

Positive Airway Pressure (PAP) Devices – Important Information for the Ordering Physician
December 2008

Dear Physician,

On March 13, 2008, CMS released a revised National Coverage Determination (NCD) for Continuous Positive Airway Pressure (CPAP) devices. In September 2008, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) published a revised Local Coverage Determination (LCDs) and a “Dear Physician” letter which reviewed the pertinent coverage criteria for these devices, including bi-level positive airway pressure devices (respiratory assist devices, RADs) when they are used to treat obstructive sleep apnea (OSA).

The DME MAC medical directors have updated the PAP LCD; consequently, we are republishing this important information for ordering physicians. In addition, there are Frequently Asked Questions (FAQs) specifically addressing issues of importance to ordering physicians on the DME MAC web sites.

The major requirements for coverage of a PAP device for OSA that pertain to the ordering physician are:

- 1) There must be a face-to-face visit with the physician prior to ordering the sleep test. This should generally include the following elements:
 - a) Sleep history and symptoms which may be caused by OSA
 - b) Epworth Sleepiness Scale (a standardized patient questionnaire which helps to assess the likelihood of sleep apnea) or other validated sleep inventory
 - c) Pertinent physical examination – e.g., body mass index, neck circumference, upper airway exam, and cardiopulmonary exam
- 2) The patient must have a facility based polysomnogram or a Type II, III, or IV home sleep study. Type IV home sleep studies are acceptable when performed by devices that either directly or indirectly allow calculation of an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI). Devices that allow direct calculation of AHI/RDI by measuring airflow or thoracoabdominal movement are acceptable. The only currently acceptable Type IV device that indirectly allows calculation of an AHI/RDI are the Watch-PAT devices (Itamar Medical), effective for tests conducted on or after January 1, 2009. Acceptable indirect measurement products are listed in the LCD.
- 3) If a home sleep study is performed, it must be interpreted by a physician who holds either:
 - a) Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or

- b) Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or
- c) Completed residency or fellowship training by a program approved by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or
- d) Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine or the Joint Commission.

Note: Physicians interpreting polysomnograms will be required to meet this requirement for coverage of PAP devices provided after January 1, 2010.

- 4) The sleep study results are:
 - a) AHI or RDI is greater than or equal to 15 events per hour, with a minimum of 30 events; or
 - b) AHI or RDI is 5-14 events per hour (minimum of 10 events) with documentation of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke. (Note: For purposes of this policy, the RDI includes only apneas and hypopneas.)

- 5) To continue coverage for the positive airway pressure (PAP) device (CPAP or RAD) beyond an initial 3 month trial period, there must be:
 - a) A face-to-face visit with the physician during the second or third month of the trial that documents an improvement of the beneficiary's symptoms; and
 - b) A data report from the PAP device which documents use the PAP device for at least 4 hours per night on 70% of nights for a 30 consecutive day period during the trial.

- 6) For beneficiaries who received a PAP device prior to FFS Medicare enrollment and are now enrolled in Medicare and are seeking a new PAP device and/or accessories, both of the following coverage requirements must be met:
 - 1. Sleep test – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the FFS Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks a replacement PAP device and/or accessories; and,
 - 2. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation by their treating physician who documents in the beneficiary's medical record that:
 - a. The beneficiary has a diagnosis of obstructive sleep apnea; and,
 - b. The beneficiary continues to use the PAP device.

Additional coverage and payment rules for sleep tests may be found in the local coverage determinations (LCDs) for the applicable Medicare Part A or Part B contractor. There may be differences between those LCDs and the DME MAC LCD. For the purposes of coverage of PAP therapy, the DME MAC coverage criteria take precedence.

The complete medical policy may be viewed on the DME MACs' individual web sites or in the CMS Medicare Coverage Database. The Epworth Sleepiness Scale may be found in the Appendices section of the LCD. Note that the formal title of the policy is Positive Airway Pressure ((PAP) Devices for the Treatment of Obstructive Sleep Apnea. The web address of the Medicare Coverage Database is: <http://www.cms.hhs.gov/mcd/search.asp>

Physicians are reminded that in order for these items to be reimbursed for your patients, the DME supplier will need to collect medical documentation including copies of your initial evaluation, the report of the sleep study, your re-evaluation during the PAP trial, and the data report from the PAP device indicating patient compliance during the trial. Please cooperate with them so that they can provide the device that you have ordered for your patient.

Paul J. Hughes, M.D.
Medical Director, DME MAC, Jurisdiction A

Robert D. Hoover, Jr., MD, MPH, FACP
Medical Director, DME MAC, Jurisdiction C

Adrian M. Oleck, M.D.
Medical Director, DME MAC, Jurisdiction B

Richard W. Whitten, MD, MBA, FACP
Medical Director, DME MAC, Jurisdiction D