CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 35 **Date: MAY 6, 2005**

CHANGE REQUEST 3843

SUBJECT: Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)

I. SUMMARY OF CHANGES: Effective for services performed on and after April 4, 2005, the Centers for Medicare & Medicaid Services (CMS) is updating the national coverage policy to state that based on a reconsideration of the current policy, there is not sufficient evidence to conclude that unattended portable multi-channel sleep study testing is reasonable and necessary in the diagnosis of OSA for CPAP therapy, and these tests will remain noncovered for this purpose. The current NCD specifies that only polysomnography performed in a facility-based sleep study laboratory can be used to identify patients with OSA requiring CPAP. The polysomnography must be performed in a facility-based sleep study laboratory, not in the home or in a mobile facility. This revision to section 240.4 of Pub. 100-03 is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR section 405.732, 405.860). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.

NEW/REVISED MATERIAL :

EFFECTIVE DATE : April 4, 2005

IMPLEMENTATION DATE : June 6, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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
R	1/240.4/Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (Effective April 4, 2005)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 20xx operating budgets.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 35	Date: May 6, 2005	Change Request 3843

SUBJECT: Continous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)

I. GENERAL INFORMATION

A. Background: The existing national coverage guidelines specify that only polysomnography performed in a facility-based sleep study laboratory, not in the home or in a mobile facility, can be used to identify patients with OSA requiring CPAP.

B. Policy: Effective for services performed on and after April 4, 2005, the Centers for Medicare & Medicaid Services is updating the national policy to state that upon reconsideration of the current policy, there is not sufficient evidence to conclude that unattended portable multi-channel sleep study testing is reasonable and necessary in the diagnosis of OSA for CPAP therapy, and these tests will remain non-covered for this purpose.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3843.1	Effective for services performed on or after April 4, 2005, contractors shall follow existing instructions currently in place for CPAP Used in the Treatment of OSA. Contractors already recognize and pay for the following HCPCS codes that can be used for billing the CPAP device and various accessories: E0601 A7030-A7039 A7044-A7046 E0561-E0562	X		X	X					

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3843.2	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X					

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting/Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: April 4, 2005 **Implementation Date: June 6, 2005** **Pre-Implementation Contact(s):** Francina Spencer (coverage) 410-786-4614 **Post-Implementation Contact(s):** Regional office	**Medicare contractors shall implement these instructions within their current operating budgets.**

*__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.35, 05-06-05)

240.4 – Continuous Positive Airway Pressure (CPAP) *Therapy For Obstructive Sleep Apnea (OSA) (Effective April 4, 2005)*

(Rev.35, Issued: 05-06-05, Effective: 04-04-05, Implementation: 06-06-05)

A. General

Continuous positive airway pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

B. Nationally Covered Indications

The use of CPAP is covered under Medicare when used in adult patients with moderate or severe OSA for whom surgery is a likely alternative to CPAP. The use of CPAP devices must be ordered and prescribed by the licensed treating physician to be used in adult patients with moderate to severe OSA if either of the following criterion using the Apnea-Hypopnea Index (AHI) are met:

- AHI *greater than or equal to* 15 events per hour, or

- AHI *greater than or equal to 5* and *less than or equal to* 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

The AHI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep recorded by polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected).

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent oxygen desaturation.

The polysomnography must be performed in a facility - based sleep study laboratory, and not in the home or in a mobile facility.

Initial claims must be supported by *medical documentation (separate documentation where electronic billing is used), such as a prescription written by the patient's attending physician that specifies:*

- *A diagnosis of moderate or severe obstructive sleep apnea, and*

- *Surgery is a likely alternative.*

The claim must also certify that the documentation supporting a diagnosis of OSA (described above) is available.

C. Nationally Non-covered Indications

Effective April 4, 2005, the Centers for Medicare & Medicaid Services determined that upon reconsideration of the current policy, there is not sufficient evidence to conclude that unattended portable multi-channel sleep study testing is reasonable and necessary in the diagnosis of OSA for CPAP therapy, and these tests will remain noncovered for this purpose.

D. Other

N/A

(This NCD last reviewed April 2005.)