



Criteria for Benefit Decisions Related to Positive Airway Pressure Devices:

Criteria for approval:

Indications and Limitations of Coverage and/or Medical Necessity

Continuous Positive Airway Pressure (CPAP)

INITIAL COVERAGE:

A single level continuous positive airway pressure (CPAP) device (E0601) is covered for the treatment of obstructive sleep apnea (OSA) if criteria A - C are met:

- A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea.
- B. The patient has a sleep test that meets either of the following criteria:
- The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
 - The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
 - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
 - b. Hypertension, ischemic heart disease, or history of stroke.
- C. The patient and/or their caregiver has received instruction from the supplier of the CPAP device and accessories in the proper use and care of the equipment.

If a claim for a CPAP (E0601) is submitted and all of the criteria above have not been met, it will be denied as not medically necessary.

Apnea is defined as the cessation of airflow for at least 10 seconds.

Hypopnea is defined 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.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.

The **respiratory disturbance index (RDI)** is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device.

If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded

events used to calculate the AHI or RDI (repectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach ≥ 30 events without symptoms or ≥ 10 events with symptoms).

Bilevel Positive Airway Pressure (BiPAP) Devices

A BiPAP is covered for those patients with OSA who have tried a single level positive airway pressure device and the trial has proven ineffective, based on a therapeutic trial conducted in either a facility or in a home setting. If a CPAP device is tried and found ineffective during the initial 3 month home trial, substitution of a BiPAP does not require a new initial face-to-face clinical evaluation or a new sleep test.

If a CPAP device has been used for more that 3 months and the patient is switched to a BiPAP, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the BiPAP.

Coverage requirements for the use of BiPAP for diagnoses other than OSA are as follows:

Restrictive Thoracic Disorders:

- Member has a progressive neuromuscular disease (e.g., amyotrophic lateral sclerosis, etc.) or a severe thoracic cage abnormality (e.g., post-thoracoplasty for tuberculosis, etc.); and
- Member has symptoms of nocturnal hypoxemia, such as fatigue, dyspnea, morning headache, etc., *and*
- COPD does not contribute significantly to the member's pulmonary limitation, and
- Member has clinically significant hypoxemia, as indicated by any of the following:
 1. An arterial blood gas PaCO₂, done while awake and breathing the member's usual FIO₂ (fractional inspired oxygen concentration), is greater than or equal to 45 mm Hg, or
 2. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing the member's usual FIO₂, or
 3. For progressive neuromuscular disease only, maximal inspiratory pressures less than 60 cm H₂O or forced vital capacity (FVC) less than 50% predicted.

Severe Chronic Obstructive Pulmonary Disease:

- Member has symptoms of hypoxemia, such as fatigue, dyspnea, morning headache, etc., and
- Member has severe COPD, as indicated by either of the following:
 1. An arterial blood gas PaCO₂, done while awake and breathing the member's usual FIO₂, is greater than or equal to 55 mm Hg, *or*
 2. An arterial blood gas PaCO₂ of 50 to 54 mm Hg and either of the following:
 - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 liters per minute (LPM) or the member's usual FIO₂, whichever is higher, or
 - Hospitalization related to recurrent (greater than or equal to 2 in a 12-month period) episodes of hypercapnic respiratory failure.

Prior to initiating therapy, obstructive sleep apnea (OSA) (and treatment with CPAP) has been considered and ruled out.

Central Sleep Apnea (CSA), i.e., apnea not due to airway obstruction:

Prior to initiating therapy, a complete inpatient, attended polysomnogram must be performed documenting the

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following:

- The diagnosis of CSA, and
- The exclusion of OSA as a primary cause of sleep-associated hypoventilation, and
- The ruling out of CPAP as effective therapy if OSA is a component of the sleep-associated hypoventilation, and
- Oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the member's usual FIO₂, whichever is higher, and
- Significant improvement of the sleep-associated hypoventilation with the use of NPPV device on the settings that will be prescribed for initial use at home, while breathing the member's usual FIO₂.

If CPAP fails as treatment for CSA or the initial sleep study interpretation strongly recommends initiation of Variable Positive Airway Pressure (VPAP), the plan will consider authorization of the use of VPAP.

Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a covered sleep test. A recognized sleep test is defined in HNE's Polysomnography Policy. The test must be ordered by the beneficiary's treating physician and conducted by an entity that qualifies as an HNE provider of sleep tests and is in compliance with all applicable state regulatory requirements.

For all PAP devices with initial dates of service on or after January 1, 2010, physicians interpreting facility-based polysomnogram must meet one of the following requirements listed below:

- 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,
- Completed residency or fellowship training 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,
- Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations – (JCAHO).

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

Continued coverage of a PAP device beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.

For PAP devices with initial dates of service on or after July 1, 2009, documentation of clinical benefit is demonstrated by:

- Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and,
- Objective evidence of adherence to use of PAP device, reviewed by the treating physician.

Adherence to therapy is defined as use of PAP \geq 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.

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not medically necessary.

Beneficiaries who fail the initial 12 week trial are eligible to requalify for a PAP device but must have both:

- Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to

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- respond to PAP therapy; and,
- Repeat sleep test in a facility-based setting.

If the physician re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the patient is benefiting from PAP therapy as defined above, continued coverage of the PAP device will commence with the date of that re-evaluation.

If a CPAP device is tried and found ineffective during the initial 3 month home trial, substitution of a BiPAP does not change the length of the trial unless there is less than 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 91st day following the initiation of CPAP.

If a CPAP device was used for more that 3 months and the patient was switched to a BiPAP, then the clinical re-evaluation would occur between the 31st and 91st day following the initiation of the RAD. There would also need to be documentation of adherence to therapy during the 3 month trial with the RAD.

If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

BENEFICIARIES ENTERING MEDICARE:

For beneficiaries who received a PAP device prior to enrollment in HNE's Medicare Advantage (MA) plan, and are seeking coverage of either a replacement PAP device and/or accessories, both of the following coverage requirements must be met:

- Sleep test – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks a replacement PAP device and/or accessories, and,
- 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 the beneficiary has a diagnosis of obstructive sleep apnea and that the beneficiary continues to use the PAP device.

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

ACCESSORIES:

Accessories used with a PAP device are covered when the coverage criteria for the device are met. If the coverage criteria are not met, the accessories will be denied as not medically necessary.

The following table represents the usual maximum amount of accessories expected to be medically necessary:

A4604	- 1 per 3 months
A7027	- 1 per 3 months
A7028	- 2 per 1 month
A7029	- 2 per 1 month
A7030	- 1 per 3 months
A7031	- 1 per 1 month
A7032	- 2 per 1 month
A7033	- 2 per 1 month
A7034	- 1 per 3 months
A7035	- 1 per 6 months

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A7036 - 1 per 6 months
A7037 - 1 per 3 months
A7038 - 2 per 1 month
A7039 - 1 per 6 months
A7046 - 1 per 6 months

Quantities of supplies greater than those described in the policy as the usual maximum amounts will be denied as not medically necessary.

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating physician for use with a covered PAP (E0470 or E0601) device.

REFERENCE:

LCD for Polysomnography and Sleep Studies (L26428): Centers for Medicare & Medicare Services

http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=26428&lcd_version=19&show=all

Last accessed 06/09/2009.

HAYES Medical Technology Directory™. Sleep Apnea Treatment, Devices. Lansdale PA: HAYES,

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