



Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) – JA6048

Note: MLN Matters article MM6048 was revised to reflect changes to Change Request (CR) 6048. The CR release date, transmittal number, and the Web address for accessing CR6048 were revised. In addition, some clarifying language was added in item 3.

Related CR Release Date : October 15, 2008 **Revised**

Date Job Aid Revised: November 10, 2008

Effective Date: March 13, 2008

Implementation Date: August 4, 2008

Key Words	MM6048, CR6048, R96NCD, NCD, CPAP, OSA, Home, Sleep, Testing
Contractors Affected	<ul style="list-style-type: none"> • Part A/B Medicare Administrative Contractors (A/B MACs) • Durable Medical Equipment MACs (DME MACs) • Fiscal Intermediaries (FIs) • Medicare Carriers
Provider Types Affected	Physicians, providers and suppliers submitting claims to Medicare Carriers, FIs, A/B MACs, and/or DME MACs for OSA-related services provided to Medicare beneficiaries



- The Centers for Medicare & Medicaid Services (CMS) is revising the existing National Coverage Determination (NCD) on CPAP therapy for OSA as well as allowing coverage of CPAP based on a positive diagnosis of OSA by home sleep testing (HST), subject to all the requirements of the new NCD, as outlined in CR6048.
- 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, subject to the requirements of CR6048.

- Provider Needs to Know...**
- The key changes in Medicare policy, as a result of the NCD in CR6048, coverage of CPAP based on positive diagnosis of OSA by HST is as follows:
 1. Coverage of CPAP is initially limited to a 12-week period for beneficiaries diagnosed with OSA as described below. CPAP is subsequently covered for those beneficiaries diagnosed with OSA whose OSA improves as a result of CPAP during this 12-week period.

NOTE: DME, Prosthetics, Orthotics, and Supplies suppliers are required to provide beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively.

2. CPAP for adults is covered when diagnosed using a clinical evaluation and a positive:
 - Polysomnography (PSG) performed in a sleep laboratory; or
 - Unattended home sleep monitoring device of Type II; or
 - Unattended home sleep monitoring device of Type III; or
 - Unattended home sleep monitoring device of Type IV, measuring at least three channels.

NOTE: In general, pursuant to 42 Code of Federal Regulations (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 Medicare 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 criteria using the Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) are met:
 - AHI or RDI greater than or equal to 15 events per hour of sleep or continuous monitoring; or
 - AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour of sleep or continuous monitoring with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

Clarification Added to CR6048

- 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 may 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 three or more channels that do not measure AHI or RDI directly.

4. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than two 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 two-hour period.
5. CMS is **deleting the distinct requirements** that an individual have moderate to severe OSA and that **surgery is a likely alternative**.
6. 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 and when that study meets the standards outlined in the *NCD Manual* revision attached to CR6048.

Background

- CMS reconsidered its 2005 NCD for CPAP Therapy for OSA to allow for coverage of CPAP based upon a diagnosis of OSA by HST.
- Medicare previously covered the use of CPAP only in beneficiaries who had been diagnosed with moderate to severe OSA when ordered and prescribed by a licensed treating physician and confirmed by PSG performed in a sleep laboratory in accordance with Section 240.4 of the *Medicare NCD Manual*.
- Following the reconsideration of its coverage policy, CMS is revising the existing NCD on CPAP therapy for OSA as well as allowing coverage of CPAP based on a positive diagnosis of OSA by HST, subject to all the requirements of the new NCD, as outlined in CR6048. (Note that billing guidelines for capped rental equipment are contained in the *Medicare Claims Processing Manual*, Chapter 20, Section 30.5, which is available at <http://www.cms.hhs.gov/manuals/downloads/clm104c20.pdf> on the CMS website.)
- As part of the NCD, 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 (is equal to the average number of episodes of apnea and hypopnea per hour. The RDI is equal to the average number of respiratory disturbances per hour.
- The following HST portable monitoring G codes (effective March 13, 2008) are provided for information only. They are not included in the CPAP for OSA NCD in Section 240.4 of the *NCD Manual*, and do not necessarily convey coverage, which is determined at local contractor discretion. The codes are as follows:
 - **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;
 - **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;

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- G0399 Short Descriptor: Home sleep test/type 3 Porta;
 - G0400: Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels; and
 - G0400 Short Descriptor: Home sleep test/type 4 Porta.
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**Operational
Impact**

Medicare will process claims according to Coverage with Evidence Development /clinical trials criteria at Section 310.1 of the *NCD Manual* and Chapter 32 and Sections 69.6-69.7 (Pub 100-04) of the *Medicare Claims Processing Manual*. These manuals are available at <http://www.cms.hhs.gov/manuals/IOM/list.asp> on the CMS website.

**Reference
Materials**

The related MLN Matters article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6048.pdf> on the CMS website.

The official instruction (CR6048) issued regarding this change may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R96NCD.pdf> on the CMS website.
