the general heading of COPD, and a large portion of the evidence related to the benefits and effectiveness of PR come from clinical trials involving COPD patients. The American Thoracic Society and the European Respiratory Society (2015) define pulmonary rehabilitation as:

> 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, designed to improve the physical and psychological condition of people with chronic respiratory disease and to promote the long-term adherence to health-enhancing behaviors

PR does not replace current medical therapy but provides additional therapy services that include (CMS, 2012):

- **Physician-prescribed exercise**: This physical activity includes techniques such as exercise conditioning, breathing retraining, and step and strengthening exercises. Some aerobic exercise must be included in each PR session. Both low- and high- intensity exercises are recommended to produce clinical benefits, and a combination of endurance and strength training should be conducted at least twice per week.
- **Nutritional counseling**: This should be closely and clearly related to the individual's care and treatment and tailored to the individual's needs, including information on respiratory problem management and, if appropriate, brief smoking cessation counseling. Any education or training must assist in achievement of individual goals toward independence in activities of daily living, adaptation to limitations, and improved quality of life (QoL).
- **Outcome assessment**: This should include: (1) beginning and end evaluations based on patient-centered outcomes, which are conducted by the physician at the start and end of the program, and (2) objective clinical measures of the effectiveness of the PR program for the individual patient, including exercise performance, self-reported measures of shortness of breath, and behavior. The assessments should include clinical measures such as the 6-minute walk, weight, exercise performance, self-reported dyspnea, behavioral measures (supplemental oxygen use, smoking status), and a QoL assessment.

- **Individualized treatment plan**: Describes the individual's diagnosis and details how components are utilized for each patient. The plan must be established, reviewed, and signed by a physician every 30 days. The plan may initially be developed by the referring physician or the PR physician. If the plan is developed by the referring physician who is not the PR physician, the PR physician must also review and sign the plan prior to implementation of the PR program. It is expected that the supervising physician would have initial, direct contact with the individual prior to subsequent treatment by ancillary personnel, and also have at least one direct contact in each 30-day period. The plan must have written specificity with regards to the type, amount, frequency, and duration of PR items and services furnished to the individual, and specify the appropriate mix of services for the patient's needs. It must include measurable and expected outcomes and estimated timetables to achieve these outcomes.

There is a multidisciplinary team of health care professionals that may be included in the patient's pulmonary rehab treatment, including but not limited to physicians, nurses, respiratory therapists, occupational therapists, physical therapists, psychologists, exercise specialists, and dieticians. The majority of PR clinical studies are derived from hospital-based outpatient programs, not home-health programs. There is limited data on the comparison of home-based PR to hospital- or clinic-based PR, and the available studies are mostly of low quality. The evidence is insufficient to determine the effects of the technology on health outcome in the home setting.

According to the American Association of Cardiovascular and Pulmonary Rehabilitation (2006), "Evidence-based support for pulmonary rehabilitation in the management of patients with chronic respiratory disease has grown tremendously." PR has been proven to reduce dyspnea, increase exercise performance, and improve health-related quality of life (HRQL) (Nici, 2006). PR also demonstrates physiological, symptom-reducing, psychosocial, and health economic benefits for patients with chronic pulmonary diseases, but is severely underutilized in health care (Rochester, 2015). The American Association for Respiratory Care (AARC) (2014) position statement on pulmonary rehabilitation indicates the program is a "physician-supervised, evidence-based, multifaceted approach to providing services designed for persons with pulmonary disease and their families." The AARC suggests PR supports improvement of respiratory disease management as well as maintenance to the highest possible level of independent functionality and quality of life (AARC, 2014). In addition to chronic pulmonary disease, PR programs improve the success of patients preparing or recovering from lung-volume reduction surgery (LVRS) or lung transplantation. Most patients in the surgical category have severe ventilatory limitation, ventilatory disability, and are at high risk of preoperative and postoperative complications (Rochester, 2008).

There has been a large increase in pulmonary rehabilitation referrals due to the high quality of the clinical trials which used valid, reproducible, and interpretable outcome measures (Nici, 2006). There were numerous published randomized controlled trials (RCTs) that focused on introducing PR for COPD patients and developed supporting evidence for PR benefits. Most recently, there was a Cochrane review that evaluated PR programs for patients who had an exacerbation of COPD (Puhan et al., 2016). PR participants showed significant reduction in the rate of hospital admissions, baseline improvements, and significant improvements in health-related quality of life (HRQOL) (Puhan et al., 2016).

Smoking is a highlighted topic that is debated among scholarly research and clinical trials for pulmonary rehabilitation programs. There are many differing recommendations surrounding patients that are actively smoking while participating in pulmonary rehabilitation programs. According to the American Thoracic Society (2006), there are some PR programs that disqualify current smokers, but there is no evidence that short-term outcomes are different between smokers and nonsmokers.

The Journal of Cardiopulmonary Rehabilitation developed an article surrounding smoking cessation, and the research shows that many patients have quit smoking at PR enrollment, but the inclusion of smokers in PR programs remains controversial (Lacasse, 2002). The collective consensus surrounding smoking status has positioned many pulmonary rehabilitation policies not to exclude smokers but to offer smoking cessation counseling during the PR treatment.

There is supportive evidence for outpatient PR patients preparing for, or recovering from, lung volume reduction surgery (LVRS) or lung transplantation which includes RCTs and observational studies (Rochester, 2008). Preoperative LVRS patients can achieve benefits from PR programs through an improved peak work rate, 6-minute-walk distance, maximum oxygen consumption, endurance time, muscle strength, quality of life, and dyspnea (Rochester, 2008). Postoperative LVRS and lung transplantation patients can achieve benefits from PR programs for optimized recovery and functional status as well as improving exercise impairment, transplantation drug anemia and/or vasodilation, and skeletal-muscle functionality (Rochester, 2008).

The benefits of pulmonary rehabilitation decline over time which is evident by observational studies that showed success at the end of a PR course but the success rate and patient improvement of additional courses decreased (Celli, 2017). There is a CMS Medicare Learning Network (*MLN) Matters* article MM6823 on pulmonary rehabilitation which is used as a benchmark tool (MLN Matters, 2010). The article denotes the length of coverage which is equivalent to the position held within this given policy which states, "Medicare will pay for up to two (2) one-hour sessions per day, for up to 36 lifetime sessions (in some cases, up to 72 lifetime sessions) of PR (MLN Matters, 2010)."
In 2007, The Center for Medicare and Medicaid Services (CMS) declined to establish a national coverage determination (NCD) for pulmonary rehabilitation services and placed the coverage responsibility on the local carriers' local coverage determination (LCD).

Classification of COPD

Classification of Severity of Airflow Limitation in COPD		
GOLD 1	Mild	$FEV_1 > 80\%$ FEV_1 FVC<0.7
GOLD 2	Moderate	$50\% < FEV_{1<80\%}$ FEV_1 FVC<0.7
GOLD 3	Severe	$30\% < FEV_1 < 50\%$ FEV_1 FVC<0.7
GOLD 4	Very severe	$FEV_1 < 30\%$ FEV_1 FVC<0.7

Reference: *Modified from GOLD Global strategies for the diagnosis, management, and prevention of chronic obstructive pulmonary disease updated 2014*

POLICY SOURCE(S)

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Policy History

Date	Activity
04/19/2017	Initial policy developed
08/09/2017	Added Disclaimer Statement
09/26/2017	EHS Revisions: Added Issue Date to opening policy box; Added 'Covered' to procedure code table Attachment D and diagnosis code table in Attachment E; added 'Informational' to Attachment B. Corrected ICD-10 code Z87.0 to Z87.09
09/27/2017	QI/UM Committee approval
11/01/2017	Provider effective date
06/19/2018	Annual Review: Under Procedure Section letters A & B have been revised regarding ordering & consulting provider; added covered procedure code 94799; no other changes; Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C
06/19/2018	QI/UM Committee Review Approval
08/15/2018	New provider effective date
07/16/2019	QI/UM Committee Review Approval
07/16/2019	Annual Review Revisions: No criteria changes; Removed the hyperlinks from the references
09/16/2019	New Provider Effective Date