

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 96	Date: October 15, 2008
	Change Request 6048

NOTE: Transmittal 96, dated October 15, 2008 rescinds and replaces Transmittal 94, dated August 29, 2008. The only change is a clarification to the verbiage under the Policy section of the Business Requirements at I.B.3. All other information remains the same. Additionally, this clarification does not in any way constitute revisions to the corresponding NCD at 240.4 of Pub 100-03.

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

I. SUMMARY OF CHANGES: After reconsideration, coverage for CPAP therapy for OSA is expanded to include a positive diagnosis of OSA made using a home sleep test under specified criteria.

This revision is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW / REVISED MATERIAL

EFFECTIVE DATE: March 13, 2008

IMPLEMENTATION DATE: August 4, 2008

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/revise 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	1/240.4/Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (Effective March 13, 2008)

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

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

Effective Date: March 13, 2008

Implementation Date: August 4, 2008

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) received a request from the American Academy of Otolaryngology-Head and Neck Surgery, to reconsider its 2005 National Coverage Determination (NCD) for CPAP Therapy for OSA to allow for coverage of CPAP based upon a diagnosis of OSA by home sleep testing (HST).

Medicare covers the use of CPAP in beneficiaries who have been diagnosed with moderate to severe OSA when ordered and prescribed by a licensed treating physician and confirmed by polysomnography (PSG) performed in a sleep laboratory in accordance with section 240.4, of the NCD Manual. There are currently a number of procedures used by physicians singly or in combination that contribute to a diagnosis of OSA: clinical evaluation, PSG performed in a sleep laboratory, HST using Type II, III, & IV devices, and other services.

After careful consideration, CMS is revising its NCD on CPAP therapy for OSA to modify certain elements as well as allowing for the coverage of CPAP based on a positive diagnosis of OSA by HST as contained in section 240.4 of Pub. 100-03 of the NCD Manual. Also refer to chapter 20, section 30.5, of Pub. 100-04 of the Medicare Claims Processing Manual, for billing guidelines for capped rental items, including CPAP.

B. Policy: Effective for claims with dates of service on and after March 13, 2008, Medicare will allow for coverage of CPAP therapy based upon a positive diagnosis of OSA by HST. Refer to section 240.4 of Pub. 100-03 of the NCD Manual.

1. Coverage of CPAP is initially limited to a 12-week period for beneficiaries diagnosed with OSA as subsequently described. CPAP is subsequently covered for those beneficiaries diagnosed with OSA whose OSA improved as a result of CPAP during this 12-week period.

NOTE: The CMS reminds the reader that durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers are required to provide beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively. 42 CFR 424.57(c)(12). Failure to meet this standard may result in revocation of the DMEPOS supplier's billing privileges. 42 CFR 424.57(d).

2. The CPAP for adults is covered when diagnosed using a clinical evaluation and a positive:

a. polysomnography (PSG) performed in a sleep laboratory; or

- b. unattended home sleep monitoring device of Type II; or
- c. unattended home sleep monitoring device of Type III; or
- d. unattended home sleep monitoring device of Type IV, measuring at least 3 channels

NOTE: The CMS reminds the reader that, in general, pursuant to 42 CFR 410.32(a) diagnostic tests that are not ordered by the beneficiary's treating physician are not considered reasonable and necessary. Pursuant to 42 CFR 410.32(b) diagnostic tests payable under the physician fee schedule that are furnished without the required level of supervision by a physician are not reasonable and necessary.

3. A positive test for OSA is established if either of the following criterion using the Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) are met:

- o AHI or RDI greater than or equal to 15 events per hour of sleep or continuous monitoring, respectively, or
- o AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour of sleep or continuous monitoring, respectively, 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 of sleep. The RDI is equal to the average number of respiratory disturbances per hour of continuous monitoring. **However, there is variability in the published medical literature about the definition of the events that constitute a respiratory disturbance. The technology assessment that supported this NCD recognized this variability and defined RDI in the context of the specific sleep test technology under review. For the purposes of this NCD, a respiratory disturbance is defined in the context of the sleep test technology of interest and does not require direct measurement of airflow.** Local contractors shall, as needed, determine, **based on their review of the published, peer-reviewed medical literature**, the equivalent test result criteria corresponding to the required AHI or RDI for Type IV devices measuring 3 or more channels that do not measure AHI or RDI directly.

4. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a 2-hour period.

5. The CMS is deleting the distinct requirements that an individual have moderate to severe OSA and that surgery is a likely alternative.

6. The CPAP based on clinical diagnosis alone or using a diagnostic procedure other than PSG or Type II, Type III, or a Type IV HST measuring at least three channels is covered only when provided in the context of a clinical study as specified in section 310.1 of Pub. 100-03 of the NCD Manual.

New HST Portable Monitoring G Codes Effective March 13, 2008:

- o G0398: Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation.
- o G0398 Short Descriptor: Home sleep test/type 2 Porta

- G0399: Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
- G0399 Short Descriptor: Home sleep test/type 3 Porta
- G0400: Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels
- G0400 Short Descriptor: Home sleep test/type 4 Porta

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	
6048.1	Effective for claims with dates of service on and after March 13, 2008, Medicare will allow for coverage of CPAP therapy for adult beneficiaries based upon clinical evaluation and a positive diagnosis of OSA by HST. Refer to section 240.4, of Pub.100-03, of the NCD Manual.	X	X	X	X						
6048.2	For coverage of routine items/services provided in the context of a clinical study, claims shall be processed according to CED/clinical trials criteria at section 310.1, of Pub.100-03, of the NCD Manual, section 240.4, of the NCD Manual, and chapter 32, sections 69.6-69.7, of Pub.100-04, of the Claims Processing Manual.	X	X	X	X						
6048.3	Contractors shall not search files to adjust claims but shall adjust claims brought to their attention.	X	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				OTHER
		MAC	MAC				FISS	MCS	VMS	CWF	
6048.4	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	X	X	X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B	DME	FI	CARRIER	RHHI	Shared-System Maintainers				OTHE
		MAC	MAC				FISS	MCS	VMS	CWF	
	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.										

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:

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 Carriers (RHHIs)* use only one of the following statements:

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)*, use the following statement:

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. 96, 10-15-08)

240.4 – Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) *(Effective March 13, 2008)*

240.4 - Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (*Effective March 13, 2008*)
(Rev. 96, Issued: 10-15-08, Effective: 03-13-08, Implementation: 08-04-08)

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).

The apnea hypopnea index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour. The respiratory disturbance index (RDI) is equal to the average number of respiratory disturbances per hour.

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% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

The AHI and/or RDI may be measured by polysomnography (PSG) in a facility based sleep study laboratory or by a Type II home sleep test (HST) monitor, a Type III HST monitor, or a Type IV HST monitor measuring at least 3 channels.

B. Nationally Covered Indications

Effective for claims with dates of service on and after March 13, 2008, the Centers for Medicare & Medicaid Services (CMS) determines that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations:

- 1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.*
- 2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.*
- 3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
 - a. attended PSG performed in a sleep laboratory; or**

- b. unattended HST with a Type II home sleep monitoring device; or*
 - c. unattended HST with a Type III home sleep monitoring device; or*
 - d. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.*
- 4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision.*
- 5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the AHI or RDI are met:*
- a. AHI or RDI greater than or equal to 15 events per hour, or,*
 - b. AHI or RDI greater than or equal to 5 events 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.*
- 6. The AHI or RDI is calculated on the average number of events per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a 2-hour period.*
- 7. 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% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.*
- 8. Coverage with Evidence Development (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions*
- a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III & IV HST in identifying subjects with OSA who will respond to CPAP?*
 - b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm?*

The study must meet the following additional standards:

- c. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.*
- d. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.*
- e. The research study does not unjustifiably duplicate existing studies.*
- f. The research study design is appropriate to answer the research question being asked in the study.*
- g. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.*
- h. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is Food and Drug Administration-regulated, it also must be in compliance with 21 CFR Parts 50 and 56.*
- i. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.*
- j. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.*
- k. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.*
- l. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.*
- m. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned for publication in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.*
- n. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in*

clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

o. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

C. Nationally Non-covered Indications

Effective for claims with dates of services on and after March 13, 2008, other diagnostic tests for the diagnosis of OSA other than those noted above for prescribing CPAP are not sufficient for the coverage of CPAP.

D. Other

N/A

(This NCD last reviewed March 2008.)