



Health Net

# National Medical Policy

**Subject: Obstructive Sleep Apnea, Diagnosis and Medical Treatments**

**Policy Number: NMP28**

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**This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document**

**The Centers for Medicare & Medicaid Services (CMS)**

For Medicare Advantage members please refer to the following for coverage guidelines first:

Use	Source	Reference/Website Link
	National Coverage Determination (NCD)	
	National Coverage Manual Citation	
X	Local Coverage Determination (LCD)	Positive Airway Pressure (PAP) Devices for the TREATMENT of OBSTRUCTIVE SLEEP APNEA (L171) Respiratory Assist Devices (L11493) Polysomnography and Other SLEEP Studies (L14467) SLEEP Disorders Testing (L27530) Polysomnography and SLEEP Studies for Testing SLEEP and Respiratory Disorders (L28292) Oral Appliances for OBSTRUCTIVE SLEEP APNEA (L28603) <a href="http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx">http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx</a>
X	Article (Local)	Polysomnography and SLEEP Studies – Supplemental Instructions Article (A48396) CPAP and Respiratory Assist Devices – APNEA/Hypopnea Index (A9) (A12530) Correct Coding of Oral Devices (A49184) <a href="http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx">http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx</a>

	Other	
	None	Use Health Net Policy

**Instructions**

- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under "Reference/Website" and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

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**Current Policy Statement** (Update April 2011 – A Medline search failed to reveal any studies that would cause Health Net, Inc. to change its current position)

### Criteria for Initial Sleep Study in Adult Patients

Health Net, Inc. considers a diagnostic sleep study (nocturnal polysomnogram) medically necessary for patients with a high pretest probability of obstructive sleep apnea (OSA) who have **any** of the following criteria:

1. Witnessed (if a bed partner is present) apnea during sleep of > 10 seconds in duration; or
2. **Any** combination of **two or more** of the following:
  - Excessive daytime sleepiness\* (especially with impairment of driving) for > 12 weeks, interfering with activities of daily living (ADLs) as evidenced by Epworth Sleepiness Scale score > 10 or Multiple Sleep Latency Test (MSLT) score < 6; or
  - Habitual, socially disruptive snoring with choking, grunting or gasping episodes; or
  - Chronic fatigue
  - Patient is restless, groggy, mentally dull, or has difficulties with concentration during the day
  - Morning headache; or
  - Large neck circumference; or
  - Patient has **any** of the following Sleep-Related Breathing Disorders (SRBDs):
    - Treatment resistant hypertension and/or arrhythmia; or
    - Obesity (BMI greater than 30 kg/m<sup>2</sup>); or
    - Stroke; or
    - Congestive heart failure

\* **Epworth Sleepiness Scale** indicates the likelihood of falling asleep in the following commonly encountered situations. The following scores are assigned to the patient's responses:

1. Sitting and reading
2. Watching TV
3. Sitting, inactive, in a public place, i.e., theater
4. As a passenger in a car for an hour without a break
5. Lying down to rest in the afternoon when circumstances permit
6. Sitting and talking to someone
7. In a car, while stopped for a few minutes in traffic

b. Epworth Sleepiness Scale	
Likelihood of dozing	

None	0
Low chance	1
Moderate chance	2
High chance	3

The scores need to be added together. A total greater than 10 is considered abnormal.

**Multiple Sleep Latency Test (MSLT)** is an accurate way to measure how severe sleepiness is during the day. During this test, the patient is allowed 20 minutes to fall asleep 4 to 6 times during a day. An EEG measures the time it takes to fall asleep. An average of 10 to 20 minutes to fall asleep is normal. An average of 5 to 10 minutes to fall asleep indicates mild to moderate daytime sleepiness. An average of less than 5 minutes to fall asleep indicates severe daytime sleepiness.

For patients under investigation for narcolepsy, primarily to rule out the possibility of other sleep disorders that might cause daytime sleepiness and give evidence of a satisfactory night's sleep prior to multiple sleep latency testing (MSLT) to help confirm the diagnosis narcolepsy and help determine the severity of daytime sleepiness.

The multiple sleep latency test (MSLT) and the maintenance of wakefulness test (MWT) are not routinely indicated in the initial evaluation and diagnosis of obstructive sleep apnea syndrome, or in assessment of change following treatment with nasal continuous positive airway pressure (CPAP).

### **Split-Night Sleep Study**

Health Net, Inc. considers a split-night study, in which the diagnosis of OSA is established in the first half of the night and the optimal CPAP pressure is determined during the second half, medically necessary as the preferred test when an AHI of at least 40 is documented during a minimum of 2 hours in the first half of the night of the diagnostic polysomnography.

**Important Note:** If the criteria above are met in the first half of the sleep study such that the patient qualifies as a candidate for a single split-night sleep study, we will **not** consider another full NPSG as medically necessary.

For patients with a high degree of clinical suspicion for OSA, an attended cardiopulmonary sleep study can be performed, but a negative study must be followed up with a full NPSG study. A cardio-respiratory sleep study without EEG channels is **not** recommended for CPAP titration.

### **Second Follow-up Sleep Study**

Health Net, Inc. considers a second sleep study medically necessary in adult patients when **all** of the following criteria are met:

1. When OSA is definitively diagnosed in the first study, however, there wasn't enough time left to titrate CPAP; and
2. The Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) meets **either** of the following:

- AHI or RDI  $\geq$  15 events per hour; or
- AHI or RDI  $\geq$  5 and  $\leq$  14 events per hour with **any** of the following symptoms:
  - Documented symptoms of excessive daytime sleepiness; or
  - Impaired cognition; or
  - Mood disorders or insomnia; or
  - Documented hypertension; or
  - Ischemic heart disease; or
  - History of stroke

Note: The AHI is equal to the average number of episodes of apnea and hypopnea per hour. The RDI is equal to the average number of respiratory disturbances per hour.

### **Repeat Sleep Studies**

Health Net, Inc. consider repeat sleep studies medically necessary up to twice a year for **any** of the following indications:

1. The initial study did not allow for the abolishment of the vast majority of obstructive respiratory events while on CPAP; or
2. When clinical response is insufficient or when symptoms return despite a good initial response to treatment
3. To determine whether positive airway pressure treatment settings need to be changed in patients who become symptomatic again; or
4. Particularly with substantial weight loss, to determine whether continued treatment with positive airway pressure treatment is necessary or to ascertain whether CPAP is still needed at the previously titrated pressure;
5. After substantial weight gain has occurred in a patient on CPAP who again is symptomatic despite continued use of CPAP in order to adjust the CPAP pressure to a higher level in order to prevent obstructive respirations; or
6. To assess treatment response after upper airway surgical procedures after at least 3 months to allow for tissue swelling to subside; or
7. After initial treatment with oral appliances to ensure therapeutic benefit; or
8. At least 3 months after surgical treatment of patients with sleep apnea whose symptoms return despite a good initial response to treatment; or
9. To routinely reassess the patient's status on CPAP on an annual basis.

Note: Follow-up sleep studies are not indicated in patients who continue to do well with treatment, i.e., whose symptoms continue to be resolved with CPAP treatment.

### **Unattended Sleep Studies**

Health Net, Inc. considers unattended portable recordings for the assessment of obstructive sleep apnea in the home, medically necessary as an alternative to standard polysomnogram according to the following:

1. Patients must have a high pretest probability of OSAHS, and
2. Patients must not be diagnosed with COPD, or suspected of having other sleep complications, such as central apnea, periodic leg movements, or narcolepsy, and
3. The portable device must be FDA approved and one of the following:
  - a) Type II home sleep monitoring device; or
  - b) Type III home sleep monitoring device; or
  - c) Type IV home sleep monitoring device that measures at least 3 channels

Note: The sleep test must be furnished under appropriate physician supervision. A post office box, commercial mailbox, hotel or motel is not considered an appropriate site to conduct a sleep study.

Type (Level)	Description of the Device
I	Standard polysomnography (PSG) with a minimum of 7 parameters measured, including EEG, EOG, chin EMG, and ECG, as well as monitors for airflow, respiratory effort, and oxygen saturation. A technician is in constant attendance. Facility based
II	Comprehensive portable PSG studies are essentially the same, except that a heart rate monitor can replace the ECG and a technician is not in constant attendance.
III	Modified portable sleep apnea testing is a cardio respiratory study in which a minimum of 4 parameters must be measured, including ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. Ventilation in this case is measured with at least two channels of respiratory movement or of airflow. Personnel are needed for preparation, but the ability to intervene is not required for all studies.
IVa	Three or more bioparameters. Pulse oximetry and at least 2 other parameters (e.g., body position, EOG, PAT: peripheral arterial tonometry, snoring, actigraphy, airflow)
IVb	Continuous (single or dual) bioparameter recording are devices that measure a minimum of one parameter, usually oxygen saturation

Diagnostic sleep studies are **not** medically necessary for **any** of the following conditions:

Snoring, except when there is a strong suspicion that sleep apnea is present	Prior to and following LAUP for the treatment of snoring
Hypersomnia	Bruxism
Insomnia	Enuresis
Parasomnias	Night terrors or dream anxiety attacks
Somnambulism (sleep walking)	Drug addiction
Nocturnal myoclonus	Migraine headaches
Restless leg syndrome	Shift work and schedule disturbances

Health Net, Inc. does **not** consider **any** of the following diagnostic and/or medical management methods medically necessary in patients with symptoms suggestive of OSA because they are still considered investigational in nature:

- Topographic electroencephalogram (EEG) mapping in the diagnosis and/or medical management of OSA syndrome; or
- Multiple sleep latency testing (MSLT) in the diagnosis of OSA syndrome except to exclude or confirm narcolepsy in the diagnostic work-up; or
- Nocturnal pulse oximetry alone as a case finding or screening method to rule out OSA (e.g. ApneaLink); or
- Limited-channel NPSG for distinguishing sleep from wake or determining sleep stage; or
- Topographic electroencephalogram (EEG) mapping; or
- The static charge sensitive bed; or
- Actigraphy alone; or
- Acoustic pharyngometry; or
- Electrosleep therapy, which uses the passage of weak electric currents to the brain to induce sleep.

### **Criteria for Initial Sleep Study in Pediatric Patients**

Health Net, Inc. considers an initial diagnostic sleep study (nocturnal polysomnogram) medically necessary for pediatric patients with a high pretest probability of obstructive sleep apnea (OSA) who have **any** of the following criteria:

1. Witnessed pauses in breath or irregular respirations associated with **any** of the following co-morbid conditions:
  - Tonsil hypertrophy; or
  - Obesity; or
  - Neuromuscular disease; or
  - Genetic syndromes; or
  - Cranial facial abnormalities; or
2. Habitual nocturnal snoring / gasping associated with **any** of the following:
  - Restless or disturbed sleep; or
  - Behavioral disturbance, or learning disorders including deterioration in school performance, hyperactivity, or attention deficit disorder; or
  - Enuresis; or
  - Frequent awakenings; or
  - Failure to thrive or growth impairment.
3. Excessive daytime sleepiness, or altered mental status unexplained by other conditions or etiologies; or
4. Decreasing scholastic performance, sudden personality changes, enuresis (bedwetting) without other obvious cause, associated with hypersomnolence and co-morbid conditions associated with sleep apnea; or
5. Presence of systemic hypertension; or
6. Pulmonary hypertension; or
7. Marked sinus arrhythmia and bradycardia; or
8. Cor pulmonale unexplained by other conditions or etiologies; or

9. Increased respiratory efforts, labored breathing, or sternal or intercostal retractions during sleep; or
10. Hypertrophy of tonsils and adenoids associated with noisy daytime respirations where surgical removal poses a significant risk and would be avoided in the absence of sleep disordered breathing.

### **Criteria for Repeat Sleep Study in Pediatric Patients:**

Health Net, Inc. considers a repeat sleep study (nocturnal polysomnogram) medically necessary for pediatric patients who have **any** of the following criteria:

1. Initial polysomnography is inadequate or non-diagnostic and the accompanying caregiver reports that the child's sleep and breathing patterns during the testing were not representative of the child's sleep at home; or
2. Titration of continuous positive airway pressure (CPAP) levels; or
3. A child with previously diagnosed and treated obstructive sleep apnea who continues to exhibit persistent snoring or other symptoms of sleep disordered breathing. In the case of adenotonsillectomy, repeat polysomnography should also be performed if the pre-operative obstructive sleep apnea was severe (RDI or AHI greater than 19). (If the treatment was surgical, testing should be deferred for 6 to 8 weeks post-operatively); or
4. To determine whether child needs intensive postoperative monitoring following adenotonsillectomy or other pharyngeal surgery; or
5. To periodically re-evaluate the appropriateness of continuous positive airway pressure (CPAP) setting based on the child's growth pattern or the presence of recurrent symptoms while on CPAP; or
6. If obesity was a major contributing factor and significant weight loss has been achieved, repeat testing may be indicated to determine the need for continued therapy.

### **Continuous Positive Airway Pressure (CPAP)**

#### **Initial Treatment**

Health Net, Inc. considers a single level continuous positive airway pressure (CPAP) medically necessary for an initial trial of treatment for OSA (12 weeks) in adult patient when all of the following are met:

1. A positive diagnosis of OSAHS as defined as:
  - a. Apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI)  $\geq$  15 events per hour; OR
  - b. AHI or RDI  $\geq$  5 and  $\leq$  14 events per hour with **any** of the following symptoms:
    - i. Documented symptoms of excessive daytime sleepiness; or
    - ii. Impaired cognition; or
    - iii. Mood disorders or insomnia; or
    - iv. Documented hypertension; or
    - v. Ischemic heart disease; or
    - vi. History of stroke

(Note: If the AHI or RDI is calculated based on less than two hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI

during sleep testing is at least the number of events that would have been required in a two hour period.)

2. The diagnosis of OSA was confirmed by one of the following:
  - a. attended PSG performed in a sleep laboratory; or
  - b. unattended HST with a Type II home sleep monitoring device; or
  - c. unattended HST with a Type III home sleep monitoring device; or
  - d. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels
3. The provider of CPAP must conduct education of the patient prior to the use of the CPAP device to ensure proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the home and willing and able to safely operate the CPAP device.

#### **Not Medically Necessary**

Health Net Inc. considers a trial of nasal CPAP as a method to diagnose sleep apnea investigational and therefore not medically necessary due to lack of evidence in the published peer review literature supporting the use of CPAP for diagnostic purposes.

Health Net, Inc. considers the Provent nasal device investigational and therefore **not** medically necessary since there is insufficient evidence in the published peer-reviewed medical literature at this time to support the safety, efficacy, and long-term outcomes of the use of this nasal expiratory resistance device in the treatment of obstructive sleep apnea.

#### **Continued Treatment with CPAP**

For continued treatment (greater than 3 months), **all** of the following criteria must be met:

1. Initial trial of CPAP demonstrates a significant decrease in the individual's AHI, an increase in the oxygen saturation level and reductions in daytime somnolence; and
2. The individual tolerates and complies with continued application of CPAP.

Note: In addition, CPAP may also be considered medically necessary for OSA patients with concomitant breathing disorders, which include restrictive thoracic disorders, COPD, nocturnal hypoventilation and progressive muscular degeneration diseases.

#### **Not Medically Necessary**

##### **Snoring**

Health Net, Inc. does **not** consider treatment of snoring without significant OSA medically necessary.

#### **BiPAP, VPAP, AutoPAP**

Health Net, Inc. considers bilevel positive airway pressure (BiPAP), variable positive airway pressure (VPAP), and automatic positive airway pressure (AutoPAP) medically necessary for an initial trial of treatment (3 months rental) in patients who meet any **one** of the following:

1. Intolerance to CPAP; or

2. Documentation shows the ineffectiveness of CPAP

Health Net, Inc. considers bilevel positive airway pressure (BiPAP) or variable positive airway pressure (VPAP) medically necessary for an initial trial of treatment (3 months rental) in patients who meet any **one** of the following:

1. Patients with obesity hypoventilation syndrome (OHS)
2. Patients with obesity hypoventilation syndrome (OHS) and coexisting obstructive sleep apnea-hypopnea (OSAH) who cannot tolerate CPAP or experience persistent alveolar hypoventilation despite CPAP therapy. \*

\*Clinical symptoms and signs suggestive of persistent sleep-related hypercapnia include dyspnea or a sensation of smothering at night, chronic morning headaches, or failure of awake blood gases to improve)

For continued treatment (greater than 3 months), **all** of the following criteria must be met:

1. Trial of nasal BiPAP demonstrates a significant decrease in the individual's RDI, an increase in the oxygen saturation level and reductions in daytime somnolence; and
2. The individual tolerates and complies with continued application of BiPAP

Notes:

1. Health Net, Inc. considers humidifiers and heaters for positive airway pressure devices medically necessary. An oral pressure appliance (OPAP) is medically necessary only on an exception basis for patients who are unable to tolerate a standard nasal/face mask due to facial discomfort, sinus pain, or claustrophobia from the masks.
2. Supplies (e.g., mask, hose, rings, and seals) are medically necessary that are necessary for the effective use of a covered positive airway pressure device. Depending on the member's contract, we consider replacements, repairs and maintenance of durable medical equipment that is not provided for under a manufacturer's warranty or purchase agreement when it is functionally necessary and medically necessary.

**Not Medically Necessary**

Note: Health Net, Inc. does not consider CPAP for the treatment of patients with upper airway resistance syndrome (UARS) medically necessary as treatment for this condition is considered investigational. There is inadequate scientific evidence in the medical literature to support its effectiveness.

**Oral Appliances**

Health Net, Inc. considers intraoral custom-fitted and prefabricated oral appliances (i.e. mandibular appliances) medically necessary with a physician prescription for OSA patients who meet **any** of the following:

1. Patients with mild OSA who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep-position change; or

2. Patients with moderate to severe OSA who have had a trial of nasal CPAP but are intolerant or refuse treatment with CPAP.

**Not Medically Necessary**

Health Net, Inc. does **not** consider intraoral appliances medically necessary for the treatment of snoring without the presence of OSA or appliances that are available over-the-counter.

Dental rehabilitation (dentures, bridgework, etc.) as treatment for OSA is **not** a covered benefit under our medical plans.

Note: Health Net, Inc. considers dual therapy of mandibular appliance and CPAP for the treatment of obstructive sleep apnea, **not** medically necessary, since there is no evidence based information that supports this.

**Codes Related To This Policy**

**ICD-9 Codes**

- 278.01 Morbid obesity with sleep apnea
- 278.8 Pickwickian Syndrome
- 780.09 Alterations of consciousness; drowsiness, somnolence
- 780.5 Sleep disturbances
- 780.51 Insomnia with sleep apnea
- 780.53 Hypersomnia with sleep apnea
- 780.54 Other hypersomnia
- 780.55 Disturbance of 24-hour sleep-wake cycle
- 780.56 Dysfunctions associated with sleep stages or arousal from sleep
- 780.57 Other and unspecified sleep apnea
- 780.59 Other sleep disturbance

**CPT Codes**

- 21083 Palatal lift prosthesis
- 21085 Oral surgical splints
- 21089 Unlisted maxillofacial prosthetic procedure
- 21299 Unlisted craniofacial or maxillofacial procedure
- 21499 Unlisted musculoskeletal procedure, head
- 94660 Initiation and management of CPAP
- 95805 Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
- 95806 Sleep study, simultaneous recording of ventilation, respiratory effort, ECG, or heart rate, and oxygen saturation, unattended by a technologist
- 95807 Sleep study, simultaneous recording of ventilation, respiratory effort, ECG, or heart rate, and oxygen saturation, attended by a technologist
- 95808 Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
- 95810 ;sleep staging with 4 or more additional parameters of sleep, attended by a technologist
- 95811 ;sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist

**HCPCS Codes**

- D7880 Occlusal orthotic device, by report (HCPCS code deleted, see code 21499)
- E0470 Respiratory assist device, bi-level pressure capability, without back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
- E0471 Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
- E0485 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non adjustable, prefabricated, includes fitting and adjustment
- E0486 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non adjustable, custom fabricated, includes fitting and adjustment
- E0601 Continuous airway pressure (CPAP) device (rental or purchase)
- G0398 Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
- G0399 Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
- G0400 Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

<b>Accessories for CPAP Device</b>		
<b>Code</b>	<b>Description</b>	<b>Maximum</b>
A7030	Full face mask used with positive airway pressure device, each	
A7031	Face mask interface, replacement for full face mask, each	
A7032	Replacement cushion for nasal application device, each	2 p/1 month
A7033	Replacement pillows for nasal application device, pair	2 p/1 month
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap	1 p/3 months
A7035	Headgear used with positive airway pressure device	1 per 6 months
A7036	Chinstrap used with positive airway pressure device	1 per 6 months
A7037	Tubing used with positive airway pressure device	1 per 1 month
A7038	Filter, disposable, used with positive airway pressure device	2 per 1 month
A7039	Filter, non disposable, used with positive airway pressure device	1 per 6 months
A7044	Oral interface used with positive airway pressure device, each	
E0561	Humidifier, nonheated, used with positive airway pressure device	
E0562	Humidifier, heated, used with positive airway pressure device	

**Scientific Rationale – Update April 2010**

Per the manufacturer, ResMed, ApneaLink is a single-channel sleep-screening tool designed to identify patients at risk for obstructive sleep apnea (OSA). The device consists of a nasal cannula attached to a small case that houses a pressure transducer. The device is held in place by a belt worn around the user's chest. The ApneaLink software analyzes data generated by the flow signal, producing a 1-page report. The device can provide information regarding snoring, inspiratory flow

limitation and AHI. The device does not discriminate obstructive from central events because the signal is based only on airflow, and there is no recording of respiratory effort.

Peer review literature evaluating the ApneaLink screening device is limited. Ragette et al (2009) evaluated ApneaLink's diagnostic performance in a patient population with high prevalence of sleep apnea. ApneaLink was applied simultaneously with in-laboratory polysomnography (PSG) (n = 102, 24 female, age 54.7 years) and sequentially with PSG in the unattended home setting (n = 131, 37 female, age 59.1 years). Predictive values were computed for apnea-defining thresholds of apnea-hypopnea index (AHI) > 5/h, >10/h, >15/h. Night-to-night variability (NNV) was assessed over three consecutive nights (n = 55, 10 female, age 48.9 years). The authors reported that ApneaLink correlated well with apnea-hypopnea index on PSG (PSG(AHI)) on simultaneous (r = 0.98, bias -0.7) and unattended home application (r = 0.95, bias -0.6). Predictive values were highest at AHI >10/h (in-laboratory: sensitivity 91.1%, specificity 87.5%, LR+ (positive likelihood ratio) 7.4, LR- 0.1; home: sensitivity 80%, specificity 85.5%, LR+5.5, LR- 0.2). NNV was low. The authors concluded that ApneaLink is an accurate screening tool for sleep apnea in a population with high prevalence of the disorder.

Weinreich et al (2009) assessed the validity of a flow-based screening classifier as an automated diagnostic test for Cheyne-Stokes respiration (CSR) in 70 study subjects (28 with obstructive sleep apnea [OSA], 20 with CSR, 11 with CSR+OSA and 11 without sleep disordered breathing SDB), performed in a sleep lab. The nasal cannula flow signal was analyzed by ApneaLink, based on a classifier algorithm using pattern recognition. In a simultaneous PSG, results were compared with manual scoring of respiratory events by certified sleep experts. The authors reported that for detecting CSR, a sensitivity of 87.1% (95% confidence interval 75.3% to 98.9%), specificity of 94.9% (95% confidence interval 87.9% to 100%), a positive likelihood ratio of 17.0, and a negative likelihood ratio of 0.14 was obtained. The area under the curve (AUC) of the according receiver operating characteristic (ROC) curve was 93.4%. This resulted in an accuracy of 91.4% for identifying CSR. They concluded the screening classifier was able to detect CSR with high diagnostic accuracy. Hence, ApneaLink equipped with CSR classifier is an appropriate screening tool that may help to prioritize patients with CSR for PSG.

Clark et al (2009) compared the ApneaLink to standard polysomnography technique for diagnosing sleep apnea (using the Embletta device), in 67 patients investigated for possible sleep apnea. The patients' average age was 52.6, 79% were male, the mean body mass index was 32.3, and the mean Epworth sleepiness score was 13.0. The authors reported that twenty-five patients (45%) were identified as having an apnea-hypopnea index of >15, as measured by the Embletta. The mean (standard deviation) apnea-hypopnea index was 21.5 +/- 23.0 as measured by the Embletta and 24.3 +/- 26.2 as measured by the ApneaLink. The sensitivity of the ApneaLink for an apnea-hypopnea index cut-off point of 15 was 92 per cent and the specificity was 96.7 per cent. The negative predictive value of the ApneaLink for an apnea-hypopnea index of < 15 was 94 per cent. The authors concluded the ApneaLink is a useful tool for screening patients thought to have possible sleep apnea, and for selecting patients for definitive diagnostic testing.

In a company sponsored validation study, Erman et al (2007) compared the AHI from the ApneaLink device at home for 1 night unattended, to that obtained during simultaneously conducted attended sleep-laboratory polysomnography to assess the sensitivity and specificity of the device in consecutive subjects with type 2 diabetes

mellitus referred from a diabetes clinic. They also compared the AHI obtained from the ApneaLink device during a study in the subjects' homes to that obtained during the in-laboratory study. The laboratory study was performed within 2 weeks of the home study. Sixty three patients were included in the study, however, 4 pts experienced technical difficulties with the device and were and were excluded, leaving fifty-nine subjects that completed the study. Mean age of subjects was 57 years; mean body mass index was 33 kg/m<sup>2</sup>. The results demonstrate a high sensitivity and specificity of the at-home ApneaLink AHI compared with the AHI from the simultaneous polysomnographic study at all AHI levels, with the best results at an AHI of > 15 events per hour (sensitivity 91%, specificity 95%). The AHI comparison from the home and laboratory studies also demonstrates good sensitivity and specificity at AHI levels of > 15 and > 20 events per hour (sensitivity 76%, specificity 94%, for both). The authors concluded that ApneaLink device demonstrates clinical utility as a screening device in pts with sleep apnea and type 2 diabetes. Limitations to this study however, include the results are not generalizable to the wider population without type 2 DM, and lack of randomization or blinding.

At this time, there is a paucity of data evaluating the use of the single channel ApneaLink as a screening tool for OSA. Although the published literature suggests that ApneaLink may be an accurate screening tool for sleep apnea in a population with high prevalence of OSA, studies have been small, non-randomized trials. In addition, none of the published studies have examined the impact of this testing on patient management or health outcomes.

### **Scientific Rationale – Update December 2009**

The Provent nasal device is manufactured by Ventus Medical, a California based company. This device fits in the nostrils, and is meant to be used for a night, then disposed of. There is no power source or air blower. This device, about the size of a quarter, uses the individual's own breathing to create pressure that keeps the airway open, acting as a splint to treat obstructive sleep apnea. The device is not indicated for central or mixed sleep apnea.

On August 7, 2008 the 'Provent™ Nasal Cannula' received 510K premarket notification from the U.S. FDA with the # K080983. Per the FDA, the indications for use are for the transmission of respiratory airflow signals between the Provent™ Professional Sleep Apnea Therapy device and the pressure transducers used with physiologic recorders during sleep studies. The FDA also states that the Provent Nasal Cannula is essentially identical to standard nasal cannula except for its custom connection to the 'Provent Professional Sleep Apnea Therapy' (PSAT). The Provent Nasal Cannula is comprised of the same design elements as a standard nasal cannula which includes a bifurcated tube with a luer lock connector, an anti-microbial filter at one end, and a component to hold the tubes in the correct location near the nostrils at the other end.

There is a Clinical Trial on 'The Study of Provent Treatment of Obstructive Sleep Apnea in Patients Who Are Non-compliant with CPAP'. This study as of July 2009 is recruiting participants. The objective of the proposed investigation is to evaluate the efficacy of the Provent device in a sample of OSA patients who have either refused or been non-adherent with PAP treatment. Both initial efficacy (evaluated after approximately one week with Provent) and efficacy after approximately 5 weeks in patients who demonstrate initial efficacy will be assessed. A secondary objective is to assess adherence with Provent treatment during the 5-week evaluation period. The

ClinicalTrials.gov Identifier is NCT00901771. The estimated study completion date is December 2009.

Colrain et al. (2008) completed a pilot study to evaluate the Provent nasal device, which included 24 patients with an AHI > 5 and six patients with primary snoring. Exclusion criteria included basal metabolic index (BMI) > 35. Patients were evaluated with polysomnogram (PSG) on two consecutive nights; PSG alone was performed on one night, and PSG was combined with the Provent device on the alternate night. The AHI and oxygen desaturation both decreased significantly with use of the device ( $p < 0.001$  and  $p < 0.1$ , respectively). The percentage of time spent above 90% oxygen saturation also increased significantly with device use ( $p < 0.05$ ). Because of the study design, small number of participants and data from a single night of treatment, conclusions cannot be drawn from this pilot study. Additional larger, randomized controlled studies are necessary which compare the results of CPAP to the Provent nasal device in individuals with OSA, to evaluate the long-term efficacy of this device.

There is insufficient evidence in the published peer-reviewed medical literature at this time to support the safety, efficacy, and long-term outcomes of the use of the Provent nasal expiratory resistance device in the treatment of obstructive sleep apnea.

### **Scientific Rationale – Update March 2009**

#### Unattended Sleep Studies

There are an extensive number of studies published about portable monitoring devices and CPAP treatment. However, these studies are difficult to compare because there are a number of different monitor types, different definitions of sleep apnea (AHI) and different study populations. There are also differing opinions on if the Type 1 polysomnogram should be considered as the "gold standard". Most of the trials of home portable monitoring devices have been non-randomized or randomized comparative trials, comparing outcomes of portable devices with standard full PSG. The task is particularly difficult because of known night to night variability in the AHI measured by full PSG, known first night effects when patients are monitored and probable differences between sleep patterns in the laboratory and at home.

The Center of Medicare and Medicaid Services (CMS) recently published a Coverage Decision Memorandum for Sleep Testing for Obstructive Sleep Apnea (OSA) (CAG-00405N) on March 3, 2009. CMS found "the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. "

The CMS based these recommendations on technology assessments provided by AHRQ, and its own independent search and review of individual clinical studies addressing this issue. CMS also reviewed other information from professional societies and other groups/organizations, searched evidence based practice guidelines, consensus statements, and position papers.

The AHRQ technology assessment was based on a systematic review of the literature, which yielded a total of 95 studies that did not include children. Eligible studies assessed the ability of sleep studies at baseline to predict response to CPAP

treatment or CPAP use; the comparison of measurements with portable monitors and facility-based PSG; and the safety of sleep studies. Review of the specific studies can be found in the references noted in the April Update and on this website:  
<http://www.cms.hhs.gov/determinationprocess/downloads/id48TA.pdf>

The CMS concluded the following:

1. A Type I Polysomnography (PSG) is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. A Type II or a Type III sleep testing device is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
3. A Type IV sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
4. A sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

The Portable Monitoring Task Force of the American Academy of Sleep Medicine published Clinical Guidelines for the Use of Unattended Portable Monitors (PM) in the Diagnosis of Obstructive Sleep Apnea in Adult Patients based performed a limited literature search to capture articles published since the last literature review and used evidence review and a consensus process to develop clinical guidelines for the use of PM in the diagnosis and management of OSA.

The Portable Monitoring Task Force was charged with answering the following questions:

1. What are appropriate indications for PM?
2. What types of PM should be used?
3. How should PM data acquisition, analysis, and interpretation be performed?
4. What is the proper application of PM results?

The search found 291 articles and the Task Force reviewed all abstracts to exclude studies that did not meet the following criteria: subjects  $\geq 18$  years of age; patient evaluated for OSA; patients had testing with a monitoring device that offered fewer channels (Type 3 devices) than polysomnography; and a minimum of 10 subjects.

Based on a review of literature and consensus, the Portable Monitoring Task Force of the American Academy of Sleep Medicine (AASM) makes the following recommendations:

- Unattended portable monitoring (PM) for the diagnosis of obstructive sleep apnea (OSA) should be performed only in conjunction with a comprehensive sleep evaluation.

- PM may be used as an alternative to polysomnography (PSG) for the diagnosis of OSA in patients with a high pretest probability of moderate to severe OSA.
- PM is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of PM, including, but not limited to, moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure, or comorbid sleep disorders.
- PM is not appropriate for general screening of asymptomatic populations.
- PM may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness.
- PM may also be indicated to monitor the response to non-CPAP treatments for sleep apnea.
- At a minimum, PM must record airflow, respiratory effort, and blood oxygenation. The airflow, effort, and oximetric biosensors conventionally used for in-laboratory PSG should be used in PM

### **Scientific Rationale – Update October 2008**

Obstructive sleep apnea-hypopnea syndrome (OSAHS) is a common sleep-related breathing disorder characterized by disruptive snoring and repetitive upper airway obstructions. In the management of OSAHS, clinicians may consider various conservative, non-invasive and surgical treatment modalities. Conservative measures and the correction of morphological airway abnormalities should be considered first. If these measures are not effective or not applicable, continuous positive airway pressure (CPAP) is currently regarded as the treatment of choice for, especially, moderate to severe OSAHS. However, due to the obtrusive nature of CPAP, the effectiveness of therapy may be compromised by poor therapeutic acceptance and adherence.

Oral-appliance therapy in the treatment of OSAHS patients may be recommended as primary treatment in patients with mild to moderate OSA. In severe OSAHS and specific patient populations (e.g., edentulous patients), CPAP therapy should always be considered first.

(2005) Stanford University Center of Excellence for Sleep Disorders, states:

"These practice parameters are an update of the previously published recommendations regarding use of oral appliances in the treatment of snoring and Obstructive Sleep Apnea (OSA). Oral appliances (OAs) are indicated for use in patients with mild to moderate OSA who prefer them to continuous positive airway pressure (CPAP) therapy, or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP. Until there is higher quality evidence to suggest efficacy, CPAP is indicated whenever possible for patients with severe OSA before considering OAs."

Ferguson et al. (2006) conducted an evidence-based review of literature regarding use of oral appliances (OAs) in the treatment of snoring and obstructive sleep apnea syndrome (OSA) from 1995 until the present. His structured search revealed 141 articles for systematic review, of which 87 were suitable for inclusion in the evidence base, including 15 Level I to II randomized controlled trials and 5 of these trials with placebo-controlled treatment. The efficacy of OAs was established for controlling OSA in some but not all patients with success (defined as no more than 10 apneas or hypopneas per hour of sleep) achieved in an average of 52% of treated patients. The

mechanism of OA therapy is related to opening of the upper airway as demonstrated by imaging and physiologic monitoring. Treatment adherence is variable with patients reporting using the appliance a median of 77% of nights at 1 year. In comparison to continuous positive airway pressure (CPAP), OAs are less efficacious in reducing the apnea hypopnea index (AHI).

Sixteen controlled trials related to efficacy of oral-appliance therapy were identified. With respect to improvements in the number of upper airway obstructions (i.e., apnea-hypopnea index [AHI]), oral-appliance therapy was clearly more effective than an "inactive" control device and possibly more effective than uvulopalatopharyngoplasty. Although patients generally preferred oral-appliance therapy, improvements in the AHI were usually better with CPAP therapy. Twelve patient-series and one controlled study related to co-morbidity of oral-appliance therapy were identified. Data suggest that oral-appliance therapy may have adverse effects on the craniomandibular and craniofacial complex. In summary, the available literature offers an evidence base for the use of oral appliances in the treatment of OSAHS. Because CPAP therapy is apparently more effective and adverse effects of oral appliances have been described, controlled studies addressing the specific indication and co-morbidity of oral-appliance therapy are warranted.

There is no evidence-based information that supports the dual therapy of mandibular appliance and CPAP, for the treatment of obstructive sleep apnea.

#### **Update September 2008**

There are varied portable OSA diagnostic devices on the market. Some are not FDA-approved for use in the United States. Those level III devices with current FDA 510(k) approval include:

- **The NovaSom OSG or QSG** is a simultaneous home sleep-monitoring device that was initially known as the Bedbugg device, and then renamed Silent Night. NovaSom QSG by Sleep Solutions (Palo Alto, CA) is a level III device with FDA approval and has been tested in the home (Reichert, et al., 2002). The indicated use is the diagnostic evaluation of adults with possible sleep apnea and can score obstructive and mixed apneas. NovaSom QSG is a level III home tested device. The device consists of a bedside unit with a cable that runs to a patient module, which is positioned, on the patients arm. The sensors are positioned on the patient's body and connect into the patient module. The current device has been expanded from previous models to include blood oxygen saturation level, pulse rate, and respiratory effort monitoring.
- **Stardust II** (Respironics, Inc, Murrysville, PA) approved in 1996 (upgraded 2004, 2005) as a class II recording device. The Stardust II is a multi-function recording device intended to be used to collect and store physiological signals related to sleep disorders and to aid in the diagnosis of related respiratory sleep disorders. The Stardust II is only to be used under the direction and supervision of a physician, technologist or clinician.
- **Somte' Patient Recording System** (Compumedics, Abbotsford, Victoria, Australia) approved in 2003 as a class II device. The indicated use is to collect and store signals related to sleep disorders, including respiratory, ECG, and limb movement signals to aid in the diagnosis of respiratory and/or cardiac related sleep disorders which are then used as an aid in the diagnosis of cardiac and/or

respiratory related sleep disorders by qualified physicians. The Somte' System is only to be used under the direction and supervision of a physician, technologist or clinician.

The FDA has approved level IV PM, class II devices through the 510(k) process. Neither of the following devices is designed to fully diagnose OSA nor do they meet the device criteria for home sleep study for the diagnosis of OSA:

- **Sleep Strip** (Influent Ltd., Herzliya, Israel), was granted 510(k) (2000). SleepStrip is intended for use in screening patients for OSA by scoring respiratory airflow that correlates with AHI in adult users in overnight sleep.
- **Watch PAT 100S** (Respironics, Murrysville, PA), was FDA-approved through the 510(k) (2003). Watch PAT 100S is worn on the finger to record peripheral arterial tone intended to diagnose OSA.

### **Scientific Rationale – Update November 2007**

Polysomnography (PSG) performed in a sleep laboratory is the "gold standard" for diagnosis of obstructive sleep apnea (OSA) and for titration of the "correct" level of continuous positive airway pressure (CPAP.) Some investigators suggest that the diagnosis of sleep apnea could be inferred from the response to a treatment trial with nasal CPAP.

A Medline search found only a few small studies investigating a trial of CPAP as compared to standard PSG to diagnose OSA. In a randomized controlled trial, Mulgrew et al. (2007) compared standard PSG with ambulatory CPAP titration in high-risk patients identified by a diagnostic algorithm. Sixty-eight patients with a high pretest probability of moderate to severe obstructive sleep apnea (apnea-hypopnea index [AHI] >15 episodes/h) identified by sequential application of the Epworth Sleepiness Scale (ESS) score, Sleep Apnea Clinical Score, and overnight oximetry were included in the study. Patients were randomly assigned to PSG or ambulatory titration by using a combination of auto-CPAP and overnight oximetry and were observed for 3 months. The investigator reported that after 3 months, there were no differences in the primary outcome, AHI on CPAP between the PSG and ambulatory groups or in the secondary outcomes, ESS score, Sleep Apnea Quality of Life Index, and CPAP. Adherence to CPAP therapy was better in the ambulatory group than in the PSG group. The authors concluded that the initial management of patients with a high probability of obstructive sleep apnea, PSG confers no advantage over the ambulatory approach in terms of diagnosis and CPAP titration. The ambulatory approach may improve adherence to treatment. When access to PSG is inadequate, the ambulatory approach can be used to expedite management of patients most in need of treatment.

A retrospective study by Skomro et al. (2007) evaluated the response of patients who had a high clinical suspicion for OSA and who were waiting for a PSG test to an empirical continuous positive airway pressure (CPAP) trial. 183 patients with a high pretest probability of having OSA began empirical CPAP testing using an arbitrary CPAP pressure. The presence of OSA, the accuracy of empirical CPAP pressure prescription, the adherence to empirical CPAP and the improvement in daytime somnolence were evaluated at the time of PSG. Of 183 patients on a CPAP trial, 91% had OSA, which was at least moderate (more than 15 apneas and hypopneas per hour of sleep) in 75% of the patients. Eighty per cent of the patients had significant

daytime somnolence, which improved with CPAP. In 40% of the patients, the arbitrary CPAP pressure was lower than that determined by manual titration. Adherence to a trial of CPAP (longer than 2 h/night) predicted OSA with a sensitivity of 82% and a specificity of 41%; the positive and negative predictive values were 92% and 22%, respectively. The author concluded that at the time of PSG testing, OSA was present in 91% of the patients who had received empirical CPAP. An empirical CPAP provided satisfactory interim treatment for excessive somnolence, despite the fact that the CPAP pressure was suboptimal in 40% of the patients.

Senn et al. (2006) investigated seventy-six patients referred for sleep apnea evaluation. CPAP treatment trial over 2 weeks as an initial diagnostic test in comparison with polysomnography, and treatment success over  $>$  or  $=$  4 months. The main outcome was diagnostic accuracy of the CPAP trial. The trial result was positive if the patient had used CPAP for  $>$  2 h per night and wished to continue therapy. This suggested sleep apnea. The trial was evaluated in terms of predicting an obstructive apnea/hypopnea index (AHI)  $>$  10/h during polysomnography performed for validation, and in terms of identifying sleep apnea patients treated successfully over  $>$  or  $=$  4 months. Forty-four of 76 patients (58%) had sleep apnea as confirmed by an AHI  $>$  10/h. The CPAP trial predicted sleep apnea with a sensitivity of 80%, a specificity of 97%, and positive and negative predictive values of 97% and 78%, respectively. In 35 of 76 sleep apnea patients (46%) with positive CPAP trial results, polysomnography could have been avoided. These patients were prescribed long-term CPAP therapy. After 4 months, 33 of 35 patients (94%) still used CPAP, and their symptoms remained improved. These patients were identified by the CPAP trial with positive and negative predictive values of 92% and 100%, respectively. The author concluded that in a selected population, a CPAP trial might help to diagnose OSA, to identify patients who benefit from CPAP, and to reduce the need for polysomnography.

In a prospective randomized controlled trial, Cross et al. (2006) evaluated whether automated CPAP titration in the home produced patient outcomes equal to those following laboratory-based automated CPAP titration. The main outcomes were Epworth Sleepiness Scale score, objective daytime sleepiness (Oxford SLEep Resistance test or OSLER test), and CPAP use. Quality-of-life questionnaires, the Functional Outcomes of Sleep Questionnaire and SF-36 were also performed. Two hundred CPAP-naïve patients with obstructive sleep apnea hypopnea syndrome (OSAHS) requiring CPAP treatment were included in the study. One hundred patients were randomly assigned to a standard 1-night in-hospital CPAP titration and 100 to 3 nights' home CPAP titration and then issued with fixed pressure CPAP. Data were analyzed on an intention-to-treat basis. The patient groups did not differ at baseline. The CPAP pressures defined at titration, number of mask leaks, and initial acceptance rates were similar in the sleep-laboratory and home-titrated groups. At 3-month follow-up, there was no significant difference in CPAP use, Epworth Sleepiness Scale score, OSLER, Functional Outcomes of Sleep Questionnaire, or SF-36 between the sleep-laboratory and home-titrated groups. The investigators concluded that home-based automated CPAP titration is as effective as automatic in-laboratory titrations in initiating treatment for OSAHS.

The American Academy of Sleep Medicine (AASM) Practice Parameters for the Use of Continuous and Bilevel Positive Airway Pressure Devices to Treat Adult Patients With Sleep-Related Breathing Disorders recommends that treatment with CPAP must be based on a prior diagnosis of OSA established using an acceptable method. The AASM states that the standard approach to diagnosing OSA is in-laboratory,

technician- attended polysomnography. The AASM Practice Parameters for the Use of Auto-Titrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome does not address the use of auto-titrating devices (APAP) for diagnostic purposes.

### **Scientific Rationale – Update August 2007**

Primary alveolar hypoventilation is rare and leads to inadequate breathing despite the lungs and airways being normal. The condition is usually worse during sleep, and periods of apnea are usually present. The disease primarily affects men 20 to 50 years old. It can also be present in male children.

Alveolar hypoventilation is often seen in patients with obesity hypoventilation syndrome (OHS), also known as "Pickwickian syndrome". OHS is defined as a combination of obesity (body mass index of  $>30$  kg/m<sup>2</sup>) and awake arterial hypercapnia (Paco<sub>2</sub>  $>45$  mm Hg) in the absence of other known causes of hypoventilation. Symptoms of OHS include excessive daytime sleepiness, fatigue, or morning headaches, which are similar to symptoms seen in obstructive sleep apnea-hypopnea syndrome. However, patients with obesity hypoventilation syndrome have daytime hypercapnia and hypoxemia, which is associated with pulmonary hypertension and right-sided congestive heart failure, which can be fatal if untreated. In patients with obesity hypoventilation syndrome (OHS) whose underlying sleep disorder is hypoventilation alone, positive pressure ventilation (PPV) is the mainstay of treatment. PPV improves nocturnal alveolar ventilation and may stabilize or improve daytime alveolar ventilation in patients with OHS. Bilevel positive airway pressure (BiPAP) and volume cycled positive pressure ventilation (VCPV) are common types of PPV.

In patients with coexisting OHS and Obstructive Sleep Apnea-Hypopnea (OSAH), nocturnal CPAP may improve alveolar ventilation during sleep. A subset of patients with OHS and OSAH may not respond to CPAP or may not tolerate it and therefore may require PPV to alleviate hypoventilation during sleep and alleviate daytime hypercapnia. Some patients with coexisting OHS and OSAH probably have an abnormal control of breathing such that hypoventilation persists even when the upper airway is patent. Ventilatory assistance during sleep may improve hypoventilation during wakefulness, suggesting that the abnormal ventilatory drive during wakefulness is related to hypoventilation during sleep. Patients with OHS plus OSAH who use nocturnal CPAP should be monitored for indications that nocturnal hypoventilation still exists despite compliance with therapy. Clinical symptoms and signs suggestive of persistent sleep-related hypercapnia include dyspnea or a sensation of smothering at night, chronic morning headaches, or failure of awake blood gases to improve. Any of these findings should prompt investigation of whether the CPAP has been appropriately titrated and applied. PPV should be considered if nocturnal hypoventilation persists despite adequate CPAP therapy.

During BiPAP therapy, an inspiratory positive airway pressure (IPAP) and an expiratory positive airway pressure (EPAP) are independently set and titrated. Tidal volume correlates with the difference between the IPAP and the EPAP. Alveolar ventilation is enhanced by a larger tidal volume, assuming that the respiratory rate is constant. Nocturnal BiPAP therapy is effective at reducing nocturnal PaCO<sub>2</sub> and daytime sleepiness. In addition, it may stabilize or improve daytime PaCO<sub>2</sub>. Advantages of BiPAP compared to CPAP include a lower mean airway pressure (which may lead to better tolerance of the therapy), better rest of the ventilatory muscles,

more rapid improvement of respiratory acidosis, and more rapid return of normal ventilatory control or chemoreceptor function.

According to the American Academy of Sleep Medicine, BiPAP treatment is an optional therapy in some cases of OSA where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present. BiPAP may be useful in treating some forms of restrictive lung disease or hypoventilation syndromes associated with daytime hypercapnia. (This recommendation as an option is based on 11 studies all graded at Level III or better that overall found improvement associated with BiPAP therapy)

In summary, patients with obesity hypoventilation syndrome (OHS) alone should be treated with nocturnal PPV (BiPAP) because CPAP is unlikely to be effective in the absence of obstructive sleep apnea-hypopnea (OSAH).

Patients with obesity hypoventilation syndrome (OHS) and coexisting obstructive sleep apnea-hypopnea (OSAH) can be treated with nocturnal CPAP initially, and then converted to nocturnal PPV if they do not tolerate CPAP therapy or have persistent alveolar hypoventilation despite CPAP therapy. In most situations nocturnal PPV can be delivered as BiPAP.

### **Scientific Rationale – Update April 2006**

Obstructive sleep apnea (OSA) is a serious, common, and underdiagnosed disorder that challenges health care resources. While polysomnography (PSG) represents the standard diagnostic test for OSA, portable devices provide an alternative diagnostic tool when issues of cost, time, geographic availability, or other constraints pose impediments to in-lab testing. Various portable devices have been developed over the past decade that are meant to be used as screening tools or replacements for the labor-intensive, complex, expensive, laboratory- or facility-based PSG for the evaluation of patients suspected of having OSA. The American Sleep Disorders Association (Ferber, 1994) classified monitors used in diagnostic testing for sleep apnea into four types. Attended PSG, Type 1, is the gold standard, and the portable monitors fall into three types (2, 3, and 4) with fewer physiologic signals monitored in each subsequent type.

The levels are briefly defined below to clarify the differences between them:

- Type 1: Measures, at a minimum, eight channels electroencephalogram (EEG), electro-oculogram (EOG), electrocardiogram (ECG), chin electromyogram (EMG), airflow, respiratory "effort," oxygen saturation (SaO<sub>2</sub>), and body position; it is attended in a laboratory setting.
- Type 2: Monitors a minimum of seven channels including EEG, EOG, chin EMG, ECG or heart rate, airflow, respiratory effort, and SaO<sub>2</sub>. This allows for sleep staging and measurement of total sleep time, and this information can be used to determine in the number of sleep-disordered breathing events per hour of sleep (e.g., the apnea/hypopnea index).
- Type 3: Includes a minimum of four channels and must monitor at least two channels of respiratory movement or respiratory movement and airflow to define an event; generally, no EEG signals are monitored.
- Level 4: Includes only one or two channels of physiologic signals and generally uses only one channel (either SaO<sub>2</sub> or airflow) to define a sleep-disordered breathing event; no EEG signals are monitored.

The effectiveness of home portable monitors is judged chiefly in terms of how well they correctly identify patients with and without clinically significant OSA. The effectiveness of home portable monitors is judged chiefly in terms of how well they correctly identify patients with and without clinically significant OSA. "Clinically significant" turns on issues of severity, measured by (for instance) an apnea/hypopnea index (AHI) or a respiratory disturbance index (RDI). Correct identification rests on whether the likelihood of a correct diagnosis or classification (as to the presence or absence of OSA) is better after the portable device test than it is before the test. Assessing this body of evidence requires appreciation of several limitations of published studies, as these problems place a ceiling on the level of internal validity (i.e., the extent to which these studies are free of systematic bias).

Most articles only compare of the results from portable monitoring done simultaneously with full PSG in the laboratory, i.e., "a side-by-side" study. Although this type of study does control for night-to-night variability in the important AHI (a measure of severity) observed by PSG, it does not provide information on the performance of the equipment unattended in patients' homes where usually no technical support is available (except, perhaps via a telephone help line). Only one home study (Golpe 2002) directly compared the data loss rate between hook-up for the portable equipment by technicians and that by patients. The investigators reported a 7% loss for technician hook-up and 33% loss for patient hook-up; thus, data loss appears to be greater when the patient performs the hook-up of the equipment.

NovaSom QSG is a level 3 device with FDA approval and has been tested in the home in situations where polysomnography may not be available in some rural areas or in some patients who decline to undergo a study in a sleep laboratory. The device consists of a bedside unit and a patient module worn on the patient's wrist and three body sensors: (1) airflow; (2) finger oximeter; and (3) respiration effort. Portable home sleep studies are not indicated for individuals who are unable to use or connect to the monitoring device unassisted and are not considered appropriate for patients with COPD or for those suspected of having other sleep complications, such as central apnea, periodic leg movements, or narcolepsy.

Claman (2001) reported a comparison study of 42 patients in a simultaneous home sleep monitoring Bedbugg device (renamed Silent Night and, ultimately, NovaSom OSG) and 53 patients in formal polysomnography, showing a correlation between PSG and Bedbugg of  $r = .96$ . The sensitivity of Bedbugg for detecting  $AHI > 15$  was 85.7%, the specificity 95.2%.

Reichert et al (2002) compared one night of in-lab, simultaneous recording of PSG and NovaSom QSG, a Type 3 five-channel home diagnostic device estimating oronasal airflow by sound, oxygen saturation, heart rate, respiratory effort and snoring, versus using the NovaSom QSG at home for three nights in 51 consecutive adults referred to their sleep lab for suspicion of OSA. Of all the patients who enrolled into the study, data could not be collected or analyzed in 13 percent; three did not use the portable system at home and three had a portable device with a faulty memory chip. Forty-five patients completed the study. Home studies were done within 7 days before or after an in-facility PSG (half before, half after). The prevalence of OSA by PSG, defined as an apnea/hypopnea index (AHI) level of  $>15$ , was 47% (20 of 44 patients); however, the authors reported that 40 of the patients had "split-night" studies in the laboratory, suggesting that a larger percentage had some degree of OSA. AHI scores for the home study were averaged across 3 nights. Using this

average would tend to decrease the effect of variability of results of the home device and thus tend to increase the observed agreement with PSG results. Using a clinical cut-off of AHI=15, the sensitivity and specificity of the in-lab NovaSom QSG vs. PSG were 95% and 91%, respectively. For home NovaSom QSG vs. in-lab PSG, the sensitivity was 91% and specificity was 83%. The intra-class correlation coefficient for the agreement between three separate nights of NovaSom QSG home data was 0.88. These values led to a positive predictive value of 83 percent and a negative predictive value of 91 percent. The sensitivity/specificity values give an LR+ of 5.35 and an LR of 0.11, indicating a modest increase in probability of OSA if the test is positive and a modest decrease in the probability if it is negative. A Bland-Altman plot showed wide confidence limits for agreement on AHI with 2 SD approximately equal to 60. The authors concluded that, in a patient population suspected of having OSA, the NovaSom QSG demonstrated acceptable sensitivity and specificity both in the lab and self-administered in the home, when compared to PSG.

Realizing that waiting times for hospital-based monitoring of the obstructive sleep apnea/hypopnea syndrome (OSAHS) are rising, Dingli et al (2003) conducted a study to evaluate whether or not a new portable device, a Type 3 Embletta equipment that measured flow by nasal pressure detector, thoracoabdominal movement, pulse oximetry, and body position, could accurately diagnose OSAHS at home. A synchronous comparison to polysomnography was performed in 40 patients and a comparison of home Embletta studies with in-laboratory polysomnography was performed in 61 patients. Overall, 18 percent of these home studies had inadequate data, leaving 50 patients in the analysis. The rate of data loss was reported to improve because of a "learning effect" among the last two-thirds of patients studied, but the rate of loss was still 12 percent even in these patients. The overall prevalence of sleep apnea defined by a PSG AHI greater than 15 was 76%. Using two different thresholds for the number of apneas plus hypopneas per hour (A+H/hr) in the home study to classify patients as positive or negative for OSA (home A+H/hr > 20 = positive; home A+H/hr < 10 = negative), no false-positive and no false-negative cases occurred. However, 36 percent of cases had home study results with values for A+H/hr in the "indeterminate" range; thus, the investigators could not classify these patients as having or not having OSA. The authors reported that agreement between the Embletta automated scoring and PSG results yielded a kappa coefficient of 0.10 (poor agreement) and agreement between Embletta manual scoring and PSG a kappa of 0.54. The A+H/hr measured on the portable study agreed more closely with that from the PSG when thoracoabdominal movement was used in conjunction with flow by nasal pressure to determine hypopneas. The authors stated that use of nasal pressure as the sole indicator of hypopneas would result in unscorable traces in approximately 8 percent of studies and recommended use of both measures to define hypopneas. In summary, in this study, although no misclassification occurred using different thresholds for a positive or a negative home study, a large proportion of patients would require additional testing. The study suggested a 42% saving in diagnostic costs over polysomnography if this approach were adopted.

Golpe et al (2002) enrolled 55 patients in their prospective case home study to determine the clinical utility of a limited sleep-recording device used unsupervised in the patient's home, compared with in-laboratory, fully supervised polysomnography for the diagnosis of sleep apnea/hypopnea syndrome (SAHS), and to assess its impact on costs. Patients were studied first in their homes with the limited sleep-recording device, a Type 4 device (Apnoescreen) that recorded body position, wrist

actimetry, pulse oximetry, pulse rate, and oronasal airflow by thermistry. Polysomnography was performed within 30 days of the first study. Both studies were read by independent investigators blinded to the results of the other study. Diagnoses and therapeutic decisions regarding the use of continuous positive airway pressure obtained from the home and laboratory studies were compared. One half of the home studies were randomly assigned to be performed with a sleep technician's set up of the equipment in the patient's home (group 1), and the other half with the patient's own setup of the sleep-recording device (group 2), after an instruction period in the hospital. An economic analysis was performed, considering the cost of repeating studies in cases with faulty or inconclusive home studies, that is, patients who should undergo polysomnography as a second step. Seven percent of the home studies in group 1, and 33% in group 2 produced no interpretable data because of artifacts. Sixteen percent of the home study findings were inconclusive. The diagnosis obtained from the limited sleep-recording device and polysomnography agreed in 75% of the interpretable home studies (89%, if inconclusive home studies were excluded). They found that the cost per study of home study recordings was less expensive than that of polysomnography, without or without intervention of the technician in the patient's home. The researchers deduced that home sleep studies are a viable form of diagnosing SAHS, and are less expensive than polysomnography. Intervention of a sleep technician in the patient's home was the least expensive strategy, because of the high percentages of faulty studies with the patient's own setup of the equipment, when using the limited sleep-recording device.

### **Scientific Rationale – Update February 2006**

Narcolepsy is a chronic neurological disorder, characterized by excessive daytime sleepiness, usually accompanied by cataplexy (attacks of weakness on emotional arousal). These symptoms are often associated with the intrusion into wakefulness of other elements of rapid eye movement sleep, such as sleep paralysis and hypnagogic hallucinations. There is at present no single definitive diagnostic test for narcolepsy. The investigations which have proved most useful in the assessment of patients with suspected narcolepsy, and which have the potential to support or cast doubt on the diagnosis, include tests of daytime sleepiness (the multiple sleep latency test [MSLT] and the maintenance of wakefulness test) and nocturnal polysomnography.

According to Littner et al. Practice parameters for the treatment of narcolepsy: an update for 2000:

“For patients suspected of having narcolepsy, an all-night polysomnogram is done primarily to ascertain the presence of concurrent sleep disorders and is followed immediately by a multiple sleep latency test (MSLT) to help confirm the diagnosis.”

Guidelines on the diagnosis and management of narcolepsy in adults and children. Evidence-based guidelines for the UK with graded recommendations (2002) states:

"Polysomnography, with assessment of respiration and of limb movement, has the advantage that it both measures sleep duration before multiple sleep latency testing and excludes other sleep disorders. In addition, a short latency to rapid eye movement sleep on the overnight polysomnogram can be included as further evidence for narcolepsy in the presence of a borderline multiple sleep latency test result. Other nonspecific abnormalities on overnight polysomnography consistent with, but not pathognomonic for, narcolepsy include

shortened sleep latency, an increased number of awakenings and a reduced amount of slow wave sleep. A long sleep duration with an increased proportion of slow wave sleep and few arousals in conjunction with confirmed excessive daytime sleepiness on multiple sleep latency testing is more suggestive of idiopathic CNS hypersomnolence. In patients where a second sleep disorder such as obstructive sleep apnea is not suspected, it may be sufficient to document the duration of sleep with a polysomnogram set up to allow sleep staging only and this may be performed at home."

### **Scientific Rationale – Update April 2005**

Obstructive sleep apnea (OSA) continues to be a major public health hazard affecting 2-4% of the adult population; only 10% of these patients are recognized by healthcare providers. In the last decade the number of referrals for sleep studies has increased 12-fold, and is expected to increase even more in the coming years. This constant demand for sleep studies is beyond the current capacity of sleep laboratories, thus preventing diagnosis for most patients with suspected OSA. Since sleep studies remain the gold standard for diagnosis of OSA, resources should be allocated to increasing the volume of beds for these studies in order to increase access to diagnosis and treatment, which in turn provides better quality of life, saves scarce resources of the healthcare system, prevents unnecessary accidents and increases workers' productivity.

The term upper airway resistance syndrome (UARS) was coined to describe a group of patients who did not meet the criteria for diagnosis of obstructive apnea-hypopnea syndrome and thus were left untreated. Today, most of the patients with UARS remain undiagnosed and are left untreated. Today, the clinical picture of UARS is better defined. We have learned that patients usually seek treatment with a somatic functional syndrome rather than sleep-disordered breathing or even a disorder of excessive daytime sleepiness. Therefore, most of these patients are seen by psychiatrists. In addition, recent technologic advances have allowed a better recognition of the problem. We have learned that obstructive apnea-hypopnea syndrome is associated with a local neurologic impairment that is responsible for the occurrence of the hypopnea and apneas. In contrast, patients with UARS have an intact local neurologic system and have the ability to respond to minor changes in upper airway dimension and resistance to airflow. Even though CPAP is not indicated for this population, new treatment options including internal jaw distraction osteogenesis are used and are promising for treatment of patients with UARS.

### **Scientific Rationale - Initial**

Sleep apnea refers to a collection of conditions and syndromes that have periods of apnea, a temporary cessation of breathing, as key occurrences. Over the years, various sleep apnea syndromes have been described and classified into three main types: (1) central; (2) obstructive; and (3) mixed. Central sleep apnea refers to apnea syndromes with origins in the central nervous system. Obstructive sleep apnea (OSA) refers to apnea syndromes due primarily to collapse of the upper airway during sleep. Mixed apnea refers to apnea with both central and obstructive characteristics. The prevalence of OSA in the United States has been estimated to be about 2-4% of middle age adults.

OSA is the type that has received the most scientific study as regards pathogenesis and pathophysiology. During sleep, the upper airway becomes occluded, resulting in

an episode of apnea. As a result of the apnea, the patient experiences a brief arousal from sleep. With the return of breathing, the patient typically returns to sleep quickly. This sequence is repeated over and over. The pharynx has been identified as the primary site of obstruction in most patients. A number of anatomical and functional factors, such as negative oropharyngeal pressure, decreased muscle activity, and possible narrowing of the oropharyngeal lumen, may also be involved in the collapse of the upper airway during sleep.

Hypopnea (episodes of reduced ventilation) have also received considerable attention and clinical consideration. While it has been shown that hypopneas can be scored reproducibly, variations in the definition of hypopnea have been common. Although there are no specific randomized, controlled trials evaluating the validity of using hypopnea as a diagnostic criterion for OSA in terms of health outcomes, the use of hypopnea appears to have been accepted as current standard of practice. This is apparent in the widespread use of the AHI as documented in the methodology of the relevant trials.

Sleep studies, or polysomnographs, refer to the continuous process of monitoring and recording a variety of physiological body functions during sleep, such as the electrical activity of the brain, eye movement, muscle activity, heart rate, respiratory effort, air flow, and blood oxygen levels. These tests are used both to diagnose sleep apnea and to determine its severity. They are scored according to how many times per hour the patient stops breathing for more than 10 seconds (apnea), or almost stops breathing (hypopnea). Hypopnea is defined as either a 33% reduction in thoracoabdominal movement or airflow for at least 10 seconds or a 4% or greater decrease in oxygen saturation while the patient is still breathing. The apnea-hypopnea index (AHI), which has been utilized extensively in recent years in the published literature, is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep recorded by polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected). Some facilities use the term respiratory distress index (RDI) to describe a calculation that includes other sleep disturbances such as leg movement, snoring, respiratory event related arousals (RERAs). An index that does not score apneas and hypopneas separately from other sleep disturbance can be very misleading in coming up with an accurate diagnosis. Most of the times, only one split overnight polysomnogram is needed to confirm a diagnosis of OSA syndrome and titrate CPAP to the most efficacious level to eliminate or significantly reduce episodes of apnea and hypopnea; sometimes, however, a second polysomnogram may be required to adjust the CPAP device, and an additional polysomnogram may be necessary for evaluating treatment response and making subsequent treatment management decisions. More than three polysomnograms in a 12-month period is almost never indicated.

With the finding that obstructive sleep apnea (OSA) is a common disorder, it has become apparent that performance of standard, in-laboratory polysomnography by sleep laboratories and centers will not be able to address the diagnostic requirements mandated by this public health problem. This has led to the development of various portable recording devices that can be used at home for the diagnosis of sleep apnea. Portable recordings are those that may be conducted outside of the sleep laboratory environment, either in the patient's home or, in the case of hospitalized individuals, in their room (including the intensive care unit). This new technology has generated significant controversy, and unfortunately too much effort has focused on whether full polysomnography or portable recordings are the

"best" test for the diagnosis of OSA. For the moment, portable recordings should be regarded as basically unreliable, making a full-attended polysomnography in a facility the best test to rule in or out significant sleep apnea. Medical treatments for an AHI > 5 include weight loss, positioning instruction, and oral appliances. Some medications have been tried, but seem to have a minimal effect on the number of episodes. On average, a 10% weight loss produces an improvement of 50% in the AHI. Oral appliances act by holding the mandible and tongue forward during sleep. While this does not result in a cure, it can reduce the AHI. Positive pressure devices used for the treatment of OSA include CPAP, BiPAP, and AutoPAP.

CPAP involves the administration of air usually through the nose by an external device at a fixed pressure to maintain the patency of the upper airway. BiPAP is similar to CPAP but the devices are capable of generating two adjustable pressure levels. Instead of providing air at a constant, steady pressure all night, the machine "senses" inspiration from expiration and varies its level of pressure accordingly. On inspiration, a higher pressure is needed to prevent apneas and hypopnea, but when a person breathes out they may feel more comfortable if there is less resistance. In the belief that the reduction of total airway flow would provide greater comfort to the patient and encourage patients to use the airway pressure treatment on a regular basis, several manufacturers have begun to offer a new generation of treatment devices. These devices incorporate flow and pressure sensors and automatic regulation systems. There are three basic 'smart' PAP approaches. AutoPAP devices that either vary the pressure delivered, providing less when problems are absent, and raising the pressure gradually when problems appear, or gradually raises and lowers the pressure as conditions require (it monitors, among other parameters, the flow), but also changes the pressure within a specific breath if an emerging problem is detected. DPAP (demand positive airway pressure) tries to keep overall pressure requirements low by using high pressure only when there is a specific problem, but this requires a very rapid increase in pressure when a problem is detected. This device is no longer manufactured.

There have been numerous studies published on OSA and CPAP. The scientific evidence, knowledge base and standards of practice have evolved considerably. The use of the AHI in determining when to treat OSA has become common in the reported literature. However, the threshold level used for initiating treatment has varied across studies. Although there are numerous studies on obstructive sleep apnea and CPAP, no randomized, controlled trial specifically evaluate or compare diagnostic criteria in relationship to health outcomes. However, since there were many related clinical trials on OSA and CPAP, indirect evidence on definitions of OSA may be extracted from the methodology of these published trials.

Three population-based or prospective cohort studies have evaluated the association between sleep apnea and hypertension and have concluded that sleep-disordered breathing was associated with systemic hypertension in middle-aged and older individuals and that the odds of hypertension and consequent cardiovascular morbidity increased with increasing AHI. Two randomized, controlled trials have evaluated CPAP for relief of symptoms in patients with mild OSA. These researchers have found that more individuals in the CPAP group had improvements in outcomes on daytime symptoms, mood and functional status compared to conservative therapy (nasal dilator). They concluded that treatment with CPAP is indicated for patients with an RHI of 5 to 30 events per hour accompanied by symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, or documented cardiovascular diseases to include hypertension, ischemic heart disease

or stroke. They defined apnea as the cessation of airflow  $\geq 10$  seconds and hypopnea as a recognizable, transient reduction of breathing with  $\geq 50\%$  decrease in the amplitude of a validated measure of breathing or a  $< 50\%$  amplitude reduction that is associated with either an oxygen desaturation of  $\geq 3\%$  or an arousal. The authors also reported that treatment with CPAP is not indicated for asymptomatic patients without cardiovascular diseases who demonstrate mild OSA on diagnostic polysomnography. Concerning BiPAP, the authors noted that a trial of bilevel PAP may be indicated for OSA patients who cannot tolerate CPAP due to persistent massive nasal mask air leakage or discomfort exhaling against positive pressure.

Although there are no specific randomized, controlled trials that evaluated diagnostic criteria of OSA and the use of hypopnea, there are a myriad of clinical trials on CPAP and OSA. Using the most current clinical trials, it is possible to adopt an up to date set of diagnostic criteria. In 2001, the American Academy of Sleep Medicine (AASM) released a position statement that addressed hypopnea and sleep-disordered breathing. AASM reported that "it is currently standard in clinical practice and epidemiologic studies to assess the severity of sleep-disordered breathing by combining the number of apneas and hypopneas per hour of sleep in an index called the apnea-hypopnea index (AHI) or the respiratory disturbance index (RDI)." In addition, the American Academy of Sleep Medicine has recently proposed a standard definition for hypopnea based on one of the largest trials on OSA, the Sleep Heart Health Study (SHHS). In the SHHS, hypopnea was defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation. This definition incorporates thoracoabdominal movement and desaturation since these two factors have been found to be reproducible and measurable during sleep studies. The American Thoracic Society has also recommended the same definition of hypopnea.

Based on review of the recent literature and supported by several evidence-based professional consensus statements, an AHI  $\geq 15$  per hour, regardless of symptomatology, should be considered the lowest value for moderate to severe OSA. An AHI  $\geq 15$  without symptoms is also based on reasonably strong epidemiologic evidence that this condition increases the risk of hypertension and cardiovascular morbidity. For patients with symptoms, three randomized, controlled trials have demonstrated that CPAP improves daytime symptoms and functioning, even for patients with mild OSA (AHI  $\geq 5$ ). BiPAP devices have been considered similar to CPAP devices since both types of devices produce positive airway pressure and appear to have similar indications for use. Although BiPAP is similar to CPAP in terms of patient complaints and usage, less treatment discontinuation (dropouts) has been demonstrated to occur. This seems to be reflected in current practices as the use of BiPAP has been reserved for patients who have not responded or tolerated standard CPAP.

Intraoral devices used to treat OSA include three basic designs: mandibular repositioners, tongue retaining devices, and palatal lifting devices. All of these devices change the position of the tongue and mandible leading to increased pharyngeal space, thus improving the patient's ability to exchange air. Some oral appliances are custom-fitted by a dental laboratory, whereas others are prefabricated units that are adapted in a clinician's office. A task force of the Standards of Practice Committee of the American Sleep Disorder Association concludes that, despite the considerable variation in the design of these devices,

their clinical effects in improving OSA have been consistent. These devices have been shown to be ineffective in the treatment of central sleep apnea.

In one 2002 report, long-term use of a dental device achieved an 81% success rate, which was significantly higher than the 53% success rate noted for uvulopalatopharyngoplasty (UPPP), the standard surgical treatment. There were also few complications with the dental device. Side effects have been reported including nighttime pain, dry lips, tooth discomfort, and excessive salivation. In general, these side effects are mild, although over the long term, nearly half of patients stop using them. Devices made of softer materials may produce fewer side effects. In some cases of long-term use, permanent changes in the position of the teeth or jaw have occurred. Periodic check-ups with a health professional are advised.

### Review History

September 23, 2003	Medical Advisory Council initial approval Subject Matter Consultant: Mark Saberman, MD (ENT specialist)
April 2005	Update - Revisions
February 2006	Revision – witnessed apnea removed and replaced by witnessed snoring, PSG medically necessary for narcolepsy
April 2006	Criteria for NovaSom OSG developed
March 2007	Coding Updates
April 2007	Update – revised criteria for initial sleep study in adult-added criteria for sleep study in children
August 2007	Update – Added obesity hypoventilation syndrome and obesity hypoventilation syndrome with coexisting obstructive sleep apnea-hypopnea unresponsive to CPAP as medically necessary indications for BiPAP or VPAP.
November 2007	Note added under CPAP stating that a trial of nasal CPAP as a method to diagnose sleep apnea is considered investigational and therefore not medically necessary due to lack of evidence in the published peer review literature supporting the use of CPAP for diagnostic purposes.
September 2008	Added the OSA diagnostic devices with current FDA 510(K) approval to the policy. This includes Stardust II, Somte' Patient Recording System in addition to NovaSom OSG or QSG, which was already noted in the policy.
October 2008	Revised policy to include dual therapy with CPAP and mandibular appliance as not medically necessary.
March 2009	Revised to allow unattended sleep studies when criteria is met and for CPAP to be consistent with Medicare policy.
December 2009	Update. Added the Provent nasal device as investigational since there is insufficient evidence at this time to support the safety, efficacy, and long-term outcomes of the use of this nasal expiratory resistance device in the treatment of OSA. Codes reviewed.
April 2010	Updated scientific rationale with information regarding the ApneaLink screening tool (a nocturnal pulse oximetry device)
April 2011	Update. Added Medicare Table with LCDs and articles. No revisions.

### **This policy is based on the following evidence-based guidelines:**

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#### **Important Notice**

##### **General Purpose.**

Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described in this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

##### **Policy Effective Date and Defined Terms.**

The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. \* In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

##### **Policy Amendment without Notice.**

Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

##### **No Medical Advice.**

The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

##### **No Authorization or Guarantee of Coverage.**

The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

##### **Policy Limitation: Member's Contract Controls Coverage Determinations.**

The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. Coverage decisions are the result of the terms and conditions of the Member's benefit contract. The Policies do not replace or amend the Member's contract. If there is a discrepancy between the Policies and the Member's contract, the Member's contract shall govern.

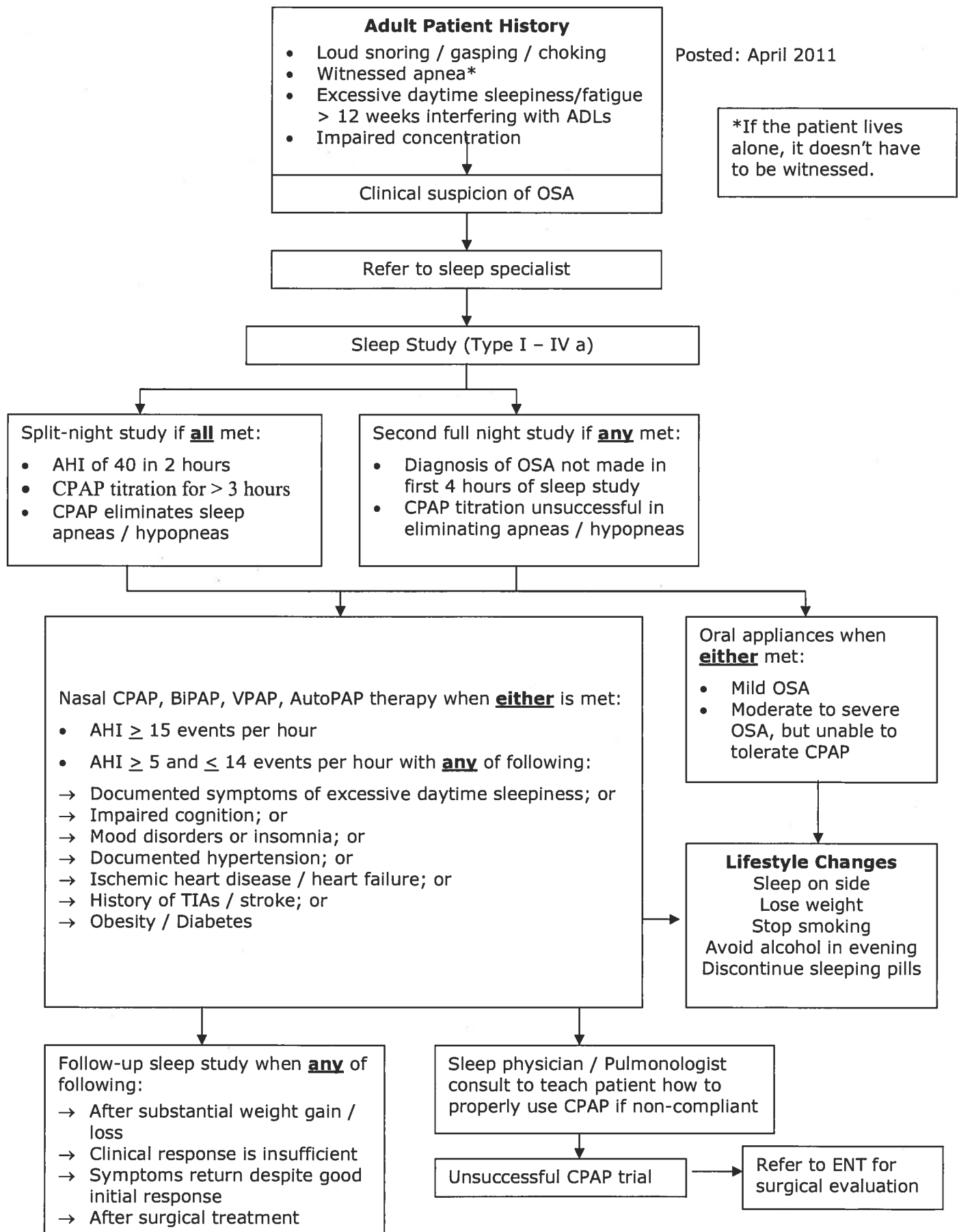
##### **Policy Limitation: Legal and Regulatory Mandates and Requirements.**

The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

**Policy Limitations: Medicare and Medicaid.**

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.

Posted: April 2011



\*If the patient lives alone, it doesn't have to be witnessed.