

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 103	Date: July 10, 2009
	Change Request 6534

SUBJECT: Sleep Testing for Obstructive Sleep Apnea (OSA)

I. SUMMARY OF CHANGES: Previously, although CPAP was nationally covered for beneficiaries with OSA if diagnosed with specific tests, coverage of the tests themselves was left to local contractor discretion. As a result of this recent NCD, effective for claims with dates of service on and after March 3, 2009, Medicare will allow for coverage of the sleep testing devices, specifically: Type 1 PSG when the test is attended in a sleep lab facility, Type II or Type III if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility, or Type IV measuring 3 or more channels, one of which is airflow, if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility. This revision is an NCD. NCDs are binding on all carriers, FIs, QIOs, QICs, the Medicare appeals council, and ALJs (see 42 CFR 405.1060(a)(4)(2005)). An NCD that expands coverage is also binding on an MA organization. In addition, an ALJ may not review an NCD (1869(f)(1)(A)(i) of the Act)

NEW / REVISED MATERIAL

EFFECTIVE DATE: MARCH 3, 2009

IMPLEMENTATION DATE: August 10, 2009

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: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/240.4.1/Sleep Testing for Obstructive Sleep Apnea (OSA) (Effective March 3, 2009)

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

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

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question

and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 103	Date: July 10, 2009	Change Request: 6534
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SUBJECT: Sleep Testing for Obstructive Sleep Apnea (OSA)

Effective Date: March 3, 2009

Implementation Date: August 10, 2009

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) received an external request from Itamar Medical requesting a National Coverage Determination (NCD) to determine whether Home Sleep Testing (HST) devices measuring the peripheral arterial tone (PAT) signal (a measure of sympathetic activation), heart rate, blood oxygen saturation, and sleep time are reasonable and necessary for the diagnosis of obstructive sleep apnea (OSA). Itamar also asked us to remove this technology from the Type IV classification in the current continuous positive airway pressure (CPAP) NCD and explicitly state that CPAP is covered in beneficiaries diagnosed with OSA using a clinical evaluation and a positive test using this technology.

The CMS has addressed the coverage of CPAP in three separate decisions in October 2001, April 2005, and March 2008. In each of those decisions, CMS limited coverage of CPAP in patients with OSA to those patients whose diagnosis was based on specific testing modalities. Initially, it limited coverage to OSA diagnosed with polysomnography (PSG). In the latest decision, it expanded coverage to OSA diagnosed with several types of HST. However, CMS has not, at a national level, specifically addressed coverage of the tests themselves. In other words, CPAP is nationally covered for beneficiaries with OSA if diagnosed with these specific tests; yet, coverage of the specific tests has previously been left to local contractor discretion.

Since Watch-PAT is only one of several diagnostic tests for OSA and there is no NCD on any of these tests, CMS broadened the scope of its analysis to include other sleep test technologies. After careful consideration, Medicare will allow for coverage of specified sleep tests for adult beneficiaries based upon clinical evaluation and a suspicion of OSA as contained in section 240.4.1 of Pub.100-03 of the NCD Manual.

B. Policy: Effective for claims with dates of service on and after March 3, 2009, Medicare will allow for coverage of the following:

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. Type II or a Type III sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
3. Type IV sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
4. Sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

NOTE: All current claims processing and associated coding remain unchanged. Consult previous Transmittal 96, Change Request 6048, dated October 15, 2008, for detailed information in this regard.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B	DME	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
		MAC	MAC				FISS	MCS	VMS	CWF	
6534.1	Effective for claims with dates of service on and after March 3, 2009, Medicare will allow for coverage of specified sleep tests for adult beneficiaries based upon clinical evaluation and a suspicion of OSA. Refer to Pub.100-03, NCD Manual, section 240.4.1.	X		X	X						
6534.2	Contractors shall not search files to adjust claims but shall adjust claims brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B	DME	FI	CARRIER	RHHI	Shared-System Maintainers				O T H E R
		MAC	MAC				FISS	MCS	VMS	CWF	
6534.3	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN 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

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

- **Pre-Implementation Contact(s):** Jean Stiller (coverage), 410-786-0708, jean.stiller@cms.hhs.gov, Pat Brocato-Simons (coverage), 410-786-0261, patricia.brocatosimons@cms.hhs.gov

- **Post-Implementation Contact(s):** Appropriate RO

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Intermediaries (RHHIs)*:

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

Section B: For *Medicare Administrative Contractors (MACs)*:

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**Medicare National Coverage
Determinations Manual**
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

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(Rev.103, 07-10-09)

*240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA) (Effective
March 3, 2009)*

240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA) (Effective March 3, 2009)

(Rev.103, Issued: 07-10-09, Effective: 03-03-09, Implementation: 08-10-09)

A. General

Obstructive sleep apnea (OSA) is the collapse of the oropharyngeal walls and the obstruction of airflow occurring during sleep. Diagnostic tests for OSA have historically been classified into four types. The most comprehensive is designated Type I attended facility based polysomnography (PSG), which is considered the reference standard for diagnosing OSA. Attended facility based polysomnogram is a comprehensive diagnostic sleep test including at least electroencephalography (EEG), electro-oculography (EOG), electromyography (EMG), heart rate or electrocardiography (ECG), airflow, breathing/respiratory effort, and arterial oxygen saturation (SaO₂) furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed. Overnight PSG is the conventional diagnostic test for OSA. The American Thoracic Society and the American Academy of Sleep Medicine have recommended supervised PSG in the sleep laboratory over 2 nights for the diagnosis of OSA and the initiation of continuous positive airway pressure (CPAP).

Three categories of portable monitors (used both in attended and unattended settings) have been developed for the diagnosis of OSA. Type II monitors have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, breathing/respiratory effort, SaO₂)-this type of device monitors sleep staging, so AHI can be calculated). Type III monitors have a minimum of 4 monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. Type IV devices may measure one, two, three or more parameters but do not meet all the criteria of a higher category device. Some monitors use an actigraphy algorithm to identify periods of sleep and wakefulness.

B. Nationally Covered Indications

Effective for claims with dates of service on and after March 3, 2009, the Centers for Medicare & Medicaid Services finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

- 1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.*

2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

C. Nationally Non-Covered Indications

Effective for claims with dates of services on and after March 3, 2009, other diagnostic sleep tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP and are not covered.

D. Other

N/A

(This NCD last reviewed March 2009.)