



News Flash - Physician Quality Reporting Initiative (PQRI) - The Centers for Medicare & Medicaid Services (CMS) will begin testing eleven new quality measures for possible adoption in the PQRI program in future years. To learn more about how you can help CMS test these measures, visit <http://www.cms.hhs.gov/pqri> on the CMS website and select the "Measures/Codes" link on the left side of the page. As a reminder, all educational resources about the 2008 PQRI are available on the dedicated PQRI webpage on the CMS website. To access this web page, visit <http://www.cms.hhs.gov/pqri> on the CMS website.

MLN Matters Number: MM6048 **Revised**

Related Change Request (CR) #: 6048

Related CR Release Date: October 15, 2008

Effective Date: March 13, 2008

Related CR Transmittal #: R96NCD

Implementation Date: August 4, 2008

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

Note: This article was revised on October 16, 2008, to reflect changes to CR 6048, which CMS revised on October 15, 2008. The CR release date, transmittal number, and the Web address for accessing CR6048 were revised. In addition, some language in item 3, on page 3 was clarified. All other information remains the same.

Provider Types Affected

Physicians, providers and suppliers submitting claims to Medicare contractors (carriers, Fiscal Intermediaries (FIs), Part A/B Medicare Administrative Contractors (A/B MACs), and/or Durable Medical Equipment (DME) MACs) for OSA-related services provided to Medicare beneficiaries.

Impact on Providers

Providers need to be aware that 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 home sleep testing (HST), subject to the requirements of CR6048.

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Background

The Centers for Medicare & Medicaid Services (CMS) reconsidered its 2005 National Coverage Determination (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 polysomnography (PSG) performed in a sleep laboratory in accordance with Section 240.4 of the *Medicare NCD Manual* (see the *Additional Information* section of this article for the official instruction and the revised section of the NCD). 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 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.

Key Points of CR6048

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 (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. 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

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- Unattended home sleep monitoring device of Type III; or
- Unattended home sleep monitoring device of Type IV, measuring at least 3 channels

NOTE: 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 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.

As previously stated, 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 will, 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. 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 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. 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 3 channels is

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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. Medicare will process claims according to Coverage with Evidence Development (CED)/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.

Note: The following HST portable monitoring G codes effective March 13, 2008, are provided for your information only, are not included in the CPAP for OSA NCD at section 240.4 of the NCD Manual, and do not necessarily convey coverage, which is determined at local contractor discretion.

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

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

Additional Information

To see the official instruction (CR6048) issued to your Medicare A/B MAC, FI, carrier, or DME MAC visit <http://www.cms.hhs.gov/Transmittals/downloads/R96NCD.pdf> on the CMS website.

If you have questions, please contact your Medicare A/B MAC, FI, carrier, or DME MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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