Clinical Review Criteria Related to Positive Airway Pressure (PAP) Devices

I. Criteria for Approval

A. BiAP requires Prior Authorization for all MHI lines of business through eviCore CPAP for Minuteman health does not require Prior authorization

B. Bi-level Positive Airway Pressure (BIPAP) Devices

1. 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.

2. 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.

3. If a CPAP device has been used for more than 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.

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

   a. 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:
     - An arterial blood gas $PaCO_2$, done while awake and breathing the member's usual FIO_2 (fractional inspired oxygen concentration), is greater than or equal to 45 mmHg, or
     - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing the member's usual FIO_2, or

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- For progressive neuromuscular disease only, maximal inspiratory pressures less than 60 cm H_20 or forced vital capacity (FVC) less than 50% predicted.

b. 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:
  - An arterial blood gas $PaCO_2$, done while awake and breathing the member's usual FIO_2, is greater than or equal to 55 mmHg, or
  - An arterial blood gas $PaCO_2$ of 50 to 54 mmHg and either of the following:
    - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least 5 continuous minutes, done while breathing oxygen at 2 liters per minute (LPM) or the member's usual FIO_2, 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.

c. 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 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 FIO_2, 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 FIO_2.

C. 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.

D. 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. 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.

E. 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:

1. current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM), or

2. current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS), or

3. 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

4. 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).

F. **Prior authorization is required for all lines of business for Pressure Support Ventilator** (PSV) which is a form of noninvasive ventilation (NIV) and also requires prior approval. NIV occurs when a ventilator-generated breath is delivered to member's upper respiratory track by mask or mouthpiece. This device is generally covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure associated with chronic obstructive pulmonary disease. These devices are not used to treat sleep apnea unless the member has a qualifying condition listed.

ICD-9 Codes and Description

327.23 Obstructive Sleep Apnea (adult, pediatric)

HCPCS Code & Description

E0601 CPAP
E0470 BiPAP
E0465 Pressure support ventilator with volume control mode, may include pressure control mode, used with non-invasive interface (e.g., mask).

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E0466 Pressure support ventilator with volume control mode, may include pressure control mode, used with non-invasive interface (trach)

REFERENCES

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

LCD for Polysomnography and Sleep Studies (L26428): Centers for Medicare & Medicaid Services (Last Accessed 9/4/15, 02/19/16)

Hayes Medical Technology Directory™. Sleep Apnea Treatment, Devices. Lansdale PA: Hayes, Inc. © Winifred S. Hayes, Inc. Reviewed March 2005. Archived 2006 (Last Accessed 9/4/15, 02/19/16)

LCD for Positive Airway Pressure (PAP) Devices for Treatment of Obstructive Apnea (L11528) Feb 2008: Centers for Medicare & Medicaid Services (Last Accessed 9/4/15, 02/19/16)

Manuel Tejada; Jesus Hector Boix; Faustino Alvarez; Reyes Balanza; Maria Morales; Chest Journal 1997;111(5)1322-1325.doi:101378/chest Comparisonof Pressure support Ventialtion and Assist-control Ventilation in the Treatment of Respiratory Failure