

# Practice Parameters for the Use of Continuous and Bilevel Positive Airway Pressure Devices to Treat Adult Patients With Sleep-Related Breathing Disorders

An American Academy of Sleep Medicine Report

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**Summary:** Positive airway pressure (PAP) devices are used to treat patients with sleep related breathing disorders (SRBD) including obstructive sleep apnea (OSA). Currently, PAP devices come in three forms: (1) continuous positive airway pressure (CPAP), (2) bilevel positive airway pressure (BPAP), and (3) automatic self-adjusting positive airway pressure (APAP). After a patient is diagnosed with OSA, the current standard of practice involves performing full, attended polysomnography during which positive pressure is adjusted to determine optimal pressure for maintaining airway patency. This titration is used to find a fixed single pressure for subsequent nightly usage. A task force of the Standards of Practice Committee of the American Academy of Sleep Medicine reviewed the available literature. Based on this review, the Standards of Practice Committee developed these practice parameters as a guideline for using CPAP and BPAP appropriately (an earlier review and practice parameters for APAP was published in 2002). Major conclusions and current recommendations are as follows: 1) A diagnosis of OSA must be established by an acceptable method. 2) CPAP is effective for treating OSA. 3) Full-night, attended studies performed in the laboratory are the preferred approach for titration to determine optimal pressure; however, split-night, diagnostic-titration

studies are usually adequate. 4) CPAP usage should be monitored objectively to help assure utilization. 5) Initial CPAP follow-up is recommended during the first few weeks to establish utilization pattern and provide remediation if needed. 6) Longer-term follow-up is recommended yearly or as needed to address mask, machine, or usage problems. 7) Heated humidification and a systematic educational program are recommended to improve CPAP utilization. 8) Some functional outcomes such as subjective sleepiness improve with positive pressure treatment in patients with OSA. 9) CPAP and BPAP therapy are safe; side effects and adverse events are mainly minor and reversible. 10) BPAP may be useful in treating some forms of restrictive lung disease or hypoventilation syndromes associated with hypercapnia.

**Keywords:** Sleep related breathing disorder; obstructive sleep apnea; continuous positive airway pressure; CPAP; sleep-disordered breathing; bilevel positive airway pressure; BPAP

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## 1.0 INTRODUCTION

OBSTRUCTIVE SLEEP APNEA (OSA) AFFLICTS AT LEAST 2% - 4% OF THE ADULT POPULATION. THIS SLEEP RELATED BREATHING DISORDER IS CHARACTERIZED by full or partial occlusion of the upper airway during sleep. The resulting occlusions restrict airflow and can produce repeated oxyhemoglobin desaturations, sleep fragmentation, or both. Con-

tinuous positive airway pressure (CPAP) is a standard treatment for patients with OSA. Standard practice involves pressure adjustment during attended laboratory polysomnography to eliminate obstructive respiratory-related events (apneas, hypopneas, oxygen desaturations, snoring, respiratory effort related arousals [RERAs]).

In 1981, Sullivan and colleagues provided the first description of positive airway pressure for treating OSA. Pressurized airflow is generated with fan-driven or turbine systems, adjustable by varying valve diameter or turbine speed. Initially, machines were large, heavy, and noisy, but have evolved to small, lightweight, almost silent units. Airflow is most often delivered using a nasal mask held snug to the face with straps, leaf springs, adjustable caps, or other headgear. Nasal pillows or full-face masks are sometimes used if nasal masks are a problem for the patient. Competition to improve mask comfort has produced a wide assortment of delivery systems from which patients can select and this has contributed greatly to clinical care.

CPAP has quickly become the standard of care for treating moderate to severe OSA. Imaging studies verified that CPAP provides pneumatic splinting of the upper airway by passive distension. Lung volume changes have also been noted. In current therapeutics, positive airway pressure is not just used in moderate to severe OSA, but also is widely used for mild OSA, upper airway resistance syndrome, and snoring. However, CPAP and BPAP can only be therapeutically effective if they are used. Acceptance and utilization are the major clinical challenges for successful positive airway pressure therapeutics.

The American Academy of Sleep Medicine (AASM) has previously published practice parameters for the diagnosis of OSA<sup>1,2</sup> and the recommendations here do not modify those guidelines. The AASM also has previously published practice parameters on the determination of CPAP pressure for the treatment of airway obstruction in OSA.<sup>1,2</sup> The present recommendations add to these previously published guidelines.

## 2.0 METHODS

The Standards of Practice Committee (SPC) of the AASM reviewed the accompanying review and cited literature to develop

**Table 1—AASM Classification of Evidence**

Evidence Levels	Study Design
I	Randomized well-designed trials with low alpha and beta error*
II	Randomized trials with high alpha and beta error*
III	Nonrandomized concurrently controlled studies
IV	Nonrandomized historically controlled studies
V	Case series

Adapted from Sackett<sup>3</sup>

\*Alpha error refers to the probability (generally set at 95% or greater) that a significant outcome (e.g.,  $p < 0.05$ ) is not a result of chance occurrence. Beta error refers to the probability (generally set at 80% to 90% or greater) that a nonsignificant result (e.g.,  $p > 0.05$ ) is the correct conclusion of the study or studies. The estimation of beta error is generally the result of a power analysis. The power analysis includes a sample size analysis to project the size of the study population necessary to ensure that significant differences will be observed if actually present.

the recommendations included in this paper. These recommendations pertain to adults and in most cases are based on evidence published in peer-reviewed journals. However, where scientific data are absent, insufficient, or inconclusive, recommendations are based upon committee consensus. Finally, an outside review of these recommendations was performed and the AASM Board of Directors affirmed approval.

All members of the SPC and the Board of Directors completed detailed conflict-of-interest statements. Most participants in this process are directors or members of sleep disorders centers, and many have substantial experience with sleep study equipment. These guidelines should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the patient and the availability of diagnostic and treatment options and resources.

The AASM expects these guidelines to have a positive impact upon the practice of sleep medicine, patient treatment outcomes, and health care costs. These practice parameters reflect the state of knowledge at publication and will be reviewed, updated, and revised as new information becomes available.

A literature search was conducted for each question addressed in the accompanying review paper. The methodology for the literature search, review of the literature, and grading of the evidence are discussed in that paper. Articles were assigned an evidence level based on Table 1. In this practice parameter paper, recommendations are designated as standard, guideline, or option (Table 2).

## 3.0 BACKGROUND

Many positive airway pressure devices are commercially available. They may be equipped with humidifiers, gradual pressure onset (ramp) settings, apnea and hypopnea detection systems, mask leak detection systems, and usage monitors. For the purposes of the review and this parameter paper, two types of PAP devices (CPAP and BPAP) and specific PAP features (humidifiers and usage monitors) were reviewed. Data regarding usefulness of other PAP device types or device features were not reviewed.

The present practice parameters use the following terminology. Unless stated otherwise OSA is used synonymously with ob-

**Table 2—AASM Levels of Recommendations**

Term	Definition
Standard	This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.
Guideline	This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.
Option	This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

Adapted from Eddy<sup>4</sup>

structive sleep apnea syndrome (OSAS), obstructive sleep apnea-hypopnea syndrome (OSAHS), and obstructive forms of either sleep-disordered breathing (SDB) or sleep related breathing disorder (SRBD). As in the companion review paper, other SRBDs are not addressed except when relevant to BPAP treatment. The respiratory disturbance index (RDI) is used synonymously with the apnea-hypopnea index (AHI) unless stated otherwise. Mild, moderate and severe OSA are defined according to criteria used in the accompanying review paper: Mild,  $5 \leq \text{RDI} \leq 15$ ; Moderate,  $15 \leq \text{RDI} \leq 30$ ; Severe,  $\text{RDI} > 30$  episodes per hour of sleep.<sup>5</sup>

#### 4.0 RECOMMENDATIONS

The following are recommendations of the Standards of Practice Committee and the Board of Directors of the American Academy of Sleep Medicine.

##### 4.1.1 Treatment with CPAP must be based on a prior diagnosis of OSA established using an acceptable method (Standard).

This recommendation is based on previous AASM practice parameters for the indications for polysomnography and related procedures (2005 update).<sup>1,2</sup>

##### 4.1.2 CPAP is indicated for the treatment of moderate to severe OSA (Standard).

This recommendation is based on 24 randomized controlled trials meeting Level I or II evidence-based medicine criteria [3.1.7].<sup>6-29</sup> Control procedures include sham-CPAP, placebo tablets, conservative management, and positional therapy. Eight studies were intention-to-treat designs.<sup>6,7,14,15,26-29</sup> Only 1 study had a power analysis<sup>18</sup> and most studies were not truly double blind. Most studies evaluated multiple outcomes and some trials had negative results. Nonetheless, all 8 studies testing whether CPAP significantly reduced sleep related respiratory events compared to a control procedure had positive outcomes.<sup>8-10,17,19,23,28,29</sup>

##### 4.1.3 CPAP is recommended for the treatment of mild OSA (Option).

This recommendation as an option is based on mixed results in 2 Level I<sup>30,31</sup> and 3 Level II<sup>32-34</sup> outcome studies in patients with mild OSA [3.1.7].

##### 4.1.4 CPAP is indicated for improving self-reported sleepiness in patients with OSA (Standard).

This recommendation is based on 10 randomized controlled trials<sup>6,9,13,15,16,18,24,25,33,35</sup> in which CPAP reduced sleepiness more than control procedures in patients with OSA [3.1.3]. The Epworth Sleepiness Scale was used in the vast majority of trials to assess subjective sleepiness.

##### 4.1.5 CPAP is recommended for improving quality of life in patients with OSA (Option).

This recommendation as an option is based on inconsistent results from 2 Level I studies<sup>18,35</sup> and 4 Level II studies<sup>12,15,33,34</sup> with placebo control, and 1 Level II study<sup>6</sup> with conservative therapy as the control [3.1.5].

##### 4.1.6 CPAP is recommended as an adjunctive therapy to lower blood pressure in hypertensive patients with OSA (Option).

This recommendation as an option is based on 9 clinical trials,<sup>7,9-11,15,26,30,32,35</sup> 6 of which did not find changes in mean arterial pressure compared to placebo<sup>7,10,11,15,32,35</sup> [3.1.6]. Currently, the results are inconsistent and variably conclusive.

##### 4.2.1 Full-night, attended polysomnography performed in the laboratory is the preferred approach for titration to determine optimal positive airway pressure; however, split-night, diagnostic-titration studies are usually adequate (Guideline).

This recommendation is based on 1 Level II and 6 Level IV studies<sup>36-42</sup> [4.1.1, 4.1.2].

##### 4.3.1 CPAP Usage should be objectively monitored to help assure utilization (Standard).

This recommendation is based on overwhelming evidence at all levels indicating patients with OSA overestimate their positive airway pressure utilization. Level I<sup>9,12,32,36,43,44</sup> and Level II<sup>33,38,45-49</sup> studies indicate that objectively-measured nightly CPAP “time on” ranges from 3.5 hrs/night in minimally symptomatic new patients to 7.1 hrs/night in established users [5.1.2].

##### 4.3.2 Close follow-up for PAP usage and problems in patients with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed. This is especially important during the first few weeks of PAP use (Standard).

This recommendation is based on 61 studies that examined management paradigms and collected acceptance, utilization, and adverse events; 17 of these studies qualified as Level I<sup>9,12,13,18,19,30,31,34,50-58</sup> [5.1.2, 5.1.3]. These studies found that PAP therapy adherence is established within the first few months of use. It was also found that adjustment of the mask or treatment of nasal conditions was important to assure utilization because the literature indicates that untreated side effects can lead to discontinuation of treatment<sup>31,47,50,51,54,55,57,59-75</sup> [5.1.3].

##### 4.3.3 The addition of heated humidification is indicated to improve CPAP utilization (Standard).

This recommendation is based on 3 Level I studies<sup>54,55,57</sup> [5.1.3]. There was 1 Level II study that did not find increased utilization with heated humidification. Three additional studies<sup>68,74,76</sup> favored heated humidification over unheated or non-humidified CPAP.

##### 4.3.4 The addition of a systematic educational program is indicated to improve PAP utilization (Standard).

This recommendation is based on 4 Level I studies<sup>51,52,77,78</sup>, 1 Level II study,<sup>79</sup> and 1 Level III study<sup>80</sup> [5.1.2, 5.1.3]. All but 1<sup>52</sup> of these studies found increased intensity of patient education or frequency of health provider contact improved utilization.

##### 4.4.1 After initial CPAP setup, long-term follow-up for CPAP-treated patients with OSA by appropriately trained health care providers is indicated yearly and as needed to troubleshoot PAP mask, machine, or usage problems (Option).

This recommendation as an option is based on task force and SPC member consensus. There is little or no published data addressing this issue.

#### **4.4.2 CPAP and BPAP therapy are safe; side effects and adverse events are mainly minor and reversible (Standard).**

This recommendation is based on more than 23 published reports<sup>31,47,50,51,54,55,57,60-75</sup> that reported information on side effects and adverse events [5.1.3, 6.1.2]. While sinusitis, mask leaks, and dermatitis are not infrequent, tinnitus and dyspnea occur more rarely. A listing of adverse events associated with PAP therapy is presented in Table 3 of the accompanying review paper.

#### **4.5.1 While the literature mainly supports CPAP therapy, BPAP is an optional therapy in some cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present (Guideline).**

This recommendation is based on 2 Level I studies<sup>81,82</sup> which yielded no evidence that BPAP improves efficacy or adherence in the management of OSA compared to CPAP [7.2.2]. APAP is also a treatment option; however, this was not incorporated in the accompanying review paper since an earlier review and practice parameters for APAP was published in 2002.<sup>83</sup>

#### **4.5.2 BPAP may be useful in treating some forms of restrictive lung disease or hypoventilation syndromes associated with daytime hypercapnia (Option).**

This recommendation as an option is based on 11 studies all graded at Level III or better<sup>84-94</sup> that overall found improvement associated with BPAP therapy [7.3.3].

### **5.0 FUTURE RESEARCH**

Additional work is needed with respect to the following:

1. The differential effects of PAP on varied outcomes in patients with mild, moderate, and severe OSA needs further study, and this stratification should also be performed among older people.
2. The effect of PAP on cognition, mood, and objectively assessed sleepiness needs to be studied in trials with sufficient power to detect small but systematic changes, if they exist. In addition, use of validated assessment tools and more research comparing treatment modalities in both the short and longer term are needed. Restriction to more standardized and previously verified assessment tools is most desirable.
3. The effect of PAP on hypertension needs more systematic and complete evaluation.
4. Outcome studies of PAP interventions based on clinical criteria as well as empirical treatment may be worthwhile.
5. Controlled studies on the effects of CPAP on micro-architectural sleep parameters (e.g., arousal index, cyclic alternating pattern, delta power) in patients with OSA are needed.
6. Finally, health services delivery studies that develop and test educational programs, intervention paradigms, and remediation algorithms are sorely needed.

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