Practice Parameters for the Use of Nasal EPAP in the Treatment of Obstructive Sleep Apnea in Adult Patients

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1.0 Introduction

Nasal Expiratory Positive Airway Pressure (EPAP) [Provent® Therapy] is a novel device for the treatment of obstructive sleep apnea (OSA). The effectiveness of nasal EPAP has been validated through multiple clinical trials demonstrating statistically significant and clinically meaningful reductions in apnea-hypopnea index, oxygen desaturation and daytime sleepiness.[1,2,3,4,5]

This document is intended to provide prescribing physicians with suggested guidelines for patient selection, acclimation support and efficacy verification when using nasal EPAP for the treatment of OSA.

It is recommended that new prescribers of nasal EPAP follow these guidelines to systematically capture and analyze data from a minimum of 10 patients to help document nasal EPAP effectiveness within their practice.

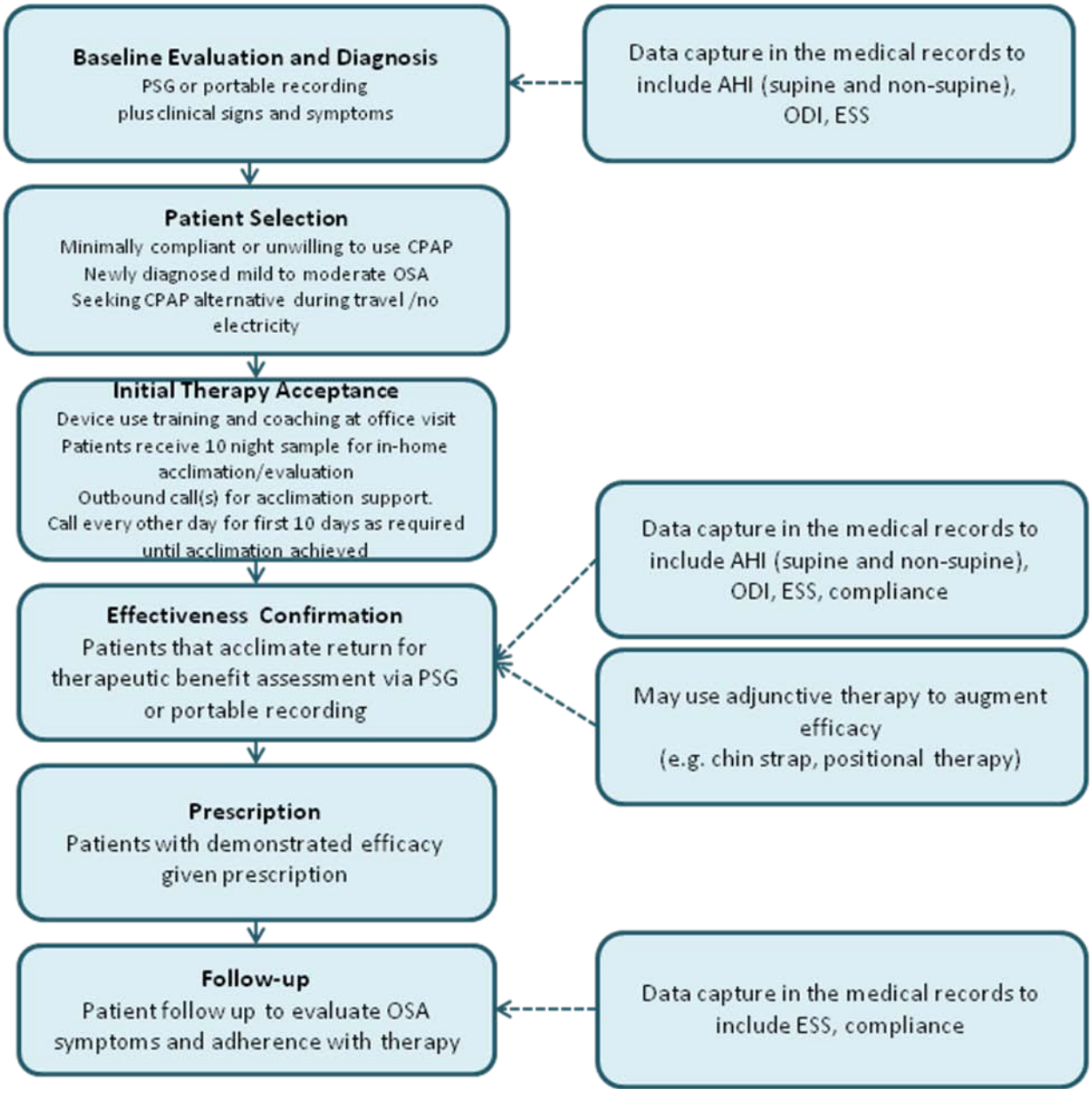
2.0 Methods

The practice parameters outlined below are based on published nasal EPAP clinical literature and best practices from high volume physician prescribers of nasal EPAP therapy in the United States.

While these parameters outline a recommended clinical practice protocol for nasal EPAP, the physician is best suited to determine how and whom to prescribe EPAP, given individual patient history, symptoms and expected follow up care.

Figure 1 summarizes a suggested pathway for patients under consideration for treatment with nasal EPAP therapy. More detailed recommendations are provided in Section 3.0.

Figure 1. Suggested Nasal EPAP Practice Parameters



3.0 Recommendations

3.1 Diagnosis and Baseline Evaluation

Newly diagnosed patients or those with a prior OSA diagnosis (within the past 12 months) may be considered for this protocol. The Berlin Questionnaire (Appendix A) may be useful as a screening tool to identify patients at risk for sleep apnea.[6]

Either in-laboratory polysomnography (PSG)[7] or portable recording[8] are recommended to confirm the diagnosis of OSA[9]. Both modalities provide objective results (AHI, ODI) that can be compared to results following the initiation of nasal EPAP treatment. Use of in-laboratory PSG or portable recording is of particular importance when a foundational data set is being established to support nasal EPAP as a new OSA therapeutic option within a clinical practice.

The following data should be collected at baseline:

- Apnea Hypopnea Index (supine and non-supine)
- Oxygen Desaturation Index
- Epworth Sleepiness Scale (ESS)

Sample ESS data collection forms are provided in Appendix B and a sample data collection spreadsheet is provided as Appendix C.

3.2 Patient Selection

Provent Therapy is indicated for the treatment of obstructive sleep apnea (OSA). The Provent instructions for use (IFU) should be consulted for a complete list of contraindications, warnings, precautions and possible adverse events (reference the current IFU supplied with the product).

Physicians in clinical practice have prescribed nasal EPAP to the following patients:

- Those who have refused CPAP or have tried CPAP and given up
- Those who are using CPAP, but not all night, every night
- Patients newly diagnosed with mild to moderate OSA
- Patients who use CPAP but need an alternative therapy for occasional travel or when electricity is not available

At this time, there is no data to predict which patients will be most effectively treated with nasal EPAP based on specific patient characteristics.

3.3 Initial Therapy Acceptance

A ten night trial of nasal EPAP in the home is recommended to evaluate the patient's initial ability to acclimate to the therapy. Prior to use, a trained practitioner or designee should instruct and allow each patient to apply the nasal EPAP devices. A patient education brochure can be used to guide this training discussion (reference LBL0227-01). It is also essential to ensure that patients have realistic expectations regarding the possible initial discomfort of nasal expiratory resistance and be informed that it may take up to one week or longer to acclimate to the therapy. Outbound calls to patients should be made every other day during the first 10 day trial of nasal EPAP until acclimation is achieved.

3.4 Effectiveness Confirmation

Patients that are able to acclimate to nasal EPAP during the 10 night trial period should undergo an assessment of effectiveness to ensure a satisfactory therapeutic benefit. It is suggested that the same methodology used for OSA diagnosis be used for effectiveness verification. As noted in section 3.1, these verification methods include in-lab PSG or portable recording to obtain objective results. The same variables evaluated at baseline should be evaluated again for comparison [AHI (supine and non-supine), ODI, ESS].

Anecdotal evidence from practicing physicians suggests that adjunctive therapy such as the use of positional therapy or chin straps may augment effectiveness of nasal EPAP.

3.4 Prescription and Device Use

Patients with demonstrated efficacy may be given a prescription for nasal EPAP by a licensed health care practitioner. Nasal EPAP devices are intended for a single night of use and should be discarded after wearing. Patients may use nasal EPAP as first line therapy or some may opt to continue with CPAP as a primary therapy and use nasal EPAP for travel or when there is no electricity available.

3.5 Follow-up

Patients should be scheduled for periodic follow-up office visits to assess patient compliance with nasal EPAP as well as to evaluate signs and symptoms of OSA. In particular, the physician should ask about device use (compliance) and use ESS to evaluate daytime sleepiness.

3.6 Other Considerations

Patients that fall outside of the selection criteria above, including patients who may refuse to undergo diagnostic testing (and are at high risk for OSA) or who may refuse follow-up consultation, may be considered for empiric evaluation with nasal EPAP because they are unlikely to otherwise be diagnosed or accept alternative therapies.

4.0 Conclusions

These guidelines were developed based on the current nasal EPAP clinical literature and with feedback from practicing physicians in the United States with significant clinical practice experience with nasal EPAP. Patient selection and effectiveness assessment with nasal EPAP are ultimately at the discretion of the prescribing physician.

5.0 References

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7. Kushida CA, Littner MR, Morgenthaler TI, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. Sleep 2005:28(4):499-521

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Berlin Questionnaire (for sleep apnea)

Scoring Berlin questionnaire

Adapted from: Table 2 from Netzer, et al., 1999. (Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP. Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. Ann Intern Med. 1999 Oct 5;131(7):485-91).

The questionnaire consists of 3 categories related to the risk of having sleep apnea. Patients can be classified into High Risk or Low Risk based on their responses to the individual items and their overall scores in the symptom categories.

Categories and scoring:

Category 1: items 1, 2, 3, 4, 5.

Item 1: if '**Yes**', assign **1 point**
Item 2: if '**c**' or '**d**' is the response, assign **1 point**
Item 3: if '**a**' or '**b**' is the response, assign **1 point**
Item 4: if '**a**' is the response, assign **1 point**
Item 5: if '**a**' or '**b**' is the response, assign **2 points**

Add points. Category 1 is positive if the total score is 2 or more points

Category 2: items 6, 7, 8 (item 9 should be noted separately).
Item 6: if '**a**' or '**b**' is the response, assign **1 point**
Item 7: if '**a**' or '**b**' is the response, assign **1 point**
Item 8: if '**a**' is the response, assign **1 point**

Add points. Category 2 is positive if the total score is 2 or more points

Category 3 is positive if the answer to item 10 is 'Yes' OR if the BMI of the patient is greater than 30kg/m^2.

(BMI must be calculated. BMI is defined as weight (kg) divided by height (m) squared, i.e., kg/m^2).

High Risk: if there are 2 or more Categories where the score is positive

Low Risk: if there is only 1 or no Categories where the score is positive

Additional question: item 9 should be noted separately.

BERLIN QUESTIONNAIRE

Height (m) _____ Weight (kg)_____ Age_____ Male / Female

Please choose the correct response to each question.

CATEGORY 1

1. **Do you snore?**
   - ☐ a. Yes
   - ☐ b. No
   - ☐ c. Don't know

If you snore:

2. **Your snoring is:**
   - ☐ a. Slightly louder than breathing
   - ☐ b. As loud as talking
   - ☐ c. Louder than talking
   - ☐ d. Very loud – can be heard in adjacent rooms

3. **How often do you snore**
   - ☐ a. Nearly every day
   - ☐ b. 3-4 times a week
   - ☐ c. 1-2 times a week
   - ☐ d. 1-2 times a month
   - ☐ e. Never or nearly never

4. **Has your snoring ever bothered other people?**
   - ☐ a. Yes
   - ☐ b. No
   - ☐ c. Don't Know

5. **Has anyone noticed that you quit breathing during your sleep?**
   - ☐ a. Nearly every day
   - ☐ b. 3-4 times a week
   - ☐ c. 1-2 times a week
   - ☐ d. 1-2 times a month
   - ☐ e. Never or nearly never

CATEGORY 2

6. **How often do you feel tired or fatigued after your sleep?**
   - ☐ a. Nearly every day
   - ☐ b. 3-4 times a week
   - ☐ c. 1-2 times a week
   - ☐ d. 1-2 times a month
   - ☐ e. Never or nearly never

7. **During your waking time, do you feel tired, fatigued or not up to par?**
   - ☐ a. Nearly every day
   - ☐ b. 3-4 times a week
   - ☐ c. 1-2 times a week
   - ☐ d. 1-2 times a month
   - ☐ e. Never or nearly never

8. **Have you ever nodded off or fallen asleep while driving a vehicle?**
   - ☐ a. Yes
   - ☐ b. No

If yes:

9. **How often does this occur?**
   - ☐ a. Nearly every day
   - ☐ b. 3-4 times a week
   - ☐ c. 1-2 times a week
   - ☐ d. 1-2 times a month
   - ☐ e. Never or nearly never

CATEGORY 3

10. **Do you have high blood pressure?**
    - ☐ Yes
    - ☐ No
    - ☐ Don't know

BASELINE

Gender:	☐ Male ☐ Female
Age:	☐☐ years
BMI = <u>**weight in kilograms**</u> **height in meters^2**	☐☐.☐ kg/m^2
Prior OSA Treatment: (check all that apply)	☐ CPAP ☐ Surgery ☐ Oral Appliance ☐ Positional Therapy ☐ Other, please specify: _____ ☐ No prior treatment
Method Used to Diagnose OSA:	☐ Polysomnography ☐ Portable Monitor
Diagnostic AHI:	☐☐.☐ total ☐☐.☐ supine ☐☐.☐ non-supine
Diagnostic ODI:	☐☐.☐
Epworth Sleepiness Scale Score:	☐.☐
Date Provent Trial Pack Dispensed:	☐☐ / ☐☐ / ☐☐☐☐ DD MM YYYY
Outbound call(s) completed for patient acclimation support	☐ Yes ☐ No
Did patient acclimate to Provent during 10-day trial period?	☐ Yes (if yes, proceed to next page) ☐ No

EFFECTIVENESS CONFIRMATION

Method Used to Confirm Effectiveness of Provent:	☐ Polysomnography ☐ Portable Monitor
AHI:	☐☐.☐ total ☐☐.☐ supine ☐☐.☐ non-supine
ODI:	☐☐.☐
Epworth Sleepiness Scale Score:	☐.☐
Was Provent Therapy deemed effective?	☐ Yes ☐ No
Date Prescription Written:	☐☐ / ☐☐ / ☐☐☐☐ DD MM YYYY ☐ Not applicable
Patient will use Provent as:	☐ Primary OSA Treatment ☐ Secondary OSA Treatment (for occasional travel) ☐ Not applicable

FOLLOW-UP

FOLLOW-UP STATUS	☐ Visit could not be completed, patient is lost to follow-up ☐ Patient discontinued Provent ☐ Patient is still using Provent (if checked, complete following questions)
Please select one category that best describes the patient's frequency of Provent device use:	☐ Regular user: >5 nights per week ☐ Frequent user: 1-4 nights per week ☐ Occasional user: <3 nights per month
COMBINATION THERAPY **On the nights when the patient is using Provent, are any other therapies used in combination with Provent ?**	☐ No ☐ Yes If yes, check all that apply ☐ Positional Therapy (e.g., ball in back, pillow, sleep position) ☐ Oral Appliance ☐ Chin Strap ☐ Other, please specify: _____
Epworth Sleepiness Scale Score:	☐ . ☐

EPWORTH SLEEPINESS SCALE

☐ **Baseline** ☐ **Effectiveness Confirmation Visit** ☐ **Follow-up Visit**

Please answer all of the questions and use the scale below to choose the most appropriate number for each situation.

0 = No chance of dozing

1 = Slight chance of dozing

2 = Moderate chance of dozing

3 = High chance of dozing

Situation	Chance of Dozing
Sitting and reading	
Watching TV	
Sitting inactive in a public place (e.g., a theater or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in traffic	

Patient Signature	
_____ Subject Signature	_____/_____/_____ (dd/mm/yyyy)

Patient ID # (3 digit)	Patient Initials	Gender	Age	BMI	Prior OSA Treatment	Specify Other OSA Treatment	Method Used to Diagnose OSA	Diagnostic AHI
001								
002								
003								
004								
005								
006								
007								
008								
009								
010								

Diagnostic AHI Supine	Diagnostic AHI Non-supine	Diagnostic ODI	Baseline ESS	Date Provent Trial Pack Dispensed	Outbound Acclimation Calls Completed	Did Patient Acclimate to Provent	Method Used to Confirm Effectiveness	AHI with Provent

AHI Supine with Provent	AHI Non-supine with Provent	ODI with Provent	ESS after Initial Provent Use	Provent effective?	Date Prescription Written	Patient will use Provent as:	Follow-up Status	Provent use frequency	Combination Therapy Used

Specify Other Combination Therapy	Follow-up ESS