CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 57

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: MAY 26, 2006

Change Request 4389

SUBJECT: Home Use of Oxygen in Approved Clinical Trials

I. SUMMARY OF CHANGES: On March 20, 2006, the Centers for Medicare & Medicaid Services (CMS) announced a National Coverage Determination (NCD) covering the home use of oxygen for Medicare beneficiaries who are enrolled in an approved clinical trial with arterial oxygen partial measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89%. CMS will cover the home use of oxygen in clinical trials identified by CMS and sponsored by the National Heart, Lung & Blood Institute. This decision does not change coverage for the home use of oxygen provided outside the clinical trials currently identified in section 240.2 of the NCD manual. Contractor discretion continues in making local determinations of reasonable and necessary (based on existing guidance provided by the Secretary) for medically accepted home uses of oxygen not addressed in 240.2 of the NCD manual.

NEW/REVISED MATERIAL
EFFECTIVE DATE: March 20, 2006
IMPLEMENTATION DATE: October 3, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/240.2.1/Home Use of Oxygen in Approved Clinical Trials (Effective March 20, 2006)

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)

Coverage Determinations

Table of Contents

(Rev. 57, 05-26-06)

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

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).

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(This NCD was last reviewed April 2006)