## 18.2.1.7 Ventilator Assist Devices

### Bi-level Positive Airway Pressure

The following policy guidelines apply to all ventilator assist devices:

1. All equipment needs, including emergency equipment, must be prior authorized. The PAU will act on emergency requests and give a decision within two working days. If not an emergency, the PAU will act on written requests and give a decision within 25 days. Unless the physician can clearly justify purchase of the equipment, a rental trial period of up to three months can be requested to have an adequate trial period to document appropriateness;

2. Other equipment, such as low pressure alarms, must be separately documented to show medical necessity. Low pressure alarms will be approved for beneficiaries who are ventilator dependent or at risk for a life threatening event. Pulse oximetry, due to its technology limitations, is not reimbursable for home use;

3. These guidelines exist to assist the physician and the fiscal intermediary to efficiently approve most applications but allow physicians to request consideration for beneficiaries which for unique reasons fall outside criteria. All medical providers are expected to preserve pertinent information which may periodically be surveyed to evaluate these criteria in the future;

4. Non-disposable, reusable supplies should be prescribed, if appropriate, for medical care and economical reasons. Periodic exacerbations may increase supply needs, therefore, an extra prescription should be written. The prescription should be written out "As needed" and **not** by using the acronym "prn" so it can be used anytime during a several month span; and

5. The use of oxygen must be considered for those beneficiaries where these devices fail to adequately improve the beneficiary's condition. There must be documentation of satisfactory clinical improvement such that mechanical ventilation through a tracheotomy tube is justifiably avoided.

## Continuous Positive Airway Pressure

A continuous positive airway pressure (CPAP) machine is used to treat beneficiaries who have moderate to severe obstructive sleep apnea.

A respiratory cycle is defined as an inspiration, followed by expiration. Polysomnography is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electrooculogram (EOG), and a submental electromyogram (EMG).

Polysomnography must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.
Apnea is defined as the cessation of airflow for at least 10 seconds documented on a polysomnogram.

Hypopnea is defined as an abnormal respiratory event lasting at least 20 seconds associated with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent decrease in oxygen saturation.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of two hours of sleep without the use of a positive airway pressure device, reported by Polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected).

## Criteria for Adults

A single level CPAP device is covered if the beneficiary has a diagnosis of obstructive sleep apnea (OSA), documented by an attended facility-based polysomnogram and meets either of the following criteria:

1. The AHI is greater than or equal to 15 events per hour; or

2. The AHI is from 5 to 14 events per hour with documented symptoms of:

    a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or

b. Hypertension, ischemic heart disease, or history of stroke.

For the purpose of this policy, polysomnographic studies must be performed in a facility based sleep study laboratory and not in the home or in a mobile facility. These labs must be qualified providers of Medicare or Medicaid services and comply with all applicable state regulatory requirements.

For the purpose of this policy, polysomnographic studies may not be performed by a DME provider.

## Pediatric Criteria (Under 21 years of Age)

A single level CPAP device is covered if the beneficiary has a diagnosis of OSA documented by an attended, facility-based polysomnogram and there is:

1. Documentation of physical exam (including airway) and of any other medical condition, which may be correctable (e.g., tonsillectomy and/or adenoidectomy) prior to the institution of assisted ventilation;

2. Documentation of how sleep disturbance reduces the quality of life and affects the activities of daily living;

3. Prescription by a physician with training and expertise in pediatric respiratory sleep disorders;

4. Documentation of the medical diagnosis, which is known to cause respiratory/sleep disorders;

5. Sleep or respiratory study documenting two or more of the following:

   a. Oxygen saturation of less than 90 percent pulse oximetry or partial pressure of transcutaneous or arterial of less than 60mm. Hg.;

   b. Carbon dioxide greater than 55 mm. Hg. Bye end tidal, transcutaneous, arterial, or capillary blood measurement; and

   c. Apnea of 10 to 20 seconds duration on the average of one per hour.

6. A follow up plan should be submitted identifying the responsible physician or facility, giving data collected to demonstrate the success or failure of intervention,

and showing a visit within the first month of use and a second assessment within the first three months of use;

7. Indication of a responsible, committed home environment and of caregivers properly trained in appropriate respiratory care; and

8. A written plan for home health follow up care.

## Humidifiers

Humidifiers are covered if CPAP, bi-level positive airway pressure (BIPAP), or oxygen therapy has been prescribed for use in connection with medically necessary DME for purposes of moisturizing the oxygen. Humidifiers are used to prevent dry mouth, stuffy, congested, or runny nose and dry, burning, itching, or bleeding nose.

Heated and non-heated humidification for use with positive airway pressure system devices requires PA. Documentation of medical necessity including the diagnosis and expected outcome must be submitted with the request for PA. Non-heated humidifiers are sufficient for beneficiaries that did not have any particular problems with sinus or dryness prior to going on CPAP.

Non-heated humidifiers make a noticeable difference by allowing a beneficiary to sleep longer before awaking due to dryness or sleep through the entire night. They are usually smaller, lighter and less expensive than heaters. The process of evaporation lowers the temperature of the air reaching the beneficiary. Most beneficiaries using non-heated humidifiers without symptoms do not need to use it year around as they tend to get enough humidification whenever their home air conditioning or heater is not on. The effectiveness of a non-heated humidifier is related to its size. Larger non-heated humidifiers are more effective.

If beneficiaries dry out most nights on CPAP or have a history of sinus troubles prior to CPAP, they will benefit from a heated humidifier. Heated humidifiers can warm the air to whatever temperature the user is most comfortable. The warmer the air, the more moisture it carries. A heated humidifier delivers air of the temperature the beneficiary prefers in addition to humidification.