

VHA PROSTHETIC CLINICAL MANAGEMENT PROGRAM (PCMP)
CLINICAL PRACTICE RECOMMENDATIONS
POSITIVE AIRWAY PRESSURE THERAPY FOR SLEEP-RELATED
BREATHING DISORDERS (SRBD)

I. BACKGROUND

VHA's Prosthetic and Sensory Aids Service Strategic Healthcare Group was directed by the Under Secretary for Health to establish a Prosthetic Clinical Management Program (PCMP). The objectives are to coordinate the development of clinical practice recommendations for prosthetic prescription practices and contracting opportunities to assure technology uniformity and ease of access to prosthetic prescriptions and patient care that will lead to valid outcome measures and analysis for research purposes.

A work group, using input from selected clinicians with expertise in sleep-related disorders, convened to recommend a clinical practice recommendation on prescribing veteran beneficiaries with Positive Airway Pressure (PAP) therapy to treat sleep-related breathing disorders.

PAP is a preferred treatment for sleep-related breathing disorders. Devices with fan-generated flow provide positive pressure delivered with a nasal mask, nasal pillows, or full-face mask. This PAP, when properly adjusted, helps maintain airway patency and improves breathing during sleep.

PAP devices come in three general forms, those that provide continuous positive airway pressure (CPAP), bi-level positive airway pressure (Bi-level PAP), and automatically self-adjusting airway pressure (APAP).

II. POLICY

The purpose of the clinical practice recommendations is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective prescribing.

III. DEFINITIONS

To avoid confusion, terminology used in this document is defined below. Sleep-related breathing disorders involve the repetitive occurrence of pathological breathing-related events during sleep. Five pivotal types of sleep-related breathing disorder events are considered here: sleep apneas, sleep hypopneas, episodes of increased airway resistance, desaturation events, and hypopneas associated with desaturation events.

Sleep apnea episode is defined as the cessation or near cessation of airflow for 10 seconds or more in an adult.

Sleep hypopnea is a reduction (usually 30% or more) in airflow. Both sleep apnea and hypopnea episodes may, but do not necessarily, produce desaturation events.

Desaturation events are transient 4% or greater decreases in arterial oxygen saturation.

Desaturating hypopneas are hypopnea events accompanied by 4% or greater declines in SaO₂.

Airway resistance events involve increased respiratory effort, increased esophageal pressure, snoring, and sometimes marked by visibly asynchronous movement of the chest wall and abdomen (paradoxical breathing). In contrast to apnea and hypopnea episodes, airway resistance episodes are not associated with obvious changes in tidal volume or desaturation events. However, these events can produce central nervous system arousals and sleep fragmentation. These sleep-related breathing disorder events are summarized using the following indices:

- Apnea index (AI) is the number of apnea episodes per hour of sleep.
- Apnea+hypopnea index (AHI) is the combined number of apnea and hypopnea episodes per hour of sleep.
- Apnea+Desaturating hypopnea index (ADI) is the combined number of apnea and only hypopneas with desaturations of 4% or more per hour of sleep. Note: ADI is calculated so that the clinician can determine if a patient meets the April 2002 Medicare criteria and it will provide a basis of comparison with these recommendations.
- Respiratory arousal index (RAI) is the number of central nervous system arousals associated with sleep-related breathing disorder events per hour of sleep.
- Sleepiness can be determined by standardized techniques (i.e., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Multiple Sleep Latency Test, and Maintenance of Wakefulness Test). However, sleepiness is largely a subjective symptom that in some cases is difficult to measure. A clinician may judge a patient as sleepy even though standard measures indicate normal alertness. In such cases, justification for such a conclusion should be documented and other symptoms that mimic sleepiness (e.g., fatigue) should be excluded.
- Sleep-related breathing disorder-related sleepiness is when the sleepiness is judged to primarily derive from sleep-related breathing disorder and not from another cause. The clinician should clinically rule-out narcolepsy; post-traumatic hypersomnia, drug-related hypersomnia, withdrawal-related hypersomnia, hypersomnia secondary to medical, neurological, or psychiatric conditions, insufficient sleep, inadequate sleep hygiene, or idiopathic hypersomnia as the principle cause of the sleepiness.

IV. CLINICAL PRACTICE RECOMMENDATIONS/MEDICAL CRITERIA

A. Diagnosis

Diagnostic criteria for prescribing PAP therapy is usually based on sleep evaluations using attended, standardized polysomnography. Standardized polysomnography includes sleep staging and four or more additional recording channels. Under special circumstances, a more limited recording montage may be used in which sleep staging and airflow, respiratory effort, and SaO₂ are recorded. In certain circumstances, cardiopulmonary sleep evaluations without sleep staging may be used if they include measures of airflow, respiratory effort, electrocardiogram (or heart rate) and SaO₂.

Option 1: Criteria when using a full night evaluation

PAP therapy during sleep is indicated for patients meeting one or more of the following criteria:

- Any patient with AI greater than 20 events per hour of sleep.
- Any patient with AHI greater than 30 events per hour of sleep.
- A sleepy patient with an AHI greater than 10 events per hour of sleep.
- A sleepy patient with an RAI greater than 10 events per hour of sleep.
- On an individual basis, a sleepy patient without other obvious cause and an RAI equal to or greater than 5 but less than 10 may be considered for PAP as one of several options including weight loss, dental appliance and positional therapy. This is especially the case if there are prominent desaturation events.

Option 2: Criteria when using a split-night diagnostic-titration evaluation

PAP therapy during sleep is indicated for patients meeting one or more of the following criteria:

- A patient with AHI greater than 40 events per hour of sleep during a two or more hour baseline portion of the sleep evaluation.
- Any patient with AHI ranging from 20 to 40 events per hour of sleep as warranted by clinical judgment (e.g., cases where the patient is sleepy or has chronic heart disease, neuromuscular disease, or hypertension).

Option 3: Criteria using a sleep evaluation with a limited recording montage

PAP therapy is indicated for patients who cannot be assessed with standard polysomnography because the sleep laboratory does not have adequate equipment. In such circumstances, obtaining appropriate equipment should be a priority but in the meantime, the limited montage (sleep staging channels, airflow, respiratory effort, and SaO₂) is acceptable. Diagnostic criteria are the same as for Option 1.

Option 4: Criteria using a sleep evaluation with a cardiopulmonary recorder

Cardiopulmonary studies, especially if they are unattended, are not recommended for routine assessment of sleep-related breathing disorders when expeditious polysomnography is available, or in mildly symptomatic or asymptomatic patients.

- REM sleep does not always occur during the interval that appears to contain the best pressure. Some situations in which this can arise include medication-related REM-suppression, the patient not having any REM sleep during the sleep evaluation, there not being enough time for REM to recur late in the night, and satiation of REM sleep drive due to rebound earlier in the study. In such cases, it becomes a matter of clinical judgment whether the titration is adequate or not. The clinician should document the basis or reasoning for deciding if a titration is adequate in such cases. The patient should be closely followed clinically with a re-evaluation, if needed.
- An unacceptable titration is one that fails to meet even minimal adequate titration criteria. The patient should be re-evaluated or other treatment options should be applied. Sometimes an estimated PAP level can be based on a clear-cut and substantial reduction in sleep-related breathing disorder events. If an estimate is made, there should be close follow-up with a re-titration if symptoms are not resolved, including but not limited to snoring, daytime somnolence and observed apneas during sleep.
- *Special cases*
 - In cases where diagnosis is met by the patient having an elevated RAI, an acceptable titration must reduce RAI according to the above criteria.
 - If an unattended autotitrating PAP is used, the patient must be instructed prior to use of the PAP machine and a mask or nasal pillow must be fitted, including if necessary, a chinstrap. A health care provider that is knowledgeable in the use of such PAP devices must order the titration and a follow-up overnight sleep study must be performed with the PAP machine being used if symptoms on follow-up are not resolved. If an acceptable response to PAP is not achieved, a full overnight PAP titration must be performed.

C. Patient Acceptance

The minimum criteria for patient acceptance for PAP are:

- The patient is able to sleep while on the PAP.
- A post-titration interview or questionnaire indicates that:
 - the patient is willing to use the therapy as prescribed or
 - the patient thinks that he/she has benefited from the therapy or
 - the patient thinks that he/she can use PAP nightly.

D. Prescription

The following criteria must be met for prescribing PAP:

- Patients are properly diagnosed with clinically significant sleep-related breathing disorders.
- Patients have an adequate or better PAP titration.
- Patients meet minimal criteria for PAP acceptance.

E. Follow-up

- *Initial follow-up (Post-polysomnography Follow-up)*
 - Before prescription, the patient should have the results of their sleep evaluation explained, the seriousness of their condition reviewed, and treatment options discussed.
 - If PAP therapy is prescribed, patients must be educated about machine operation; machine care; maintenance, filter replacement; mask fitting; mask and tubing care and cleaning, and proper utilization practices.
 - Measures recorded include: verification that results, seriousness, and treatment options were reviewed; pre-treatment Epworth Sleepiness Scale total score; rating of patient's self-assessed benefit from the therapy; and rating of patient's self-assessed ability to use the therapy nightly.
- *Intermediate Follow-up (PAP Utilization and Troubleshooting)*
 - A clinician with training in sleep medicine should provide follow-up of diagnosed sleep-related breathing disorder. A clinical support specialist with training in sleep medicine should provide equipment-related training and support with specific training in sleep-related treatment and devices.
 - It is relatively easy and inexpensive to train local personnel to serve as clinical support specialists to provide technical support for PAP therapy. Personnel appropriate for this training include respiratory care practitioners, polysomnographic technologists, physician assistants, and clinical sleep specialists. This clinical support specialist may be referred to as a *CPAP Therapist*. Whatever the initial background or credential, the CPAP Therapist must be trained and skilled in effectively introducing, training, fitting, adjusting, and troubleshooting equipment used to treat sleep-related breathing disorders. This is needed to provide local equipment support for patients.
 - Problems with PAP mask fit, nasal congestion or dryness, and other potential side effects should be monitored, documented and addressed. Utilization should be determined and documented. Remedial training and additional

follow-up appointments are needed if the patient is using PAP therapy less than 4 hours per night and less than 5 nights per week. By contrast, if a patient is doing well and is using PAP therapy regularly, they can be followed thereafter yearly, or as needed.

- *Longer Term Follow-up*

- Patients should be followed yearly. They should be monitored for recurrence of symptoms, particularly sleepiness, snoring, nocturnal awakenings with gasping or choking, and witnessed cessation of breathing. Nasal congestion, mask fit, and utilization should be checked.
- Clinical judgment should be used to determine if pressure changes are needed or a re-evaluation/re-titration is needed.

