

January 2018

Positive Airway Pressure Devices

Dear Clinician,

Data from the Comprehensive Error Rate Testing (CERT) program projects that ~\$500M in inappropriate payments are made each year for positive airway pressure (PAP) devices used to treat obstructive sleep apnea (OSA). A significant proportion of the claim errors observed in the data relate to inadequate or missing documentation supporting the need for the PAP device and/or supplies. The information below is intended to assist you in documenting that your patient meets Medicare guidelines for initial coverage of PAP devices. A separate “Dear Clinician” letter addresses documentation necessary for your patient to receive a replacement PAP device or ongoing supplies.

For your patient diagnosed with OSA for the first time after becoming Medicare-eligible, the major requirements for coverage of a PAP device for OSA that pertain to the ordering clinician are:

1. There must be a face-to-face visit with the clinician prior to ordering the sleep test and within 6 months prior to the clinician writing the order for the PAP device. This should generally include the following elements:
 - Sleep history and symptoms which may be caused by OSA
 - Pertinent physical examination — e.g., body mass index, neck circumference, upper airway exam, and focused cardiopulmonary exam
 - Epworth Sleepiness Scale (a standardized patient questionnaire which helps to assess the likelihood of sleep apnea) or other validated sleep inventory
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. A list of acceptable Type IV devices are listed in the DME MAC Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCD (L33718).
3. If a home sleep study is performed, it must be interpreted by a physician who holds:
 - Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or
 - Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA); or
 - Completed residency or fellowship training by a program approved by an ABMS or AOA 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

- Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine, Accreditation Commission for Health Care (ACHC) or the Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).
4. The sleep study results must demonstrate:
- AHI or RDI is greater than or equal to 15 events per hour, with a minimum of 30 events; or,
 - 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. Respiratory effort-related arousals or RERAs must not be used in the calculation of the AHI or RDI. In addition, Medicare defines hypopnea as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

5. Written Order Prior to Delivery: Within six (6) months of the face-to-face examination, you must write an order for the PAP device and the supplier of the PAP device must receive your order before they can deliver the device.
6. Continued coverage beyond the initial three (3) month trial: To continue coverage for the PAP device beyond an initial 3month trial period, no sooner than the 31st day but no later than the 91st day after initiating therapy, you must conduct a clinical re-evaluation and document that your patient is benefiting from PAP therapy. This is demonstrated by:
- A face-to-face visit with your patient during the second or third month of the trial (but not before that time) that documents an improvement in their sleep-disordered breathing symptoms; and,
 - Review of the adherence report from the PAP device which documents use of the PAP device for at least 4 hours per night on 70% of nights for a 30 consecutive day period during the trial (i.e., 21 nights in a rolling 30 consecutive day period).

It is critical to stay in communication with your patient's DME company or track compliance yourself so that once your patient meets the 30 day adherence metric, a follow-up visit can be scheduled within the 31st to 90th day window.

Additional coverage and payment rules for sleep tests may be found in the LCDs for the applicable Medicare A/B MAC 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 websites or in the CMS Medicare Coverage Database. The Epworth Sleepiness Scale may be found in the Appendices section of the LCD. Clinicians are reminded that in order for these items to be reimbursed for your patients, the DME supplier may 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 adherence to therapy

during the trial. Please cooperate with them so that they can provide the device that you have ordered for your patient.

Sincerely,

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