Respiratory Services and Equipment

Policy Number: MCS081.11
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Instructions for Use

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Related Policies
None

Coverage Guidelines

Pulmonary rehabilitation services and home use of oxygen are covered when Medicare coverage criteria are met.

DME Face to Face Requirement: Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including stationary compressed gas oxygen system; cough stimulating device; high frequency chest wall oscillation system; oscillatory positive expiratory device and nebulizer). For DME Face to Face Requirement information, refer to the Coverage Summary titled Durable Medical Equipment (DME), Prosthetics, Orthotics (Non-Foot Orthotics), Nutritional Therapy, and Medical Supplies Grid.

Note: The guidelines in this Coverage Summary are for specific procedures only. For procedures not addressed in this Coverage Summary, refer to the Medicare Coverage Database to search for applicable coverage policies (National Coverage Determination, Local Coverage Determinations and Local Coverage Articles).
(Accessed February 12, 2024)

Pulmonary Rehabilitation

As specified in 42 CFR 410.47, Medicare Part B covers pulmonary rehabilitation for beneficiaries:
- With moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease.
- Who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks (effective January 1, 2022).
- Additional medical indications for coverage for pulmonary rehabilitation may be established through a national coverage determination (NCD).

Pulmonary rehabilitation programs must include the following components:

- Physician-prescribed exercise during each pulmonary rehabilitation session; and
- Education or training closely and clearly related to the individual's care and treatment which is tailored to the individual's needs and assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life. Education must include information on respiratory problem management and, if appropriate, brief smoking cessation counseling; and
- Psychosocial assessment; and
- Outcome's assessment; and
- An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

Pulmonary rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all time items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision of physician office services as specified at 42 CFR 410.26 and for hospital outpatient therapeutic services as specified at 42 CFR 410.27.

The number of pulmonary rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time.

Refer to the:

- Medicare Claims Processing Manual, Chapter 32, §140.4 – Pulmonary Rehabilitation Program Services Furnished On or After January 1, 2010.
- Medicare Benefit Policy Manual, Chapter 12, §40.5 – Respiratory Therapy Services for respiratory therapy services provided to CORF patients.
- Coverage Summary titled Skilled Nursing Facility, Rehabilitation, and Long-Term Acute Care and Hospital.

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.
(Accessed February 12, 2024)

High Frequency Chest Wall Oscillation (HFCWO) Devices

Medicare does not have a National Coverage Determination (NCD) for high frequency chest wall oscillation devices. DME MAC (L33785) Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) **exist for all states/territories** and compliance with these policies is required where applicable.

For coverage guidelines, refer to the DME MAC LCD for High Frequency Chest Wall Oscillation Devices (L33785).
(Accessed February 12, 2024)

Nebulized Beta Adrenergic Agonist Therapy

On September 10, 2007, CMS posted a National Coverage Determination (NCD) for nebulized beta adrenergic agonist therapy for lung diseases. After examining the available medical evidence, CMS determined that no NCD is appropriate at this time and that section 1862(a)(1)(A) reasonable and necessary decisions should continue to be made by local Medicare contractors through the local coverage determination process or case-by-case adjudication. Refer to the NCD for Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases (200.2). (Accessed February 12, 2024)

Bronchial Thermoplasty (CPT Codes 31660 and 31661)

Medicare does not have a National Coverage Determination (NCD) for bronchial thermoplasty. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled Bronchial Thermoplasty.

Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
(Accessed February 12, 2024)

Lung Volume Reduction Surgery (LVRS)

Lung volume reduction surgery (LVRS) is covered when coverage criteria are met.

For coverage guidelines, refer to the NCD for Lung Volume Reduction Surgery (Reduction Pneumoplasty) (240.1).

LVRS must be performed in Medicare approved facility. The list of Medicare approved LVRS Facilities can be accessed at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Volume-Reduction-Surgery-LVRS.html.
(Accessed February 12, 2024)

Coverage Criteria for Oxygen and Oxygen Equipment

Medicare coverage of home oxygen and oxygen equipment, under the durable medical equipment (DME) benefit, is considered reasonable and necessary only for patients with significant hypoxemia who meet the Medicare coverage criteria.

For coverage criteria, refer to the National Coverage Determination (NCD) for Home Use of Oxygen (240.2). Also refer to the DME MAC LCD for Oxygen and Oxygen Equipment (L33797).

For other oxygen related equipment and supplies, refer to the Coverage Summary titled Durable Medical Equipment (DME), Prosthetics, Orthotics (Non-Foot Orthotics), Nutritional Therapy, and Medical Supplies Grid.
(Accessed February 12, 2024)

Overnight Oximetry Studies

Overnight sleep oximetry are covered when coverage criteria are met. Refer to the DME MAC LCD for Oxygen and Oxygen Equipment (L33797). (Accessed February 12, 2024)

For oximetry studies related to sleep apnea, refer to the Coverage Summary titled Sleep Apnea Diagnosis and Treatment.

Portable Oxygen System

Portable oxygen system may be purchased for chronic use when patient is mobile within the home and the qualifying blood gas study was performed while rest (awake) or during exercise. If the only qualifying blood gas study was performed during sleep, portable oxygen will be denied as not reasonable and necessary. If patient meets the above requirement, the portable oxygen system is usually paid for separately in addition to the stationary system.

Notes:

- If a patient qualifies for additional payment for greater than 4 LPM of oxygen and also meets the requirements for portable oxygen, payment will be made for either the stationary system of oxygen (at higher allowance) or the portable system (at the standard fee schedule allowance for portable system), but not both.
- When a portable system is added to a stationary system or vice versa a need for blood gas study is not required.
- If a portable oxygen system is covered, the supplier must provide whatever quantity of oxygen the patient uses; Medicare's reimbursement is the same, regardless of the quantity of oxygen dispensed.

Refer to the DME MAC LCD for Oxygen and Oxygen Equipment (L33797).

Portable (preset) oxygen system is not covered; considered precautionary equipment; essentially not therapeutic in nature.

Refer to the NCD for Durable Medical Equipment Reference List (280.1).
(Accessed February 12, 2024)

Emergency or Stand-By Oxygen

Emergency or stand-by oxygen tanks, concentrators and other oxygen systems for patients who are not regularly using oxygen are not covered and will be denied as not reasonable and necessary since they are precautionary and not therapeutic in nature.

Refer to the DME MAC LCD for Oxygen and Oxygen Equipment (L33797) and NCD for Durable Medical Equipment Reference List (280.1).
(Accessed February 12, 2024)

Home Oxygen for Chronic Obstructive Pulmonary Disease (COPD)

The home use of oxygen is covered for those members with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung, and Blood Institute [(NHLBI); CMS, 2006)]. The additional Group II criteria do not apply to these patients.

Refer to the NCD for Home Use of Oxygen in Approved Clinical Trials (240.2.1).

The list of Medicare approved clinical trials is available at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Home-Oxygen-for-COPD.html.

For payment rules for NCDs requiring CED, refer to the Medicare Managed Care Manual, Chapter 4, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).
(Accessed February 12, 2024)

Home Oxygen Use to Treat Cluster Headaches (CH)

Home Oxygen Use to Treat Cluster Headaches is covered when coverage criteria are met. Refer to the DME MAC LCD for Oxygen and Oxygen Equipment (L33797). (Accessed February 12, 2024)

Oxygen Services Furnished by an Airline

Oxygen services furnished by an airline to a member are non-covered. Refer to the DME MAC LCA for Oxygen and Oxygen Equipment - Policy Article (A52514). (Accessed February 12, 2024)

Definitions

Pulmonary Rehabilitation (PR): The American Thoracic Society (ATS) defines pulmonary rehabilitation (PR) as a multidisciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and autonomy and 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 systematic manifestations of the disease. Refer to the NCD for Pulmonary Rehabilitation Services (240.8). (Accessed February 12, 2024)

Respiratory Therapy (Respiratory Care): The services prescribed by a physician or a non-physician practitioner for the assessment, diagnostic evaluation, treatment, management, and monitoring of members with deficiencies and abnormalities of cardiopulmonary function. Noridian LCD for Respiratory Care (L34149). (Accessed February 12, 2024)

Policy History/Revision Information

Date	Summary of Changes
03/13/2024	**Coverage Guidelines** • Removed content/language addressing bronchoscopy (CPT code 31626) ***Pulmonary Rehabilitation*** • Revised list of components required for a pulmonary rehabilitation program; replaced:

Date	Summary of Changes
	○ "Physician-prescribed exercise*; some aerobic* exercise *must be included in* each pulmonary rehabilitation session" with "physician-prescribed exercise *during* each pulmonary rehabilitation session" ○ "Education or training closely and clearly related to the individual's care and treatment which is tailored to the individual's needs, *including* information on respiratory problem management and, if appropriate, brief smoking cessation counseling" with "education or training closely and clearly related to the individual's care and treatment which is tailored to the individual's needs *and assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life; education must include* information on respiratory problem management and, if appropriate, brief smoking cessation counseling" • Added language to indicate the number of pulmonary rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time ***Bronchial Thermoplasty (CPT Codes 31660 and 31661)*** • Removed language pertaining to individual consideration for U.S. Food and Drug Administration (FDA) approved indications **Administrative** • Archived previous policy version MCS081.10

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.