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C. Nationally Non-covered Indications

1. LVRS is not covered in any of the following clinical circumstances:

a. Patient characteristics carry a high risk for perioperative morbidity and/or mortality;

b. The disease is unsuitable for LVRS;

c. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery;

d. The patient presents with FEV1 $\leq$20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of $\leq$20% of predicted value (high-risk group identified October 2001 by the NETT); or

e. The patient satisfies the criteria outlined above in section B(1), and has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 w for women and 40 w for men (under the measurement conditions for cycle ergometry specified above).

2. All other indications for LVRS not otherwise specified remain noncovered.

(This NCD last reviewed November 2005.)

240.2 - Home Use of Oxygen

(Rev. 1, 10-03-03)
CIM 60-4

A. General

Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6)of the Act) is considered reasonable and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections B, C, and D. This section also includes special coverage criteria for portable oxygen systems. Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included in subsection F.

B. Medical Documentation

Initial claims for oxygen services must include a completed Form CMS-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to

ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation. The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. Use Form CMS-484 for recertifications. (See the Medicare Program Integrity Manual, Chapter 5, for completion of Form CMS-484.)

The medical and prescription information in section B of Form CMS-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information. While this section may be completed by non-physician clinician or a physician employee, it must be reviewed and the Form CMS-484 signed by the attending physician.

A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen must also be supported by medical documentation in the patient's record. Separate documentation is used with electronic billing. This documentation may be in the form of a prescription written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:

- A diagnosis of the disease requiring home use of oxygen;
- The oxygen flow rate; and
- An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime).

NOTE: A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

A member of the carrier's medical staff should review all claims with oxygen flow rates of more than four liters per minute before payment can be made.

The attending physician specifies the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed Form CMS-484. In addition, the supplier or physician may use the space in section C for written confirmation of additional details of the physician's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the

specifics of varying flow rates, and/or the noncontinuous use of oxygen as appropriate. The physician confirms this order information with their signature in section D.

New medical documentation written by the patient's attending physician must be submitted to the carrier in support of revised oxygen requirements when there has been a change in the patient's condition and need for oxygen therapy.

Carriers are required to conduct periodic, continuing medical necessity reviews on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in the Medicare Program Integrity Manual, Chapter 5, "Items and Services Having Special DMERC Review Considerations." When indicated, carriers may also request documentation of the results of a repeat arterial blood gas or oximetry study.

NOTE: Section 4152 of OBRA 1990 requires earlier recertification and retesting of oxygen patients who begin coverage with an arterial blood gas result at or above a partial pressure of 55 or an arterial oxygen saturation percentage at or above 89. (See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," §100.2.3, for certification and retesting schedules.)

C. Laboratory Evidence

Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is usually in the form of a measurement of the partial pressure of oxygen (PO_2) in arterial blood. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services.

When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines.

This prohibition does not extend to the results of blood gas test conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the initial claim, i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are, existing physician and/or hospital records that reflect the patient's medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests, the carrier needs to request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood gas test is performed

during the patient's hospital stay, the test result obtained closest to, but no earlier than two days prior to the hospital discharge date is required as evidence of the need for home oxygen therapy.

For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease.

Carriers may accept an attending physician's statement of recent hospital test results for a particular patient, when appropriate, in lieu of copies of actual hospital records.

A repeat arterial blood gas study is appropriate when evidence indicates that an oxygen recipient has undergone a major change in their condition relevant to home use of oxygen. If the carrier has reason to believe that there has been a major change in the patient's physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

D. Health Conditions

Coverage is available for patients with significant hypoxemia in the chronic stable state, i.e., not during a period of acute illness or an exacerbation of their underlying disease, if:

1. The attending physician has determined that the patient has a health condition outlined in subsection D.1,

2. The patient meets the blood gas evidence requirements specified in subsection D.3, and

3. The patient has appropriately tried other treatment without complete success. (See subsection B.)

1. Conditions for Which Oxygen Therapy May Be Covered

- A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or

- Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2. Conditions for Which Oxygen Therapy Is Not Covered

- Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments;

- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;

- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO_2 improves the oxygenation of tissues with impaired circulation; or

- Terminal illnesses that do not affect the lungs.

3. Covered Blood Gas Values

If the patient has a condition specified in subsection D.1, the carrier must review the medical documentation and laboratory evidence that has been submitted for a particular patient (see subsections B and C) and determine if coverage is available under one of the three group categories outlined below.

(a) - Group I - Except as modified in subsection d, coverage is provided for patients with significant hypoxemia evidenced by any of the following:

- An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken at rest, breathing room air.

- An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO_2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5 percent) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation.

- An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

(b) - Group II - Except as modified in subsection d, coverage is available for patients whose arterial PO_2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89 percent, if there is evidence of:

- Dependent edema suggesting congestive heart failure;

- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or

- Erythrocythemia with a hematocrit greater than 56 percent.

(c) - Group III - Except as modified in subsection d, carriers must apply a rebuttable presumption that a home program of oxygen use is not medically necessary for patients with arterial PO_2 levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90 percent. In order for claims in this category to be reimbursed, the carrier's reviewing physician needs to review any documentation submitted in rebuttal of this presumption and grant specific approval of the claims.

The CMS expects few claims to be approved for coverage in this category.

(d) - Variable Factors That May Affect Blood Gas Values - In reviewing the arterial PO_2 levels and the arterial oxygen saturation percentages specified in subsections D. 3.a, b and c, the carrier's medical staff must take into account variations in oxygen measurements that may result from such factors as the patient's age, the altitude level, or the patient's decreased oxygen carrying capacity.

E. Portable Oxygen Systems

A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself or (2) to use in addition to a stationary oxygen system. Portable oxygen is not covered when it is provided only as a backup to a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

- The claim meets the requirements specified in subsections A-D, as appropriate; and

- The medical documentation indicates that the patient is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep.

F. Respiratory Therapists

Respiratory therapists' services are not covered under the provisions for coverage of oxygen services under the Part B durable medical equipment benefit as outlined above. This benefit provides for coverage of home use of oxygen and oxygen equipment, but does not include a professional component in the delivery of such services.

(See §280.1, and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §110)

240.2.1 – Home Use of Oxygen in Approved Clinical Trials (Effective March 20, 2006)

(Rev. 57, Issued: 05-26-06; Effective: 03-20-06; Implementation: 10-03-06)

A. General

Oxygen is a colorless, odorless gas that comprises 21 percent of the atmospheric gases at sea level. Historically, long term supplemental oxygen has been administered in higher than atmospheric concentrations to patients with chronic hypoxemia, generally resulting from cardiac and/or pulmonary disease. The need for supplemental oxygen is assessed by direct or indirect measurement of the partial pressure of oxygen (conventionally expressed in millimeters of mercury, mmHg) and the oxygen saturation of hemoglobin in arterial blood (expressed as a percent). Chronic oxygen therapy is generally administered via nasal cannulae, face mask, or tracheostomy, from a stationary or portable oxygen tank or an oxygen concentrator.

The medical literature documents health benefits as well as serious adverse events associated with supplemental oxygen use. In this light, it is clear that the decision to initiate, continue, or discontinue the use of supplemental oxygen should be guided by high quality scientific evidence.

B. Nationally Covered Indications

Effective for services performed on or after March 20, 2006 the home use of oxygen is covered for those beneficiaries 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 the Centers for Medicare & Medicaid Services and sponsored by the National Heart, Lung & Blood Institute (NHLBI).

C. Nationally Non-Covered Indications

N/A

D. Other

This policy does not alter Medicare coverage for items and service that may be covered or non-covered according to the existing national coverage determination for the home use of oxygen provided outside the context of approved clinical trials (National Coverage Determination Manual, section 240.2and 310.1).

(This NCD was last reviewed April 2006)