

December 2008

## **Positive Airway Pressure (PAP) Devices - Clinician Frequently Asked Questions**

Based on questions received from the clinical community, the following Frequently Asked Questions will address issues in the Positive Airway Pressure (PAP) Devices local coverage determination (LCD). The complete medical policy may be viewed on the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) individual web sites or in the CMS Medicare Coverage Database. 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.gov/mcd/search.asp>. Additional information may also be found in the "Dear Clinician" letter published in December 2008 on the DME MAC web sites.

Clinicians 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.

### **Ordering/Treating Clinician Issues**

**1. Question:** Explain the clinician visits required for patients who are being evaluated for sleepdisordered breathing.

**Answer:** Two face-to-face evaluations are required for a patient to be considered for Medicare coverage for PAP therapy. There must be a face-to-face visit with the treating clinician prior to ordering of any sleep test. This should generally include documentation in the patient's medical record the following elements:

- a. Sleep history and symptoms
- 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

Medicare coverage is conditional for the first 3 months. Continued coverage beyond the first 3 months is contingent upon demonstration of benefit from the use of a PAP device. Therefore, following the sleep test the patient must see the treating clinician again, sometime between the 31st and 91st day, to document improvement of the patient's symptoms. In addition, the clinician must review data from the PAP device which documents use at least 4 hours per night on 70% of nights for a 30 consecutive day period during the trial.

**2. Question:** The LCD uses the term "treating clinician" in various places. What is the definition of a treating clinician?

**Answer:** Medicare statute defines treating clinician as one "...who furnishes a consultation or treats the beneficiary for a specific medical problem and who uses the [diagnostic x-ray tests, diagnostic laboratory tests and other diagnostic tests] results in the management of the beneficiary's specific medical problem." In a scenario where the beneficiary visits their primary care provider (PCP) who then refers the beneficiary to a sleep specialist for a polysomnogram and subsequent treatment with PAP and follow-up, both the PCP and the sleep specialist would be considered a "treating clinician" within the context of Medicare regulations. Both clinicians are engaged in diagnosing and treating the beneficiary for sleep disordered breathing. This scenario is quite common in medical practice where the primary medical care for the patient is rendered by the PCP and subspecialty clinician consultation is engaged for specific diagnostic and/or therapeutic treatment outside the scope of the PCP's area of medical expertise.

**3. Question:** Are nurse practitioners, clinical nurse specialists and clinician assistants allowed to conduct the initial clinical evaluation and/or follow-up evaluation since the LCD states this must be done by the treating clinician?

**Answer:** Yes. Medicare regulations provide for the use of nurse practitioners, clinical nurse specialists and clinician assistants in the care of Medicare beneficiaries. The Social Security Act §1861(s) addresses the provision of Medical and Other Services as follows:

clinician Assistants: (K)(i) services which would be clinicians' services if furnished by a clinician and which are performed by a clinician assistant under the supervision of a clinician and which the clinician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered if furnished incident to a clinician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

Nurse Practitioners and Clinical Nurse Specialists: (K)(ii) services which would be clinicians' services if furnished by a clinician and which are performed by a nurse practitioner or clinical nurse specialist working in collaboration with a clinician which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered if furnished incident to a clinician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

**4. Question:** Can a registered nurse (RN) conduct the follow-up evaluation?

**Answer:** No, the treating clinician (defined and discussed above) must be directly involved in the follow-up evaluation.

**5. Question:** The policy states that the data that the clinician evaluates must be for a period of 30 consecutive days. The policy is silent on a time frame in which the clinician must see the patient in relationship to the data.

**Answer:** The clinician may see the patient and conduct the follow-up evaluation between the 31st and 91st day. Continued coverage of a PAP device requires that a determination be made by the treating clinician that the patient is benefiting from the use of the selected device as evidenced by a face-to-face clinical follow-up evaluation and adherence to therapy. While the documentation of adherence may occur following the treating clinician's follow-up evaluation, the adherence report must be provided to the treating clinician for inclusion in the patient's medical record in order to fulfill the requirement to assess therapy benefit.

**6. Question:** Does the treating clinician who does the initial face-to-face examination have to write the order for the PAP therapy or can it be ordered by the interpreting clinician from the sleep lab?

**Answer:** The treating clinician that does the initial face to face exam does not have to be the same clinician that orders the CPAP.

**7. Question:** Is there a time limit from initial face-to-face evaluation to the sleep study?

**Answer:** No time limit is specified in the policy; however, one would anticipate that these two events occur reasonably close together in time, typically within 3 months.

**8. Question:** Can the face-to-face evaluation be done after the sleep test or after initiation of PAP therapy and will that meet the LCD documentation requirements?

**Answer:** The NCD and LCD require that prior to initiating PAP therapy, the patient has a clinical evaluation and sleep test. There is a sound clinical rationale for this specific sequence of events; therefore, a face-to-face evaluation performed after the sleep test or after the initiation of PAP therapy would not meet the coverage requirements.

**9. Question:** If a patient is put on a respiratory assist device (RAD) device with less than 30 days left in the initial 91 day period, the LCD indicates that the patient will be given to 120 days after the initiation of PAP therapy to document adherence. If the patient had a face to face exam in the 31 to 91 day period while on a CPAP device, must they have another face to face exam after they are on RAD? Certainly if they did not have a face to face exam in the 31 to 90 days we understand that one would need to be done before the 120th day.

**Answer:** Yes, the patient would need to have a follow-up evaluation before the 120th day to determine benefit from the RAD device. This answer is based on the assumption that the reason the patient changed from a CPAP to RAD is the failure to show clinical benefit with the CPAP device. According to the NCD, continued coverage requires demonstration of therapy benefit within the first 90 days. The LCD recognizes that some patients may require a change in therapy to a RAD device and this transition may happen late in the first 90 day period such that an extension to 120 days is necessary.

**10. Question:** What happens if the patient does not get in to see the treating clinician within the 31st-91st day?

**Answer:** If the patient does not get in to see the treating clinician for the re-evaluation between the 31st and 91st day of PAP treatment, coverage of the PAP device will end after 3 months. If the clinician performs the re-evaluation at a later date, coverage would resume on the date of the re-evaluation. The patient may be responsible for payment of the device and accessories during the intervening time period between the end of the third month and whenever the re-evaluation takes place.

**11. Question:** What is required for patients who may have received their PAP device from a private insurer and are now enrolled in fee for service (FFS) Medicare? What is needed for those patients to get a new device and/or supplies?

**Answer:** For beneficiaries who received a PAP device prior to enrollment in FFS Medicare and are now seeking Medicare coverage of either a replacement 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 clinician 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.

If either criteria 1 or 2 above are not met, the claim will be denied as not medically necessary.

### **Sleep Test**

**12. Question:** The LCD notes that Type IV devices that do not directly measure airflow or thoracoabdominal movement to calculate an AHI/RDI will be considered for coverage after evaluation of the medical literature. Are there any Type IV devices that meet the requirements for coverage? If so, where can we find this list?

**Answer:** The DME MAC medical directors have received information regarding Watch-PAT. After review of the scientific literature, these devices have been added to the local coverage determination (LCD) as a covered Type IV device, effective for tests conducted with dates of service on or after January 1, 2009. The LCD also now includes in the Appendices a list of Type IV devices approved for coverage that indirectly measure AHI/RDI. This coverage expansion will be reflected in an upcoming policy revision.

**13. Question:** Who is allowed to interpret home sleep tests?

**Answer:** If a home sleep study is performed after November 1, 2008, it must be interpreted by a clinician 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 clinician 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.

clinicians interpreting facility-based polysomnograms will be required to meet this requirement for coverage of PAP devices provided after January 1, 2010.

**14. Question:** What if my local Part A or Part B contractor has an LCD for polysomnography that is different from the DME MAC LCD. Which one applies?

**Answer:** Additional coverage and payment rules for sleep tests may be found in the LCD 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.

### **Adherence Monitoring**

**15. Question:** Help us understand the term "visual inspection" as it relates to adherence monitoring. What does this mean and how can it be documented?

**Answer:** The LCD was revised to include allowance for visual inspection, in addition to direct download of information from the PAP device. Visual inspection means determining adherence by looking at information on the PAP device's display screen and documenting the values in a written report. The medical equipment supplier is allowed to contact the beneficiary via telephone or during an in-person visit and ask them to read values from their device. Alternatively, the clinician may read the values during a home/office visit and document the adherence information in the patient's medical record. The values must document that the patient is using the device for 4 or more hours per night for 70% of the nights in a consecutive 30-day period.

**16. Question:** Can the report be based on hours used, for example with information from a device with an hour meter, and meet the requirement for documenting adherence? For example, "Spoke to patient and she states that as of 12/01/08, there are a total of 650 hours on her CPAP machine. She states that she uses the CPAP every night and it is very beneficial. On 11/01/08, the beginning reading was 500 hours. This calculates to 5 hours per night for 30 days."

**Answer:** No. Devices that simply report device "on" time or "blower on" time will not provide enough information to determine that the PAP device was used = 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

**17. Question:** Several manufacturers have devices that report "sessions" of use. Are these types of devices acceptable to meet the LCD requirement for adherence?

**Answer:** Possibly, depending on the definition of "session" which can vary based on the manufacturer or the session definition if a user-defined option. For example, consider a device that measures a "session" as use greater than X hours and also reports number of days used. Assuming that a session was set up to measure use = 4 hours, one could use the number of sessions in conjunction with total days of use over a 30 day period and determine whether or not the patient met the adherence requirement.

**18. Question:** Some devices report adherence information on a rolling 30 day basis. Information is displayed in a window on the device; however, adherence may vary depending on which 30 day period is examined. Can this device still meet the adherence requirement?

**Answer:** Devices that report information on a rolling 30 day interval can be problematic if using visual inspection as the reporting method. One solution is to engage the beneficiary in their care and emphasize the importance of monitoring their therapy, including the potential loss of Medicare reimbursement for their PAP device due to failure to meet the adherence requirements. In the scenario with this specific piece of equipment, the supplier or clinician should instruct the beneficiary to monitor their device after the initial 30 days of use and report back to the supplier the point at which they meet the adherence metric.

**19. Question:** Must adherence as defined in the LCD continue to be documented after the initial 3 month period?

**Answer:** No. Following the initial 3 month trial and documentation of use =4 hrs. per night on 70% of nights in a 30 consecutive day period, the medical equipment supplier can document continued use of the device. This may be accomplished via documentation of attestation by the beneficiary.