

Diagnosis and Treatment Services for Obstructive Sleep Apnea (OSA) and Upper Airway Resistance Syndrome (UARS)	
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Description

Obstructive sleep apnea syndrome (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. Obstructive sleep apnea is often suspected on the basis of the patient's clinical history and physical appearance (i.e., obesity), as well as at the urging of a bed partner observing habitual, disruptive snoring and episodes of gasping for breath or cessation of breathing at night. Patients may complain of excessive fatigue, daytime drowsiness or falling asleep while engaged in activities. The severity of OSA is determined by symptoms, frequency of obstructions and degree of desaturation.

Upper airway resistance syndrome (UARS) is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort required results in multiple sleep fragmentations as measured by very short alpha electroencephalographic (EEG) arousals.

Polysomnography is a multi-channel recording of sleep and breathing that is used to diagnose OSA or UARS and other causes of sleep disruption. There are a variety of sleep studies available; however a complete in-laboratory polysomnography is the gold standard for the diagnostic evaluation of OSA or UARS. Polysomnography is distinguished from sleep studies by the inclusion of sleep staging, multiple physiologic variables including EEG, and a sleep technician in attendance.

Behavioral therapy including weight loss and repositioning of the body during sleep may assist in resolving symptoms of OSA/UARS however, non-surgical treatment including continuous positive airway pressure (CPAP) and intraoral appliances may be required. If these conservative procedures fail or are not tolerated, surgical therapy such as adenotonsillectomy, or more complex procedures such as uvulopalatopharyngoplasty (UPPP) or maxillary-mandibular advancement may be indicated.

This medical policy addresses polysomnography, portable/home sleep studies, multiple sleep latency testing (MSLT), actigraphy, medical treatment and surgical procedures as they relate to the specific diagnoses of OSA and UARS. Snoring without the diagnosis of OSA is also discussed.

Policy

I. Diagnosis of OSA/UARS

Polysomnography in a Sleep Laboratory

Supervised polysomnography performed in a sleep laboratory may be considered **medically necessary** as a diagnostic test in patients with **any** of the following clinical presentations:

- Observed apneas during sleep
- Moderate or severe congestive heart failure, stroke/transient ischemic attack, coronary artery disease, or significant tachycardic or bradycardic arrhythmias who have nocturnal symptoms suggestive of a sleep related breathing disorder (i.e., frequent awakenings, gasping, choking) or otherwise suspected of having sleep apnea
- A combination of at least **two** of the following:
 - Excessive daytime sleepiness or fatigue evidenced by an Epworth Sleepiness Scale greater than 10, inappropriate daytime napping (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions
 - Habitual snoring or gasping/choking episodes associated with awakenings at night
 - Unexplained hypertension
 - A body mass index greater than 35 kg/m²
 - Craniofacial or upper airway soft tissue abnormalities
 - In children, symptoms may include habitual (nightly) snoring (often with intermittent pauses, snorts, or gasps), disturbed sleep, and daytime neurobehavioral problems (i.e., hyperactivity) rather than daytime sleepiness

A **split-night** in-laboratory **polysomnography** (PSG) study in which severe OSA/UARS is documented during the first half of the study using PSG, followed by a CPAP trial during the second half of the study, is considered **medically necessary** when **either** of the following criteria is met:

- An Apnea/Hypopnea Index (AHI) of 20-40 with symptoms indicative of significant OSA (e.g., repetitive long obstructions, major oxygen desaturations)

- An Apnea/Hypopnea Index (AHI) of at least 40 is documented during a minimum of two hours in the first half of the night of the diagnostic polysomnography

Two separate night in-laboratory polysomnography studies, one night for the diagnosis of sleep disorders and the second night to titrate CPAP, are considered **not medically necessary** if the above criteria were met in the first half of the first night polysomnography study. Circumstances where repeat in-laboratory polysomnography or split-night polysomnography may be considered **medically necessary** are listed below.

Repeat Supervised Polysomnography in a Sleep Laboratory

A repeat supervised polysomnography (PSG) performed in a sleep laboratory may be considered **medically necessary** in **one** of the following circumstances:

- To initiate and titrate CPAP in **adult** patients (age 18 or over) with clinically significant OSA/UARS when **one** of the following criteria is met:
 - An Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of at least 15 events per hour
 - An AHI or RDI greater than or equal to five, and less than or equal to 14 events per hour with documentation demonstrating **any** of the following symptoms or conditions:
 - Excessive daytime sleepiness
 - Impaired cognition, mood disorders or insomnia
 - Hypertension
 - Cardiac arrhythmias
 - Ischemic heart disease
 - History of stroke
- To initiate and titrate CPAP in **children** (under age of 18) with clinically significant OSA/UARS when the following is met:
 - An AHI \geq 1.0
- CPAP titration after a split-night PSG study; when the positive airway pressure (PAP) titration portion of the original study was insufficient (e.g., less than 3 hours of titration or failure to effectively eliminate respiratory events)
- Failure of resolution of symptoms or recurrence of symptoms during treatment
- To assess the efficacy of upper airway surgery (usually should be delayed 6-8 weeks postoperatively)
- To assess the efficacy of intraoral appliances
- To reevaluate the diagnosis of OSA and need for CPAP retitration or continuation in **either** of the following situations:
 - Significant weight loss or weight gain
 - Changes in OSA/UARS symptoms

Note: Polysomnography may also be performed in patients with symptoms suggestive of narcolepsy (excessive sleepiness, cataplexy, sleep paralysis and sleep-related hallucinations), unrefreshing sleep with daytime fatigue/sleepiness but without snoring or witnessed apneas, obesity hypoventilation syndrome (obesity with poor breathing, leading to hypoxia and hypercarbia), parasomnias, periodic limb movements during sleep, sleep related seizure disorder,

and neuromuscular disorders with sleep-related symptoms. This policy does not address these conditions.

Home/Portable Sleep Studies

Unattended portable PSG, home sleep studies or overnight oximetry studies done in the home are considered **investigational** for the diagnostic evaluation or assessment of OSA or UARS.

Multiple sleep latency testing (MSLT)

Multiple sleep latency testing (MSLT) is considered **medically necessary** only when used to exclude or confirm suspected narcolepsy in the diagnostic workup of OSA/UARS.

Other Procedures

The following devices or procedures for the diagnostic evaluation or assessment of OSA/UARS are considered **not medically necessary**, including but not limited to, the following:

- Watch PAT™
- Nap Studies
- SleepStrip™
- Diagnostic Audio Recording
- MSLT when performed in the routine diagnosis of OSA/UARS
- Maintenance of Wakefulness Test (MWT)

Actigraphy, a technique to record and analyze body movement, is considered **investigational** in the diagnostic evaluation or assessment of OSA/UARS.

II. Medical Management of OSA/UARS

Continuous positive airway pressure (CPAP)

Continuous positive airway pressure (CPAP) for **adults** (18 years or older) may be considered **medically necessary** for the treatment of:

- Obstructive Sleep Apnea (OSA) when **one** the following criteria are met:
 - o An AHI or RDI of at least 15 events per hour
 - o An AHI or RDI greater than or equal to five, and less than or equal to 14 events per hour, with documentation demonstrating **any** of the following symptoms or conditions:
 - Excessive daytime sleepiness
 - Impaired cognition, mood disorders or insomnia
 - Hypertension
 - Cardiac arrhythmias
 - Ischemic heart disease
 - History of stroke
- Upper Airway Resistance Syndrome (UARS) when **one** of the following criteria are met:
 - o Greater than 10 EEG arousals per hour of sleep associated with increased respiratory efforts (or reduced intrathoracic pressures)
 - o Presence of increased negative intrathoracic pressures (i.e., more negative than 10 cm) measured by an esophageal manometer

Note: The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram.

Continuous positive airway pressure (CPAP) for **children** (under age 18) may be considered **medically necessary** for the treatment of OSA/UARS when **both** of the following criteria are met:

- Documentation of a diagnosis of OSA/UARS and PSG demonstrates an apnea index (AI) or apnea-hypopnea index (AHI) equal to or greater than 1.0 event per hour
- **One** of the following circumstances:
 - o Adenotonsillectomy is delayed
 - o Adenotonsillectomy is contraindicated
 - o Adenotonsillectomy is unsuccessful in relieving symptoms of OSA/UARS

Auto-adjusting CPAP (APAP)

Auto-adjusting CPAP (APAP), as an alternative to CPAP, may be considered **medically necessary** in adult patients with OSA/UARS when **all** of the following are documented:

- Supervised polysomnography (PSG) in a sleep lab was performed
- CPAP criteria met
- **One** of the following:
 - o CPAP trial failure
 - o Demonstrates intolerance to the pressures of standard CPAP therapy either at the time of CPAP titration or during a 2-week trial

Bilevel positive airway pressure (BiPAP)

Bilevel positive airway pressure (BiPAP), without a back up rate, may be considered **medically necessary** in adult patients with OSA/UARS when **all** of the following are documented:

- Supervised polysomnography (PSG) in a sleep lab was performed
- CPAP criteria met
- CPAP, or APAP trial failure or intolerance

Bilevel positive airway pressure (BiPAP) with a back up rate is considered **not medically necessary** for the treatment of Obstructive Sleep Apnea or Upper Airway Resistance Syndrome.

Accessories and Supplies for Positive Airway

The following accessories and supplies are considered **medically necessary** for patients who meet the criteria for a positive airway pressure airway device as described above (this may not be an all inclusive list):

- Full face mask
- Face mask interface, replacement for full mask
- Replacement cushions and pillows for nasal application device
- Nasal interface, mask or cannula type
- Oral interface
- Headgear
- Chinstrap
- Tubing

- Disposable or non-disposable filters
- Heated or non-heated humidifier
- Exhalation port/Whisper valve

Note: Blue Shield of California (BSC) follows the Medicare Durable Medical Equipment Regional Carrier (DMERC) rules with respect to the usual medically **necessary** quantity of supplies for positive airway devices. See DMERC Policy on Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea; Local Coverage Determinations (LCD) (L171).

Intraoral Appliances

A prescription tongue-retaining device or a mandibular repositioning device, also referred to as a mandibular advancement appliance (MAA), or mandibular advancement splint (MAS), as an alternative to CPAP, may be considered **medically necessary** in adult patients when **all** of the following are met:

- CPAP criteria met
- The device meets **all** of the following:
 - Prescribed and recommended by a sleep disorders specialist Medical Doctor (MD) or Doctor of Osteopathic (DO) Medicine
 - Has United States (U.S.) Food and Drug Administration (FDA) 510(k) clearance
 - Laboratory fabricated and custom made for jaw repositioning

Oral appliances/devices that can be fitted by the patient themselves are considered **not medically necessary**.

Over the counter (OTC) oral appliances that can be obtained without a prescription are **not a covered benefit**.

III. Surgical Management of OSA/UARS

Uvulopalatopharyngoplasty (UPPP), Palatopharyngoplasty (PPP), or Maxillomandibular osteotomy and advancement (MMO or MMA), with or without inferior sagittal mandibular osteotomy (ISO) and genioglossal (tongue) advancement with hyoid myotomy and suspension (GAHM) is considered **medically necessary** for the treatment of patients with Obstructive Sleep Apnea Syndrome (OSAS) and UARS when **all** of the following diagnosis specific criteria are met:

- Obstructive Sleep Apnea (OSA) when **both** of the following diagnosis specific criteria are met:
 - Clinically significant OSA defined as **one** of the following:
 - An AHI or RDI of at least 15 events per hour
 - An AHI or RDI greater than or equal to five, and less than or equal to 14 events per hour with documentation demonstrating **any** of the following symptoms or conditions:
 - Excessive daytime sleepiness
 - Impaired cognition, mood disorders or insomnia
 - Hypertension

- o Cardiac arrhythmias
 - o Ischemic heart disease
 - o History of stroke
- o Continued sleep apnea after a trial of CPAP and **one** of the following:
 - CPAP failure
 - CPAP not tolerated
- Upper Airway Resistance Syndrome (UARS) when **both** of the following diagnosis specific criteria are met:
 - o Clinically significant upper airway resistance syndrome (UARS) defined as **one** of the following:
 - Greater than 10 EEG arousals per hour of sleep associated with increased respiratory efforts (or reduced intrathoracic pressures) on polysomnogram
 - Presence of increased negative intrathoracic pressures (i.e., more negative than 10 cm) measured by an esophageal manometer
 - o Continued UARS after a trial of CPAP and **one** of the following:
 - CPAP failure
 - CPAP not tolerated

Note: The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram

Radiofrequency Volumetric Tissue Reduction (RFVTR) of the soft palate, uvula or tongue base (e.g., Somnoplasty and Coblation) is considered **medically necessary** through August 17, 2009 when **all** of the following criteria are met:

- Arterial oxygen saturation less than 90%
- Respiratory Disturbance Index (RDI) greater than 20
- If the RDI is 20 or less, concurrent medical problems and medical necessity are required

Radiofrequency Volumetric Tissue Reduction (RFVTR) of the soft palate, uvula or tongue base (e.g., Somnoplasty and Coblation) is considered **investigational** as of August 18, 2009.

The following surgical procedures or services for the treatment of obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) are considered **investigational**:

- Laser-Assisted Uvulopalatoplasty (LAUP)
- Palatal procedures including but not limited to palatal injections, palatal stiffening, and alternative palatal flaps (e.g., Cautery-Assisted Palatal Stiffening Operation (CAPSO), Pillar™ Palatal Implant System)
- Tongue procedures including but not limited to, the Repose™ Bone Screw system
- Cardiac (Atrial) Pacing

Snoring

Snoring in the absence of documented obstructive sleep apnea is not considered a medical condition; therefore any surgical procedure, service or device for the treatment of snoring in the absence of documented obstructive sleep apnea is considered **not medically necessary**.

Policy Guidelines

Polysomnography

The following Polysomnography (in a sleep laboratory) Current Procedural Terminology (CPT) codes that apply to the Medically Necessary criteria above for OSA/UARS include:

- **95808:** Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
- **95810:** Polysomnography; sleep staging with four or more additional parameters of sleep, attended by a technologist
- **95811:** Polysomnography; sleep staging with four or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist

Home/Portable Sleep Studies

The following Sleep Study CPT codes do not meet the Medically Necessary criteria required for the Diagnosis of OSA/UARS because both do not include an EEG. In addition, 95806 is unattended and unsupervised. Both an EEG and attendance by a technologist are required for Sleep Staging for the diagnosis of OSA/UARS:

- **95806:** Sleep Study, simultaneous recording of ventilation, respiratory effort, electrocardiogram (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

The following Healthcare Common Procedure Coding System (HCPCS) codes created by Medicare are considered investigational for the diagnosis of OSA/UARS because they are portable sleep studies and are unattended:

- **G0398:** Home sleep study test (HST) with type II portable monitor, unattended; minimum of seven channels: EEG, electromyography (EMG), ECG/heart rate, airflow, respiratory effort and oxygen saturation
- **G0399:** Home sleep test (HST) with type III portable monitor, unattended; minimum of four channels: two respiratory movement/airflow, one ECG/heart rate and one oxygen saturation
- **G0400:** Home sleep test (HST) with type IV portable monitor, unattended; minimum of three channels

CPAP

Examples of Failed CPAP that should be documented in the medical record include but are not limited to:

- Claustrophobia
- Inability to breathe through the nose
- Patient intolerance
- Discomfort or pain
- Patients requiring high pressures of CPAP (>10 cm H₂O) complaining of pressure discomfort

Note: There is one HCPCS code identifying a CPAP device; E0601. There are two HCPCS codes for a BiPAP device; E0470 and E0471. The HCPCS codes do not distinguish among fixed CPAP or BIPAP devices and APAP devices.

Intraoral Appliances

Note: Intraoral appliances for mandibular advancement or positioning are also known as: Mandibular advancement appliances (MAA), Mandibular advancement splint (MAS), Mandibular repositioning devices (MRD), and Mandibular advancement devices (MAD).

Common laboratory fabricated mandibular repositioning devices (MRD) with FDA 510K clearance (as of 03/06/2009; not an all inclusive list)

- TAP I[®], TAP II[®], TAP Titanium[®] (Thornton Adjustable Positioner)
- OASYS[™]
- SommoMed MAS
- Adjustable PM (APM) Positioner[™], APM Ultra
- Klearway Oral Appliance
- Silent Nite[®]
- Full-Breath Solution (FBS)

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found at the following Web site or by clicking on the link below:

http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Rationale

I. Diagnosis of OSA/UARS

Obstructive sleep apnea (OSA) also referred to as obstructive sleep apnea syndrome (OSAS) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. OSA occurs in persons of all ages and its incidence increases with age. Studies indicate that 2%-4% of adult Americans have the disease and that OSAS is as common as asthma. The American Sleep Apnea Association research indicates that up to 12 million Americans may have OSA and 10 million remain undiagnosed. While the initial description of OSA was in obese, middle age males, women now account for a third of OSA patients.

Obstruction anywhere along the upper airway can result in apnea. Apnea is defined as a complete cessation of airflow at the nose and mouth that lasts at least 10 seconds. Hypopnea is defined as a partial (30-50%) decrease in airflow that lasts at least 10 seconds and is often associated with a decrease in oxygen saturation of 4% or higher.

The hallmark clinical symptom of OSA is excessive snoring. Snoring abruptly ceases during apneic episodes and the brief period of patient arousal and then resumes when the patient again falls asleep. Sleep fragmentation associated with repeated arousal during sleep causes excessive

daytime sleepiness that can lead to impairment of almost any daytime activity. Furthermore, patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or heavy equipment. In addition, excessive daytime sleepiness indirectly affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to daytime sleepiness.

Upper airway resistance syndrome (UARS) is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort required results in multiple sleep fragmentations as measured by very short electroencephalographic (EEG) arousals. Snoring may not be a feature of UARS. The resistance to airflow is typically subtle and does not result in apneic or hypopneic events. However, it does result in increasingly negative intrathoracic pressure during inspiration, which can be measured using an esophageal manometer as an adjunct to a polysomnogram. Therefore, this diagnosis rests on polysomnographic documentation of >10 EEG arousals per hour of sleep correlated with episodes of reduced intrathoracic pressures.

Obstructive sleep apnea is often suspected on the basis of the clinical history and physical appearance. A detailed medical history includes information on current medications and the use of alcohol or sedatives before bedtime. A physical exam includes an assessment for known risk factors for OSA. The strongest risk factors for OSA are obesity (body mass index (BMI) of more than 30), a neck circumference greater than 17 inches in men or 16 inches in women and nasopharyngeal crowding. Some patients present with anatomic risk factors including a deviated septum, nasal polyps, enlarged uvula and soft palate, enlarged tonsils and hypertrophy of the lateral pharyngeal musculature or a variety of craniofacial abnormalities, including micrognathia (undersized jaw), retrognathia (overslung or jutting lower jaw), or maxillary hypoplasia (abnormally small maxilla). Patients with OSA appear to be unable to maintain oropharyngeal muscle dilator activity during sleep sufficient to prevent airway collapse during negative pressure of inspiration. Apneas and hypopneas are common during rapid eye movement (REM) sleep, as the muscles completely relax. When the pharyngeal muscles relax, the palate may fall backward, and relaxation of the genioglossus muscle at the base of the tongue allows the tongue to fall backward, occluding the airway. The apneic event ends by a brief arousal to wakefulness or a lighter stage of sleep, which is accompanied by activation of the upper airway dilator and abductor muscles and restoration of airway patency and other physiologic responses.

The risk for OSA correlates on a continuum with obesity, large neck circumference, and hypertension (ICSI 2008). The most common symptoms are snoring (habitual and intense), and excessive daytime sleepiness. Excessive daytime sleepiness may be subjective, and may be assessed by questionnaires such as the Epworth Sleepiness Scale (ESS); a short self-administered questionnaire that asks patients their likelihood of falling asleep in eight situations ranked from 0 (would never doze) to three (high chance of dozing). The maximum score on the ESS is 24 and a score of 10 or below is considered normal. The eight situations are as follows:

- Sitting and reading

- Watching TV
- Sitting inactive in a public place, i.e., theater
- As a passenger in a car for one hour without a break
- Lying down to rest in the afternoon when circumstances permit
- Sitting and talking with someone
- Sitting quietly after lunch without alcohol
- In a car, while stopped for a few minutes in traffic

Multiple Sleep Latency Test (MSLT)/ Maintenance of Wakefulness Test (MWT)

Daytime sleepiness may also be measured objectively with tests such as the multiple sleep latency test (MSLT) or the maintenance of wakefulness test (MWT). The MSLT is a measure of how quickly the patient falls asleep when instructed to relax in a quiet and dimly lit room. The MSLT is not routinely indicated in the initial evaluation and diagnosis of obstructive sleep apnea syndrome (OSAS), or in assessment of change following treatment with nasal CPAP, nor is it routinely indicated for evaluation of sleepiness in medical and neurological disorders other than narcolepsy, or for insomnia, or circadian rhythm disorders (Littner et al., 2005). MSLT may be medically necessary only when used to exclude or confirm narcolepsy in the diagnostic workup of OSAS/UARS.

The MWT measures sleep latency when the patient is instructed to attempt to remain awake in an unstimulating environment. The test may be indicated in the assessment of individuals in whom the inability to remain awake constitutes a safety issue, or in patients with narcolepsy or idiopathic hypersomnia to assess response to treatment with medications. There is little evidence linking MWT results with risk of accidents. MWT is not considered medically necessary to evaluate sleep apnea.

Polysomnography for OSA/UARS

The final diagnosis of OSA rests on a combination of clinical evaluation and objective criteria to identify those levels of obstruction that are considered to be clinically significant. The gold standard diagnostic test for sleep disorders is considered a polysomnogram, performed in a sleep laboratory. A standard polysomnogram, supervised by a sleep lab technician, typically includes:

- EEG (to stage sleep, detect arousal)
- Submental electromyogram
- Electro-oculogram (to detect arousal, rapid eye movement (REM) sleep)

Additional parameters of sleep that may be measured include:

- Respiratory airflow and effort (to detect apnea)
- Oxygen desaturation
- Electrocardiography
- Sleep position
- Penile tumescence
- Gastroesophageal reflux
- Continuous blood pressure monitoring
- Snoring

The first three elements listed here (EEG, submental electromyogram, and electro-oculogram) are required for sleep staging. By definition, a polysomnogram always includes sleep staging, while a cardiorespiratory "sleep study" does not. The actual components of the study will be dictated by the clinical situation. Attended polysomnography performed in a sleep lab provides supervision of the test which ensures that the monitors are attached appropriately to the patient and do not become dislodged during the night. In the evaluation of sleep apnea, sleep staging is performed by the sleep technician by assessing arousals from sleep, and determining the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow and respiratory effort. In studies known as "split-night" studies, in which the diagnosis of OSA is established during the first half of the night and CPAP titration is conducted during the second half of the night, an attendant can identify severe OSA so that the effective level of continuous positive airway pressure (CPAP) therapy can be determined. If successful, this strategy can eliminate the need for an additional polysomnogram for CPAP titration.

An obstructive apnea is defined as at least 10 seconds cessation of respiration associated with ongoing ventilatory effort. Obstructive hypopneas are reductions, but not cessation of air exchange, with an associated fall in oxygen saturation (at least 3% - 4%) or arousal. The apnea/hypopnea index (AHI), which may also be referred to as the respiratory disturbance index (RDI). The AHI is defined as the total number events per hour of sleep. When sleep onset and offset are unknown, the RDI may be calculated based on the total recording time. A diagnosis of OSA syndrome is accepted when an adult patient has an AHI of > 5 and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI greater than or equal to 15 is typically considered moderate OSA, while an AHI greater than 50 is considered severe OSA. However, there are no widely accepted criteria regarding the severity of OSA. In example, the Institute for Clinical Systems Improvement (ICSI) in 2008 advised that the severity of OSA is determined by the most severe ratings of three domains: sleepiness (defined as mild, moderate, and severe), respiratory disturbance (AHI), and gas exchange abnormalities. The authors advised that respiratory disturbance is mild with an AHI of 5-15; moderate with an AHI of 16-30; and severe with an AHI greater than 30. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of greater than 15. Mortality has not been shown to be increased in patients with an AHI between five (considered normal) and 15. Sources of measurement error with polysomnography include data loss, artifact, event recognition errors, measurement errors, use of different types of leads, and night-to-night variability.

In 1997 the American Sleep Disorders Association (now the American Academy of Sleep Medicine (AASM)) published practice parameters for polysomnography and related procedures; these were most recently updated in 2005. The guidelines suggested that patients had a 70% likelihood of having an AHI index of at least 10 if all of the following were present: habitual snoring, excessive daytime sleepiness, a body mass index greater than 35, and observed apneas. In 2005, full-night PSG was recommended for the diagnosis of sleep-related breathing disorders and for PAP titration in patients with an RDI of at least 15 per hour, or with an RDI of at least five per hour in a patient with excessive daytime sleepiness. For patients in the high-pretest-probability stratification group, an attended cardiorespiratory sleep study (Type 3 with respiratory effort, airflow, arterial oxygen saturation, and ECG or heart rate) was considered an

acceptable alternative to full-night PSG, provided that repeat testing with full-night PSG was permitted for symptomatic patients who had a negative cardiorespiratory sleep study.

The AASM Practice Parameter indications for Polysomnography (2005) also advised that a split-night study is an alternative to one full night of diagnostic PSG followed by a second night of titration if the following criteria are met:

- An AHI of at least 40 is documented during a minimum of two hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI of 20 to 40, based on clinical judgment (e.g., if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP pressure requirements, based on split-night studies may be less accurate than in full night calibrations.
- CPAP titration is carried out for more than three hours (because respiratory events can worsen as the night progresses).
- PSG documents that CPAP eliminates or nearly eliminates the respiratory events during REM and non-REM (NRE) sleep, including REM sleep with the patient in the supine position.
- A second full night of PSG for CPAP titration is performed if the diagnosis of a Sleep Related Breathing Disorder (SRBD) is confirmed but criteria two and three are not met. Additionally, a split-night study may eliminate the need for a repeat or follow-up PSG study for CPAP or PAP titration. However, it may be necessary to perform a follow up PSG when the diagnosis of OSA is confirmed during a split-night study but the PAP titration portion of the study was not sufficient (e.g., less than three hours of titration or failure to effectively eliminate respiratory events).

Sleep Study Monitoring Devices:

Sleep study monitoring devices are generally classified, according to an approach utilized by the American Academy of Sleep Medicine (AASM), as:

- Type 1 - Standard devices utilized in laboratory, technician-attended, overnight polysomnography testing. They have a minimum of seven monitoring channels including electroencephalogram (measures electrical activity of the brain), electrocardiogram (ECG; measures electrical activity and heart rate), electrooculogram (measures movement of the eyes during sleep), chin electromyogram (measures muscle activity of the chin), airflow, respiratory effort and oxygen saturation.
- Type 2 - Comprehensive portable devices that have a minimum of seven monitoring channels as outlined above, with the exception of the ECG, which can be replaced by a heart rate monitor.
- Type 3 - Modified portable sleep apnea devices that have a minimum of four monitoring channels including airflow (two different channels), electrocardiogram, and oxygen saturation.
- Type 4 - Only measure one or two monitoring parameters, typically including oxygen saturation or airflow.

Sleep Study Levels:

The American Academy of Sleep Medicine (AASM) uses four levels to classify the complexity of recording technology used for the diagnosis of sleep related breathing disorders. The recent proliferation of devices that measure parameters has made this classification system less clear.

- Level I - Standard polysomnography (PSG) with a minimum of seven parameters measured, including EEG, electrooculogram (EOG), chin EMG, and ECG, as well as monitors for airflow, respiratory effort and oxygen saturation. A technician is in constant attendance.
- Level 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.
- Level III - Modified portable sleep apnea testing is a cardiorespiratory study in which a minimum of four 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.
- Level IV - Continuous (single or dual) bioparameter recording are devices that measure a minimum of one parameter, usually oxygen saturation.

Portable/Home Sleep Studies (Unattended or Unsupervised sleep studies)

Portable monitoring systems typically consist of a small recording device, sensors, belts and related accessories. The system is worn by patients while they sleep at home. The home recordings are then analyzed by a sleep specialist and scoring of apneas and hypopneas are performed. Various portable sleep study systems have been developed for home use, with each new system claiming to be the best method. However, there is limited published scientific information evaluating the efficacy, accuracy, validity, utility, cost effectiveness and limitations of these portable systems. Attaining a clear assessment of the role of these devices has also been complicated by the multiplicity of the recording systems and the variability of settings in which they have been analyzed. In the diagnosis of OSA or UARS, portable testing does not assess sleep architecture or staging and therefore can not calculate AHI based on actual sleep time. Home/portable monitors (as they imply) are rarely attended and in some cases do not include an EEG.

In 2003, a joint project of the American Academy of Sleep Medicine, the American Thoracic Society, and the American College of Chest Physicians developed revised practice parameters for the use of portable monitoring (PM) devices. In this report, "portable" is meant to encompass the entire range of devices except for comprehensive laboratory-based polysomnography. They also published an extensive review of the literature on which the practice parameters are based.

The recommendations included:

- The clinical use of Type 2 PM devices in the attended setting is not recommended to evaluate patients with suspected OSA.
- The clinical use of Type 2 PM devices in the unattended setting is not recommended to evaluate patients with suspected OSA.
- Although Type 2 devices would be classified as polysomnography because they measure sleep, the recommendation was negative because of lack of published evidence.

- The use of some Type 3 PM devices in an attended setting can decrease the probability that a patient has an AHI greater than 15.
- The use of Type 3 PM devices in an unattended setting is not recommended to decrease the probability that a patient has an AHI greater than 15.
- The phrase "can decrease the probability" means that in this setting, among patients who have low pre-test probability of disease, these devices can reasonably "rule out" sleep apnea. This "rule out" indication represents an indication beyond the prior 1997 guideline, which only included a "rule in" indication. There was little evidence regarding these devices in an unattended setting.
- Some Type 3 PM devices can be used in an attended setting to increase the probability that a patient has an AHI greater than 15.
- The phrase "increase the probability" means that the device can "rule in" disease in patients with high pre-test probabilities, which is a reiteration of the 1997 guideline. There was little evidence regarding the use of these devices in an unattended setting.
- Additional guideline statements reiterated this same pattern of recommendations regarding Type 3 devices to both "rule in" and "rule out" a diagnosis of sleep apnea. Attended, in laboratory studies may be acceptable (statement 7), but unattended studies are not (statement 8).
- Finally, all possible uses of Type 4 devices in both the attended and unattended setting were not recommended (statements 9, 10, 11, 12).

An additional recommendation of note is that sleep studies are not recommended in patients with comorbid conditions or secondary sleep complaints (statement 14). Most of the literature reviewed specifically excluded patients with comorbid conditions.

The 2003 AASM clinical guideline acknowledged previous statements regarding unattended studies and reiterated support. However, stated that unattended portable sleep studies may be acceptable when the patient has severe symptoms requiring immediate treatment and polysomnography is not available, the patient cannot be studied in a sleep laboratory (i.e., nonambulatory), or for follow-up studies to evaluate response to therapy. The authors recognized that a variety of unattended sleep study technologies and vendors are widely disseminated, and in some areas there is not ready access to supervised, laboratory studies.

In 2007, the Agency for Healthcare Research and Quality (AHRQ) conducted a technology assessment on portable monitoring for the Medicare Evidence Development and Coverage Committee (MedCAC). The report concluded:

- Baseline AHI (or other indices obtained from sleep studies) is only modestly associated with response to CPAP or CPAP use among people with high (pre-test) probability for obstructive sleep apnea-hypopnea syndrome (OSAHS). None of the eligible studies assessed hard clinical outcomes (i.e., mortality, myocardial infarctions, strokes, and similar outcomes).
- Based on limited data, type 2 monitors may identify AHI suggestive of OSAHS with high positive likelihood ratios (>10) and low negative likelihood ratios (<0.1) both when the portable monitors were studied in the sleep laboratory and at home.

- Type 3 monitors may have the ability to predict AHI suggestive of OSAHS with high positive likelihood ratios and low negative likelihood ratios compared to laboratory-based PSG, especially when manual scoring is used. The ability of type 3 monitors to predict AHI suggestive of OSAHS appears to be better in studies conducted in the specialized sleep unit compared to studies in the home setting.
- Studies of type 4 monitors that record at least three bioparameters showed high positive likelihood ratios and low negative likelihood ratios. Studies of type 4 monitors that record one or two bioparameters also had high positive likelihood ratios and low negative likelihood ratios, at least for selected sensitivity and specificity pairs from Receiver Operating Characteristic (ROC) curve analyses. Similarly to type 3 monitors, the ability of type 4 monitors to predict AHI suggestive of OSAHS appears to be better in studies conducted in specialized sleep units.
- Patients older than the studied subjects (the median average age was approximately 50 years in the analyzed studies) may have more comorbidities that affect sleep (i.e., non-OSAHS conditions such as cardiac insufficiency; chronic obstructive pulmonary disease; obesity hypoventilation syndrome; or periodic limb movements in sleep and restless leg syndrome). These conditions may be misdiagnosed if the sleep monitors do not record channels necessary for differential diagnosis from OSAHS.
- For studies in the home setting, there are no direct data on whether and to what extent technologist support and patient education affect the comparison of portable monitors with facility-based PSG.
- Overall, manual scoring or manual editing of automated scoring seems to have better agreement with facility-based PSG. The automated scoring algorithms may vary across different monitors, or even with the specific software version or settings. Thus, their ability to recognize respiratory events may differ.
- Signal loss was more often observed in home studies, and one study associated discrepancies in the AHI measurement with poor quality airflow signals in the unattended home-based recordings.

The AHRQ report addressed the available literature through February 2007, and a supplemental search of the MEDLINE database was performed for the period of March 2007 through December 2007. Evidence at this time suggested that portable monitoring could potentially provide an effective alternative to PSG for evaluating patients suspected of having OSA. There were, however, a number of limitations with available devices and procedures. First, there was no standardization of recording and scoring parameters for the monitoring devices that are available. A variety of scoring algorithms had been used, and the appropriate screening and cutoff values for each device had not been established.

Mulgrew et al (2007) published a randomized validation study of the diagnosis and management of OSA without PSG. They developed a diagnostic algorithm (ESS score greater than 10, Sleep Apnea Clinical Score of 15 or greater, and an RDI of 15 or over on overnight oximetry) that was found to have a 94% positive predictive value for moderate to severe OSA assessed by PSG. Patients who passed the screening (n = 68) were randomized to either attended in-laboratory PSG with CPAP titration or to home monitoring with a portable APAP unit. Home monitoring consisted of autotitration for one week, followed by download and assessment of efficacy data

for the week (i.e., CPAP, mask leak, residual respiratory events, and use) and determination of the pressure for CPAP by the study physician. A second assessment of efficacy data was conducted for one week of CPAP use, and the pressure setting was adjusted by the CPAP coordinator in conjunction with the study physician. After three months of CPAP use the subjects returned to the laboratory for PSG (with CPAP); no difference was observed between lab-PSG and home-managed patients in any of the outcome measures (median AHI of 3.2 vs. 2.5, median ESS of 5.0 vs. 5.0 and Sleep Apnea Quality of Life Index of 5.5 vs. 5.8).

Analysis of data from the Swiss Respiratory Polygraphy Registry found that in patients selected for portable monitoring (based on high clinical suspicion of OSA by licensed pulmonary physicians by a combination of hypersomnia, snoring, or observed apneas), confirmation or exclusion of sleep disordered breathing was possible in 96% of the 8,865 diagnostic sleep studies. From these Type 3 studies (four channels including airflow and respiratory movement, heart rate or ECG, and oxygen saturation), 3.5% were not conclusive and required additional PSG (Thurnheer et al., 2007).

In a study by Bridevaux and coworkers (2007), 88 ambulatory sleep recordings were independently scored by eight physicians. Intraclass correlation coefficients were 0.73 for AHI, 0.71 for hypopnea index, and 0.98 for desaturation index. Automated analysis was found to underestimate AHI by an average of 5.1 events. The authors concluded that in a clinical setting, agreement on AHI was limited, and that efforts should be directed toward standardization of visual analysis, and improvement and quality control of ambulatory sleep studies. A third European study assessed the sensitivity and specificity of home respiratory polygraphy and actigraphy to diagnose OSA in relation to laboratory PSG. The cohort consisted of 65 consecutive patients referred to the sleep laboratory for PSG because of suspected OSA. Using an AHI cutoff of 15 or more, two independent evaluators were found to identify PSG-defined OSA in 90% to 92% of the patients (sensitivity of 84%-88% and specificity of 97%).

Evidence suggests that portable monitoring could potentially provide an effective alternative to PSG for evaluating patients suspected of having OSA. There are, however, a number of limitations with currently available devices and procedures. First, there is no standardization of recording and scoring parameters for the monitoring devices that are available. A variety of scoring algorithms are used, and the appropriate screening and cutoff values for each device have not been established. Questions also remain about the reliability of unattended automated recordings, and about the expertise of the medical personnel who might request, assist, and interpret the home sleep studies. Therefore, use of home portable monitoring devices for the diagnosis of OSA is considered investigational.

Actigraphy

Actigraphy consists of a small portable device that senses physical motion and stores the resulting information. Actigraphy is used in research studies for the evaluation of rest activity cycles, to measure sleep disturbances reflective of a variety of clinical sleep disorders, including insomnias, and obstructive sleep apnea syndrome. The AASM Practice Parameters for the use of actigraphy in the assessment of sleep and sleep disorders were updated for 2007. Although the 2005 update focused on the comparison of actigraphy with PSG-recorded sleep, the 2007 update included 108 additional studies comparing actigraphy to a number of standard clinical assessment tools including PSG, sleep logs, subjective questionnaires, care giver reports, and circadian phase markers.

Actigraphy was recommended as a "standard" only as a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when PSG is not available. Other indications changed from "option" to "guideline," but failed to reach a recommendation of "standard" due primarily to the absence of high-quality trials. Few of the studies reviewed had provided technical details related to the administration and scoring of actigraphy. In addition, most of the studies lacked a description of blinding, and there was "an inadequate description of whether visual inspection of data is performed, how missing data is handled, and other important decisions made in the analysis of actigraphy data."

The AASM Standards of Practice Committee indicated the need for additional research in the following areas:

- Comparison of results from different actigraphy devices and the variety of algorithms use
- Standards for setting start and stop times
- Reliability and validity compared to reference standards
- Clarification of the relative and unique contributions of actigraphy, polysomnography, and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects

II. Medical Treatment of OSA/UARS

Treatment decisions for OSA are based on condition severity, the presence of comorbidities and complicating factors, and the patient's tolerance and response to treatment. Medical management of OSA includes weight loss, oral appliances, and various types of continuous positive airway pressure (CPAP) (i.e., fixed CPAP, bilevel positive airway pressure [BiPAP], or auto-adjusting CPAP [APAP]). 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 these devices are capable of generating two adjustable pressure levels. APAP adjusts the level of pressure based on the level of resistance, and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both BiPAP and APAP are more comfortable for the patient, and thus might improved patient compliance or acceptance. Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue retaining devices. Oral appliances can either be "off the shelf" or custom made for the patient by a dental laboratory or similar provider. The use of atrial overdrive pacing is also being evaluated in the treatment of obstructive sleep apnea. This approach is being tried because of the bradycardia that generally occurs during episodes of apnea.

Continuous positive airway pressure (CPAP)

CPAP is the most common treatment for sleep apnea in adults. CPAP consists of a nasal or oronasal mask or modified nasal prongs (e.g., nasal pillows) held in position with elastic headgear that is connected by tubing to a flow generator. The flow generator is set to a specific pressure sufficient to maintain airway patency and overcome respiratory disturbances by forcing air through the nasal passages, and opening the back of the throat. In OSA, tissues in the upper airway, including the tongue, soft palate and nasal passages sag and block the airway. The pressurized air through CPAP forces the upper airway tissues out of the way, which allows for normal breathing to occur. The peer reviewed medical literature supports the use of CPAP for the treatment of OSA and UARS.

In 2001, the Centers for Medicare and Medicaid Services (CMS, formerly Health Care Financing Administration (HCFA)), published a decision memorandum for CPAP that addressed the issue of how to define moderate to severe OSA as a guide to a coverage policy for CPAP. This review of the literature suggested that there is a risk of hypertension with an AHI greater than 15, and thus treatment is warranted for these patients without any additional signs and symptoms. For patients with an AHI between five and 15 and associated symptoms, the CMS document concluded that the data from three randomized controlled trials demonstrated improved daytime somnolence and functioning in those treated with CPAP. While the patient selection criteria in this policy are based on the Medicare policy, the CMS decision memorandum does not document the rationale underlying the patient selection criteria of ischemic heart disease or history of stroke.

An initial 12 week period of a CPAP device is covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adults with OSA (obstructive sleep apnea) if either of the following criteria using the Apnea-Hypopnea Index (AHI) or Respiratory Distress Index (RDI) are met. The AASM also recommends the following parameters:

- AHI or RDI \geq 15 events per hour, or
- AHI or RDI between five and 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

The AHI or RDI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of two hours of sleep using actual recorded number of hours of sleep (i.e., the AHI or RDI may not be extrapolated or projected). Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is 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.

Cochrane conducted a systematic review of the effectiveness of CPAP for the treatment of OSA which included 36 trials and 1718 patients (Giles et al., 2006). Included trials compared CPAP with an inactive control or use of an oral appliance in adults with OSA and an AHI greater than five per hour. The authors reported the following results:

- Compared to control, CPAP showed significant improvements in objective and subjective sleepiness and several quality of life, cognitive function and depression measures
- Twenty-four (24) systolic and diastolic pressures were lower with CPAP compared to control

- There was stronger evidence of effectiveness in symptomatic patients with moderate to severe AHI
- Compared to oral appliances, CPAP significantly reduced the AHI and improved sleep efficiency and minimum oxygen saturation
- There was no obvious difference in symptoms, however, patients who responded to both CPAP and oral appliance therapy expressed a strong preference for the oral appliance

The authors concluded that available evidence supports the use of CPAP as first-line treatment for OSA patients with high AHI and moderate to severe daytime sleepiness. They further concluded that patients who do not accept or struggle to continue with CPAP should be provided with alternative options.

In 2008 the United Kingdom's National Institute for Health and Clinical Excellence (NICE) issued guidance on CPAP treatment of OSA, based on a review of the literature and expert opinion. The recommendations included:

- Moderate to severe OSAHS can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person's home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the apnea/hypopnea index (AHI) or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5-14 in a sleep study, moderate when the AHI is 15-30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.
- Continuous positive airway pressure (CPAP) is recommended as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnea/hypopnea syndrome (OSAHS). CPAP is only recommended as a treatment option for adults with mild OSAHS if: they have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate.
- Treatments aim to reduce daytime sleepiness by reducing the number of episodes of apnea/hypopnea experienced during sleep. The alternatives to CPAP are lifestyle management, dental devices and surgery. Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption. Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS. Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice. The diagnosis and treatment of OSAHS, and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.
- The Committee discussed the use of CPAP therapy for children and adolescents with OSAHS. The Committee heard that OSAHS is less common among children than in adults and that the clinical issues and etiology in children are different from those

encountered in adults. The Committee concluded that the recommendations for CPAP should apply only to adults with OSAHS.

Auto CPAP (APAP)

Auto CPAP (APAP) is designed to vary pressures to meet the needs of the patient's sleep disordered breathing. Pressure changes are determined by monitoring variably a combination of apneas, hypopneas, inspiratory flow limitation and snoring. While CPAP provides constant pressure, APAP provides minimal pressure to stabilize the airway. APAP devices may aid in the pressure titration process, address possible changes in pressure requirements throughout a given night and from night to night, aid in treatment of OSA when attended CPAP titration has not or cannot be accomplished, or improve patient comfort. Evidence-based guidelines from the American Academy of Sleep Medicine concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals (Kushida, 2006). However, increased compliance with APAP devices has not been well documented in clinical trials. APAP may be considered medically necessary in patients who have failed a prior trial of CPAP. In addition to the studies described above, (Senn et al., 2006; Berry et al., 2008; Mulgrew, 2007), that used unattended APAP devices to titrate CPAP pressure, the 2007 American Academy of Sleep Medicine (AASM) practice parameters on autotitration identified five randomized trials supporting the use of unattended APAP to determine a fixed CPAP treatment pressure for patients with moderate to severe OSA without significant comorbidities affecting respiration. This new practice parameter was considered an option (uncertain clinical use), with automatic titration or treatment requiring close clinical follow-up (standard). The practice parameters for the use of APAP issued by the AASM point out that results may vary with different APAP devices based on different underlying technologies, and thus caution must be exercised in selecting a particular device for use.

The AASM current recommendations for APAP are as follows:

- APAP devices are not recommended to diagnose OSA
- Patients with congestive heart failure, patients with significant lung disease such as chronic obstructive pulmonary disease; patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome); patients who do not snore (either naturally or as a result of palate surgery); and patients who have central sleep apnea syndromes are not currently candidates for APAP titration or treatment
- APAP devices are not currently recommended for split-night titration
- Certain APAP devices may be used during attended titration with polysomnography to identify a single pressure for use with standard CPAP for treatment of moderate to severe OSA
- Certain APAP devices may be initiated and used in the self-adjusting mode for unattended treatment of patients with moderate to severe OSA without significant comorbidities (congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), central sleep apnea syndromes, or hypoventilation syndromes)
- Certain APAP devices may be used in an unattended way to determine a fixed CPAP treatment pressure for patients with moderate to severe OSA without significant

comorbidities (CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes)

- Patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must have close clinical follow-up to determine treatment effectiveness and safety
- A reevaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or the APAP treatment otherwise appears to lack efficacy

As stated above by the AASM practice parameters, there is insufficient evidence in the published medical literature to determine the safety and efficacy of home APAP titration for initiation of CPAP or APAP treatment.

Bilevel Positive Airway Pressure (BiPAP)

Bilevel PAP is a non-invasive respiratory device that delivers different levels of inspiratory (IPAP) and expiratory (EPAP) pressure to a spontaneously breathing patient to keep the airway open. By applying pressure in the expiratory phase, the total pressure applied on the airway can then be reduced, therefore achieving more normal physiologic breathing. BiPAP devices have additional flow and pressure delivery methods to meet the needs of patients with various respiratory conditions, such as those requiring ventilatory support, and have been shown to be therapeutic for OSA. Reported advantages of BiPAP include lowering mean treatment pressure, decreasing the work of breathing and creating a more normal breathing pattern. The application of BiPAP is through a nasal mask or full-face interface. Although certain patients may benefit from BiPAP, the use of BiPAP as initial treatment is not recommended. BiPAP devices have not demonstrated superiority to CPAP in improving adherence, symptom scores, nasal discomfort or patient complaints regarding therapy. If BiPAP is used, therapeutic IPAP and EPAP pressures will require manual titration during an attended polysomnogram. Many patients can resume CPAP if retitration shows improvement in OSA with the adjustment of pressure. (ICSI, 2008)

The AASM practice parameters advise the following (Kushida et al., 2006):

- BiPAP can be used as optional therapy in some cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure
- BiPAP may also be indicated when coexisting central hypoventilation is present

The term BiPAP[®] is a registered trademark of Respironics Inc., but is widely used to describe any bi-level positive airway pressure device. In example, VPAP[®] (Variable Positive Airway Pressure), is a variation of BiPAP, however it delivers differing levels of inspiratory and expiratory pressure in order to maintain airway patency during sleep. These devices are in the FDA category of non-continuous ventilator, and as such, are primarily intended to augment patient ventilation. According to the Medicare Local Coverage Determination (LCD) (L171), BiPAP with a back up rate is considered not medically necessary if the primary diagnosis is OSA. Bi-level positive airway pressure with back-up rate is not appropriate for obstructive sleep apnea and has little proven value in the medical literature however, it is appropriate for patients with neuromuscular respiratory insufficiency or restrictive lung disease from thoracic wall deformity and for some patients with central sleep apnea. BiPAP with a back up rate for an OSA patient is subject to further Medical Director review for medical necessity.

Intraoral Appliances

The role of oral appliances in the management of upper airway obstruction was recognized in the early 1900's. Various oral appliances have been developed for the treatment of OSA. These devices were designed based on the principal that advancing the mandible (thereby holding it forward) may act to increase the size of the pharyngeal airway or other wise reduce its collapsibility. The appliance is attached to the upper and lower dental arches allowing for additive advancement of the mandible. Cephalometric radiographic studies have shown that mandibular repositioning appliances (MRA) or mandibular advancement devices (MAD), lower the tongue position, reduce the mandibular plane-to-hyphoid distance, and widen the upper oropharynx. These appliances may be prefabricated and adapted to the patients dimensions, or custom made based on dental impressions.

Tongue retaining appliances (TRA) or devices (TRD) act by holding the tongue forward thereby affecting the genioglossus muscle activity. TRAs may be custom made or fitted by the patient. These devices are helpful for patients with limited or loose natural dentition, temporomandibular disorders and limited mouth opening. They are generally used in patients who have contraindications to the use of an MRA.

Soft palate lifters act as scaffolding, reaching back and supporting the soft palate. This reduces the vertical drooping of the soft palate and uvula, and minimizes the fluttering effect and snoring noise. This device is effective in reducing or eliminating snoring but not in treating obstructive sleep apnea. Although the soft palate lifter is FDA approved, and has been shown to be effective in eliminating snoring there has been no scientific evidence of its usefulness in treating OSA or UARS.

Two studies compared the use of the mandibular repositioning device with nasal CPAP. The authors reported a 45% reduction in AHI score however; this was less effective than nasal CPAP which achieved a 70% reduction in AHI score. The studies concluded that the use of oral appliances is an effective treatment in some patients with mild to moderate OSA and is associated with fewer side effects and greater satisfaction than nasal CPAP (Ferguson et al., 1996; Marklund et al., 1998)

Cochrane conducted a systematic review to determine the effects of oral appliances in the treatment of sleep apnea in adults. Twelve randomized controlled trials including 509 patients compared MRAs to control or other treatments. The authors concluded that there was increasing evidence that oral appliances improve subjective sleepiness and sleep disordered breathing compared to inactive control treatment. However, the data was limited and there were some methodological weaknesses. The authors recommended that mandibular oral devices be offered to patients with mild symptomatic OSA and those who are unwilling or unable to comply with CPAP (Lim et al., 2004).

The AASM practice parameters for the use of oral appliances advise the following (Kushida et al., 2006):

- The presence or absence of OSA must be determined before initiating treatment with an oral appliance to identify patients at risk due to complications of sleep apnea and to provide a baseline to establish the effectiveness of subsequent treatment

- In patients with OSA, the desired outcome of treatment includes the resolution of the clinical signs and symptoms of OSA and the normalization of the AHI and oxyhemoglobin saturation
- Although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer oral appliances to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or behavioral measures such as weight loss or sleep position change
- Patients with severe OSA should have an initial trial of CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating the OSA
- To ensure satisfactory therapeutic benefit from oral appliances, patients with OSA should undergo PSG or attended cardiorespiratory (Type III) sleep study with the oral appliance in place after adjustments of fit have been performed

In summary, the success of any positive airway pressure device or intraoral appliances in the treatment of OSA depends primarily on patient adherence, which can be enhanced by education, proper mask or interface fit, proper oral appliance fitting, and frequent follow up by the durable medical equipment (DME) provider, sleep medicine specialty physician, dentist or orthodontist.

Atrial Pacing

Because of the bradycardia that is noted during episodes of apnea, atrial pacing has been studied as a treatment for sleep apnea. A study by Simantirakis (2005) compared pacing to CPAP and a study by Krahn (2006) compared pacing to no treatment. In neither study was an effect seen on the AHI for those treated with pacing. Thus, atrial pacing is considered investigational.

III. Surgical Treatment of OSA/UARS

Patients with OSA or UARS who fail or are unable to comply with conservative medical management (i.e., CPAP failure) may be candidates for surgical interventions. The surgical techniques used to treat OSA specifically modify either the retropalatal or retrolingual region of the pharyngeal airway, or in severe cases bypass the pharyngeal portion of the upper airway. The aim of surgical intervention is to alleviate symptoms of daytime sleepiness, improve quality of life, and reduce the signs of sleep apnea recorded by polysomnography. Traditional surgical procedures include uvulopalatopharyngoplasty (UPPP) and a variety of maxillofacial surgeries such as mandibular-maxillary advancement (MMA). Minimally invasive procedures include laser-assisted uvulopalatoplasty (LAUP), radiofrequency ablation of palatal tissues and the tongue and palatal stiffening procedures.

Uvulopalatopharyngoplasty (UPPP), Palatopharyngoplasty (PPP), or Uvulopharyngoplasty (UPP)

The most common procedure for adult sleep apnea is the Uvulopalatopharyngoplasty (UPPP). Uvulopalatopharyngoplasty increases the area of the retropalatal airway by resection of the free edge of the uvula and soft palate in patients with collapse of the oropharyngeal and hypopharyngeal airways, or with some other anatomical impediment such as small retrolingual

airways. The UPPP procedure may also be combined with tonsillectomy. The success of UPPP is variable, with positive results most often seen in patients whose obstruction is limited to the retropalatal airway. Thus patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue. Fiberoptic endoscopy and/or cephalometric measurements have been used as methods to identify hypopharyngeal obstruction in these patients.

A Cochrane systematic review assessed the results of any surgery in the treatment of OSA in adults. UPPP was one of several procedures evaluated. The authors concluded that available studies do not provide evidence to support the use of surgery in OSA because overall significant benefit has not been demonstrated. Long-term follow-up of patients who undergo surgical treatment is required to determine whether surgery is curative or whether the signs and symptoms of OSA tend to recur, requiring further treatment.

Sher (1996) conducted a systematic literature review with meta-analysis to provide an overview of the surgical treatment of OSA to provide the basis for the AASM practice parameters on this subject. Studies included in the meta-analysis provided preoperative and postoperative PSG data on at least nine patients treated with UPPP for OSA. Analysis of the UPPP studies revealed that this procedure is, at best, effective in treating less than 50% of patients with OSA. The AASM based its practice parameters on this review and stated that UPPP, with or without a tonsillectomy, may be appropriate for patients with narrowing or collapse in the retropalatal region. The recommendations also state that effectiveness of UPPP is variable, and the procedure should only be performed when nonsurgical treatment options, such as PAP, have been considered.

Inferior Sagittal Mandibular Osteotomy (ISO) and Genioglossal Advancement with Hyoid Myotomy and Suspension (GAHM)

Jaw realignment is an aggressive, multi-step procedure requiring a three to six month interval between each step. According to the medical literature, jaw realignment surgery is generally reserved for those patients who fail other treatment approaches for OSA. The AASM Practice Parameters for the surgical treatment of OSA (Thorpy et al., 1999) concluded that inferior sagittal mandibular osteotomy and genioglossal advancement with or without hyoid myotomy and suspension appears to be the most promising of procedures directed at enlarging the retrolingual region. The purpose of the procedures is to pull the tongue base forward, resulting in a larger hypopharyngeal airway. The genoid tubercle of the mandible, which acts as the anterior attachment of the tongue, is advanced by a limited mandibular osteotomy. Modifications of the procedure include stabilization of the hyoid bone anteriorly and inferiorly by attachment to the thyroid cartilage. These procedures may be performed with or following a UPPP procedure.

The AASM assessment stated that most of the experience with genioglossal advancement with or without hyoid suspension has been in conjunction with or following UPPP. Jaw fixation is necessary for two to three weeks following surgery, and a soft diet is necessary for a total of six weeks. Patients undergoing jaw realignment surgery must usually also undergo orthodontic therapy to correct changes in occlusion associated with the surgery.

Maxillomandibular Osteotomy and Advancement (MMO)

The Maxillomandibular osteotomy (MMO) and advancement procedure is successful for patients with base of tongue obstruction, severe OSA, morbid obesity and failure of other treatments (ICSI 2008). Skeletal movement of the maxilla and mandible has a broad effect on the upper airway without cicatricial scarring and has demonstrated positive results. MMA is a surgical technique that modifies the airway space by advancing the maxilla, the mandible, and therefore the tongue. The procedure is usually performed after a failed UPPP. Maxillomandibular osteotomy and advancement may also be utilized as the sole procedure for OSA patients with mandibular skeletal deformities associated with a narrowed posterior airway space and tongue base obstruction (Sher et al., 1996). MMO surgery is usually a two-phase surgical procedure.

The AASM practice parameters for the surgical treatment of OSA state that a stepwise approach to surgical management is acceptable if the patient is advised of the likelihood of success of each procedure and that multiple operations may be necessary. In selected patients for whom UPPP and other surgical procedures have failed MMO may be successful in effectively treating the OSA. However, MMO is not generally considered initial therapy (Thorpy et al., 1999).

Tracheostomy

Tracheostomy, bypasses the obstruction lesion of the upper airways and has been shown to be the most effective and predictable surgical approach to OSA. However, because of the cosmetic effects and morbidity associated with tracheotomy, it is rarely performed for the treatment of OSA. According to the AASM practice parameters, tracheotomy is the only operation shown to be consistently effective as a sole procedure in the treatment of OSA, but should only be considered when other options do not exist, have failed or are refused, or when deemed necessary due to clinical urgency.

Laser-Assisted Uvuloplasty (LAUP)

The LAUP is an outpatient alternative that has been proposed as a treatment of snoring with or without associated OSA. In this procedure, superficial palatal tissues are sequentially reshaped using a carbon dioxide laser. The extent of the surgery is typically different than standard UPPP, since only part of the uvula and associated soft-palate tissues are reshaped. The procedure, as initially described, does not remove or alter tonsils or lateral pharyngeal wall tissues. The patient undergoes from 3-7 sessions at 3-week to 4-week intervals. One purported advantage of LAUP is that the amount of tissue ablated can be titrated such that the treatment can be discontinued once snoring is eliminated. The LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, raising unique issues of safety and, in particular, effectiveness.

In August 1994, the American Sleep Disorders Association published a policy statement regarding LAUP, which offered the following conclusion: "Because adequate peer-reviewed objective data do not exist regarding the effectiveness of LAUP for the treatment of sleep related breathing disorders, including OSA, LAUP is not recommended for the treatment of these disorders."

In 1998, the American Academy of Otolaryngology Head and Neck Surgery updated the policy statement on their Web site on surgical management of obstructive sleep apnea to include

uvulopalatoplasty (including laser assisted and other techniques) to state these procedures are "effective and not considered investigational when considered as part of a comprehensive approach in the medical and surgical management of adults with Obstructive Sleep Apnea." While this organization previously noted further studies were needed to document the effects of LAUP, it did not provide citations of any studies supporting its rationale for the amended statement.

In 2001, the American Academy of Sleep Medicine published a policy statement regarding LAUP, which concluded that LAUP is not recommended for treatment of sleep-related breathing disorders.

While LAUP has been shown to be an effective treatment of snoring alone, the data are inadequate in terms of pre- and postoperative apneic indices to validate its effectiveness in patients with clinically significant obstructive sleep apnea (OSA). Ferguson and colleagues (2003) reported on a trial that randomized 45 subjects with mild sleep apnea (defined as an apnea-hypopnea index [AHI] ranging between 10 and 27 per hour) to either LAUP or no treatment. Detailed patient symptoms were not reported, so it is not known what percentage of the patients in each group would be considered to have clinically significant OSA, as defined in the Policy Guidelines section. The LAUP procedure was repeated at 1-month to 2-month intervals until either the snoring was significantly reduced, no more tissue could safely be removed, or the patient refused further procedures. The primary outcome measurement was the reduction in AHI in the LAUP group versus the control group. An AHI of less than 10 was considered a successful treatment. In the treatment group a total of 24% were considered treatment successes, and 76% were failures. In the control group (who received no therapy), 16.7% were considered treatment successes. The authors concluded that LAUP can be effective in some patients, but the reduction in AHI and the level of symptomatic improvement were minor overall.

Radiofrequency Volumetric Tissue Reduction (RFVTR)

Radiofrequency ablation of the soft palate is similar in concept to LAUP, although a different energy source is used, and radiofrequency is used to produce thermal lesions within the tissues, rather than using a laser to ablate the tissue surface, which may be painful. For this reason, radiofrequency ablation appears to be growing in popularity as an alternative to LAUP. The Somnoplasty[®] device is approved by the United States Food and Drug Administration (U.S. FDA) for radiofrequency ablation of palatal tissues for simple snoring and of the base of the tongue for OSA. In some situations, radiofrequency of the soft palate and base of tongue are performed together as a multilevel procedure.

The policy on radiofrequency volumetric tissue reduction (i.e., Somnoplasty[®]) is based on a 2000 TEC Assessment. The published literature includes four primary studies on palatal radiofrequency ablation and one study on tongue base radiofrequency ablation. All studies were nonrandomized and enrolled pre-selected patients. The assessment concluded that:

- The published literature has the following limitations: 1) there are only a small number of trials with only a few patients enrolled in each study. Within each study, the enrolled patients had a variety of sleep-related breathing disorders ranging from obstructive sleep apnea to simple snoring. 2) Patients included in each study represented a very select

population. In two of the main studies, patients represented a group of individuals seeking alternative surgical therapy in a tertiary care setting. All studies were considered pilot studies, and patients were advised about the preliminary nature of the procedure. Furthermore, in 23 of the main studies, patients were evaluated with nasopharyngoscopy to pre-select those who would likely benefit from the procedure and suffer the lowest risk of harm. These selection biases have a significant effect on the overall results

- Using the Epworth sleepiness scale and a visual analogue scale on snoring severity, both of which are subjective in nature, represents a major limitation of the current research
- An objective improvement, a decrease in the apnea index, was seen with radiofrequency ablation of the tongue base. This treatment essentially cured patients by reducing the average apnea index from over 22 to four. Unfortunately, these results only represented the experiences of one surgeon on 18 pre-selected non-randomized, non-controlled patients. While this treatment may prove beneficial, data are inadequate to make a general conclusion at this time

In 2008, Farrar and colleagues published a meta-analysis of radiofrequency ablation for the treatment of obstructive sleep apnea in patients with an RDI of five or more. Sixteen studies met the inclusion criteria, three were randomized and 13 were non-randomized. Six studies treated both the base of the tongue and the soft palate, two treated the soft palate only, and eight ablated the base of the tongue only. The population was in the overweight, but not obese category, with a mean body mass index (BMI) of 28.5. In half of the studies, the average baseline RDI was less than 30, and in six of the studies, the average baseline Epworth Sleepiness Scale (ESS) was less than 10. The meta-analysis indicated a 31% reduction in both ESS and RDI. The lowest oxygen saturation level was not improved by radiofrequency ablation. The mean number of treatments required for patient satisfaction was 3.7 for the soft palate, 4.3 for the base of the tongue, and 4.8 for both sites (range three to 7). Complications were noted in 4% of patients, two tongue abscesses progressed to airway obstruction requiring tracheotomy. Only two of the studies provided 2-year follow-up, with a 32% reduction in ESS and a 45% reduction in RDI. The number of patients who were successfully treated (e.g., 50% reduction in RDI) was not reported. This meta-analysis is limited by the inclusion of poor quality uncontrolled studies.

Only one study, by Woodson and colleagues (2003), has compared the use of multilevel radiofrequency ablation with the current gold standard of CPAP in a randomized, controlled trial. The study included patients with mild obesity levels (BMI of 34 or greater) who had mild to moderate sleep apnea with an AHI between 10 and 30. Statistically significant improvement was noted with RFA and CPAP over placebo in OSA-specific quality of life using the Functional Outcomes of Sleep Questionnaire. However, the small size of the trial resulted in most outcomes not being statistically significant. The same group of authors reported a further subgroup analysis from the same trial, focusing on the 26 randomized to the RFA arm of the trial to determine whether additional treatments improved outcomes (Steward et al., 2004). Specifically, the authors focused on multi-level treatments on various combinations of palatal and tongue tissues. The authors reported that greater improvements in quality of life were reported for those patients who had a total of five treatments compared to three. Another subgroup analysis focused on multi-level treatments in 26 patients (Steward 2004). This subgroup likely contains overlapping

patients with the previous report, and the results were similar; i.e., greater improvements were reported in those patients who had a total of five treatments.

Van den Broek and colleagues (2008) assessed the incremental value of RFA of the tongue in combination with uvulopalatopharyngoplasty (UPPP) in a retrospective cohort study. All patients with both palatal and retroglossal obstruction, an RDI between five and 50 and no previous OSA surgery were included in the study. Seventy-five patients meeting the inclusion criteria had been treated with UPPP during the three-year period, 38 had UPPP alone, and 37 had UPPP plus RFA. The groups were comparable for age, gender, BMI, AHI, and mean oxygen saturation (SaO₂), however, no details were provided regarding the choice of procedure. With surgical success rate defined as more than 50% reduction of the AHI and AHI below 20, the success rate was 42% with UPPP alone and 49% with RFA (not significantly different). Two patients had an additional RFA treatment. No major complications were observed. The authors concluded that the addition of RFA to UPPP resulted in only limited improvement, but there was no major downside to it.

Other studies suggest that the primary benefit of minimally invasive procedures of the soft palate (e.g., radiofrequency channeling and radiofrequency-assisted uvulopalatoplasty) maybe reduced snoring (Bassiouny et al., 2007). While snoring is not the focus of this policy, it is interesting to note that Stuck and colleagues reported only modest benefits in snoring of questionable clinical significance in a randomized, placebo-controlled trial of radiofrequency ablation as a treatment of snoring in 26 patients without associated obstructive sleep apnea (Stuck et al., 2005). Overall, the evidence is insufficient to support the efficacy of this procedure for OSA.

Palatal Stiffening Procedures

Palatal stiffening procedures include a cautery-assisted palatal stiffening operation (CAPSO) and insertion of palatal implants. The CAPSO procedure uses cautery to induce a midline palatal scar designed to stiffen the soft palate to eliminate excessive snoring. The Pillar™ Palatal Implant System (Restore Medical, St Paul, MN) is an implantable device that has been cleared by the FDA 510(k) process. The device is a cylindrical-shaped segment of braided polyester filaments that is permanently implanted submucosally in the soft palate. The labeled indication of the device is as follows: "The Pillar™ Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (obstructive sleep apnea)."

There are minimal published data regarding cautery-assisted palatal stiffening operation (CAPSO) and palatal implants. Wassmuth and colleagues (2000) reported on the results of a case series of 25 patients with OSA who underwent CAPSO. Responders were defined as patients who had a reduction in AHI of at least 50%. Mean AHI improved from 25.1+/-12.9 to 16.6+/-15.0. The broad confidence intervals limit any scientific interpretation of these data. Mair and Day (2000) reported on a larger case series of 206 consecutive patients who underwent the CAPSO procedure. This case series appears to be focused on the treatment of snoring alone; patients with obstructive sleep apnea were excluded from the trial. Maurer and colleagues (2005) reported on the short-term results of 15 patients who underwent palatal implants. Outcomes were assessed only in terms of snoring. Similarly, a German study of 106 patients (Kuhnel et al., 2005) and a Hong Kong study of 12 patients (Mauer et al., 2005) only reported the outcomes in terms of snoring. A retrospective review by Walker and colleagues (2006) was published

describing results on 125 patients. However, the study did not have a control group and there are questions about how the cohort was identified and possible loss to follow up.

Walker and colleagues (2006 and 2007) published 90-day and 15-month follow-up of a multi-center study on palatal implants (Pillar System) in 63 subjects. The AHI decreased from a baseline of 25 to 22 in the 53 patients (84%) who were evaluated at 90 days. Twenty-two patients (35%) were available for the follow-up study; 13 had shown a decrease in AHI (from a baseline of 20 to 13) at 90 days. Of these, 10 (77% of the 13) maintained the decrease at 15 months. The nine patients whose AHI had not improved at 90 days had no subsequent improvement at the extended follow-up. Mean snoring was rated as eight at baseline (visual analog scale [VAS]), and four at both 90 days and 15 months. Subjective daytime sleepiness measured by the Epworth Sleepiness Scale (ESS) was reduced at 90 days (from 11 to seven), but returned to a score of 11 at the longer follow-up. In addition to the very large loss to follow-up, questions remain about the clinical significance of a 3-point to 7-point improvement in AHI.

Steward and colleagues (2008) reported on a study of 100 patients with mild to moderate OSA and suspected retropalatal obstruction who were randomly assigned treatment with palatal implants or sham placebo. Patients with BMI >32kg/m² were excluded from the study. About 1000 patients were evaluated to identify the 100 study patients. Final apnea-hypopnea index (AHI) increased in both groups at three months from a baseline of about 17, although the increase was greater in the placebo group (8.9 vs. 2.9). A reduction in AHI by at least 50% or to below 20 was more common in the implant group (26% vs. 10%), P=0.05). Improvement in Epworth Sleepiness Score did not differ from that of sham (P=0.62). Partial implant extrusion occurred in two patients (4%). The authors concluded that palate implants for mild to moderate obstructive sleep apnea demonstrated efficacy over placebo for several outcomes measures, but overall effectiveness was limited.

Based on the above peer reviewed scientific literature; the evidence is insufficient to support the efficacy of these palatal stiffening procedures for OSA.

Obstructive Sleep Apnea/Upper Airway Respiratory Syndrome in Children

The clinical presentation and criteria for the diagnosis of OSA in children differ from those in adults. Adult criteria for diagnosis and treatment of OSA cannot be applied to the pediatric population. Obstructive sleep-disordered breathing is common in children. From three percent to 12 percent of children snore, while obstructive sleep apnea syndrome affects one percent to 10 percent of children (AAP, 2002). The majority of these children have mild symptoms, and many outgrow the condition. The most frequently reported symptoms by parents include mouth breathing, diaphoresis, paradoxical rib-cage movement, restlessness, frequent awakenings, and witnessed apneic episodes. Children may have sleep disruption because of an increased effort to breathe but show no evidence of apnea on polysomnography. This condition is called upper airway resistance syndrome. Older children (five years and older) more commonly exhibit enuresis, behavior problems, deficient attention span, and failure to thrive, in addition to snoring. If a parent suspects that his or her child may suffer from a sleep disorder, the American Academy of Pediatrics (AAP) recommends that the child have a thorough physical examination by his or her pediatrician. A pediatrician, pulmonologist or physician specializing in sleep disorders should diagnose the condition and recommend treatment.

Consequences of untreated obstructive sleep apnea include failure to thrive, enuresis, attention-deficit disorder, behavior problems, poor academic performance, and cardiopulmonary disease. The most common etiology of obstructive sleep apnea is adenotonsillar hypertrophy. The gold standard for the evaluation of OSA in children is overnight polysomnography. Polysomnography is necessary for the diagnosis of OSA in children, but it has not been well standardized in its performance or interpretation. Polysomnography can be performed satisfactorily in children of any age, providing that appropriate equipment and trained staff is used.

Some studies have been done on abbreviated screening techniques such as videotaping, nocturnal pulse oximetry, and daytime nap polysomnography which tend to be helpful only if the results are positive. However, they have a poor predictive value if results are negative. Therefore, children with negative study results will need to have a comprehensive evaluation with PSG. The use of these techniques for the evaluation of severity of OSAS (which is essential in determining management) has not been evaluated.

The parameters originally used to evaluate childhood polysomnograms were based on adult values. OSA in adults is defined as a respiratory pause lasting more than 10 seconds. Because of a child's different physiology and higher baseline respiratory rate, clinically relevant apneas may not last this long. Apneas of three to four seconds' duration can be accompanied by desaturations. These findings have led to the development of separate guidelines for the interpretation of polysomnograms in children. The International Classification of Sleep Disorders, Second Edition guidelines for the diagnosis of pediatric OSA, require an AHI of at least one [average: 0.1 to 0.5 events per hour] scorable respiratory event lasting at least two respiratory cycles (Hoban, 2007). However, Schechter (2002), reporting for the American Academy of Pediatrics and others, notes that, while this value of one is of statistical significance based on normative data, it is unclear what level of AHI is of clinical significance or is associated with the development of adverse health outcomes.

In 2002 the American Academy of Pediatrics (AAP) published a guideline on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treatment in the primary care setting. OSA occurs most commonly in preschool aged children when the tonsils and adenoids are the largest, in relation to the airway size. For this reason, adenotonsillectomy (AT) is generally recognized as the most appropriate first-line treatment of choice for childhood OSA (Marcus, 2002; Hoban, 2007; Benninger, 2007; Darrow, 2007). The AAP also advised that adenotonsillectomy should be considered first-line treatment for sleep-disordered breathing in children when there is physical evidence of adenotonsillar hypertrophy and remains the treatment of choice for most children with a strong clinical history of OSA or with OSA documented by polysomnography (AAP, 2002). Success rates for AT in relieving OSA have been reported to be in the 75%-85% range, although lower rates have been reported in other studies, and Tauman (2006) reported a reduction in AHI to one or less (i.e. complete resolution of OSA) in only 25% of 110 children, with obesity being associated with the lesser rates of success.

Evidence has been shown that adenotonsillectomy improves snoring, OSA, weight problems, enuresis, and behavior problems in children who have the entire clinical spectrum of sleep-disordered breathing and is curative in most patients. While most children with sleep-disordered breathing can be treated safely on an outpatient basis, children with severe OSA demonstrated on

polysomnography, those younger than three years, and those with medical co-morbidities, neuromuscular disease, bleeding diatheses or syndromes should be admitted and monitored overnight after surgery. Postoperative respiratory complications occur in children with a high preoperative apnea-hypopnea index, with rates of complications ranging from zero to 27 percent. (Chan et al., 2002). Additionally, in children with craniofacial syndromes, preoperative polysomnography suggestive of severe OSA, or OSA that is refractory to standard management, repeating polysomnography six weeks after surgery is recommended. However, in most patients, postoperative polysomnography remains unnecessary.

Other surgical alternatives may include uvulopalatopharyngoplasty which may be indicated when a thick soft palate and a long uvula are present. Additionally, uvulopalatopharyngoplasty may be considered for children with modest adenotonsillar hypertrophy but severe symptoms of OSA, those with polysomnographically documented severe OSA, and children with trisomy 21. Tracheotomy, the definitive surgery for upper airway obstruction, is reserved for use in children with severe OSA who have failed to improve with other medical and surgical treatments and in special cases in which these modalities are contraindicated or not tolerated (Chan, 2002).

For children whose OSA has failed to resolve following AT, or who have a condition not amenable to AT (e.g., craniofacial anomaly as the primary underlying cause of OSA), or where AT is contraindicated, CPAP has been shown to be effective therapy with success rates in the 74%-97% range (Hoban, 2007). However, as reported in a small study of 29 patients (Marcus, 2006), adherence to CPAP therapy may be suboptimal in the pediatric age group. CPAP is difficult for approximately 20 percent of children to tolerate. Because children grow rapidly, frequent follow-up visits are necessary, and the mask must be adjusted at least every six months. Other adjunctive measures in the treatment of childhood OSAS have not been prospectively evaluated. Avoidance of environmental tobacco smoke and other indoor pollutants, avoidance of indoor allergens, and treatment of accompanying rhinitis may be helpful. In obese patients, weight loss strategies should be used. However, implementation of adjunctive therapies should not delay specific treatment of OSAS.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy.

Type	Number	Description
CPT	Actigraphy	
	0089T	Actigraphy testing, recording, analysis and interpretation (minimum of three-day recording)
	95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
	CPAP	
	94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
	Multiple sleep latency testing	
	95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
	Polysomnography	
	0203T	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone) and sleep time
	0204T	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)
	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	Polysomnography; sleep staging with four or more additional parameters of sleep, attended by a technologist

Type	Number	Description
	95811	Polysomnography; sleep staging with four or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist
Surgical Management		
	0088T	Sub-mucosal radiofrequency tissue volume reduction of tongue base, one or more sites, per session (i.e., for treatment of obstructive sleep apnea syndrome)
	21198	Osteotomy, mandible, segmental;
	21199	Osteotomy, mandible, segmental; with genioglossus advancement
	21206	Osteotomy, maxilla, segmental (e.g., Wassmund or Schuchard)
	21685	Hyoid myotomy and suspension
	41512	Tongue base suspension, permanent suture technique
	41530	Sub-mucosal ablation of the tongue base, radiofrequency, one or more sites, per session
	42145	Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
	42299	Unlisted procedure, palate, uvula
HCPC	Accessories and Supplies	
	A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each
	A7028	Oral cushion for combination oral/nasal mask, replacement only, each
	A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair
	A7030	Full face mask used with positive airway pressure device, each
	A7031	Face mask interface, replacement for full face mask, each
	A7032	Cushion for use on nasal mask interface, replacement only, each

Type	Number	Description
	A7033	Pillow for use on nasal cannula type interface, replacement only, pair
	A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
	A7035	Headgear used with positive airway pressure device
	A7036	Chinstrap used with positive airway pressure device
	A7037	Tubing used with positive airway pressure device
	A7038	Filter, disposable, used with positive airway pressure device
	A7039	Filter, non-disposable, used with positive airway pressure device
	E0561	Humidifier, non-heated, used with positive airway pressure device
	E0562	Humidifier, heated, used with positive airway pressure device
BiPAP		
	E0470	Respiratory assist device, bi-level pressure capability, without backup 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)
CPAP		
	E0601	Continuous airway pressure (CPAP) device
Home/ Portable Sleep Study		
	G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of seven 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 four channels: two respiratory movement/airflow, one ECG/heart rate and one oxygen saturation

Type	Number	Description
	G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of three channels
	Intraoral Appliances	
	E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
	E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
	S8262	Mandibular orthopedic repositioning device, each
	Surgical Management	
	C9727	Insertion of implants into the soft palate; minimum of three implants
	S2080	Laser-assisted uvulopalatoplasty (LAUP)
ICD9 Procedure	Surgical Management	
	27.64	Insertion of palatal implant
	27.69	Other plastic repair of palate
	27.73	Repair of uvula
	29.4	Plastic operation on pharynx
	Polysomnography	
	89.17	Polysomnogram
	89.18	Other sleep disorder function tests
	CPAP	
	93.90	Non-invasive mechanical ventilation
ICD9 Diagnosis	327.2	Organic sleep apnea
	327.20	Organic sleep apnea, unspecified
	327.21	Primary central sleep apnea
	327.22	High altitude periodic breathing
	327.23	Obstructive sleep apnea (adult) (pediatric)
	327.27	Central sleep apnea in conditions classified elsewhere

Type	Number	Description
	327.29	Other organic sleep apnea
	347	Cataplexy and narcolepsy
	347.0	Narcolepsy
	347.00	Narcolepsy, without cataplexy
	347.01	Narcolepsy, with cataplexy
	347.1	Narcolepsy in conditions classified elsewhere
	347.10	Narcolepsy in conditions classified elsewhere, without cataplexy
	347.11	Narcolepsy in conditions classified elsewhere, with cataplexy
	780.5	Sleep disturbances
	780.50	Unspecified sleep disturbance
	780.51	Insomnia with sleep apnea, unspecified
	780.52	Insomnia, unspecified
	780.53	Hypersomnia with sleep apnea, unspecified
	780.54	Hypersomnia, unspecified
	780.55	Disruption of 24 hour sleep wake cycle, unspecified
	780.56	Dysfunctions associated with sleep stages or arousal from sleep
	780.57	Unspecified sleep apnea
	780.58	Sleep related movement disorder, unspecified
	780.59	Other sleep disturbances
Place of Service	All Places of Service	

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-343-1691 or visit the Provider Portal www.blueshieldca.com/provider.

Documentation Required for Clinical Review

- History and Physical, or Consultation notes, or Office Notes: including reason for request, diagnosis, height, weight, BMI, symptoms, conservative treatment trials, treatment plan, documented test results (if applicable)
- Polysomnography Report (if applicable)
- Sleep Specialty Physician recommendation and prescription for Positive Airway Pressure device or Intraoral device (if applicable)
- Operative report (if applicable)
- Copy of FDA 510 K clearance document for intraoral appliance or MRA/MRD/MAA/MAS (if applicable)

References

- *American Academy of Pediatrics (AAP). Clinical Practice Guideline: Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. 2002;109(4):704-712*
- *American Academy of Pediatrics. American Academy of Pediatrics Clinical Practice Guideline: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome Section on Pediatric Pulmonology and Subcommittee on Obstructive Sleep Apnea Syndrome PEDIATRICS Vol. 109 No. 4 April 2002, pp. 704-712*
- *American Academy of Sleep Medicine. Practice Parameters for the Use of Autotitrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome: An Update for 2007. Sleep. 2008 January 1; 31(1): 141-147*
- *American Thoracic Society. Standards and indications for cardiopulmonary sleep studies in children. Am J Respir Crit Care Med. 1996; 153:866-878*
- *Bassiouny A, El Salamawy A, Abd El-Tawab M et al. Bipolar radiofrequency treatment for snoring with mild to moderate sleep apnea: a comparative study between the*

- radiofrequency assisted uvulopalatoplasty technique and the channeling technique. Eur Arch Otorhinolaryngol* 2007; 264(6):659-67
- *Benninger M, Walner D. Obstructive sleep-disordered breathing in children. Clinical Cornerstones.* 2007; 9, Issue Suppl 1
 - *Berry RB, Hill G, Thompson L et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. Sleep* 2008;31(10):1423-31
 - *Berry RB, Parish JM, Hartse KM. The use of auto-titrating continuous positive airway pressure for treatment of adult obstructive sleep apnea. Sleep* 2002; 25(2):148-73
 - *Blue Cross Blue Shield Association Medical Policy Reference Manual. Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome DRAFT. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual (February 2009) Medicine 2.01.18*
 - *Blue Cross Blue Shield Association Medical Policy Reference Manual. Minimally Invasive Surgery for Snoring, Obstructive Sleep Apnea Syndrome/Upper Airway Resistance Syndrome DRAFT. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual (February 2009) Surgery 7.01.101*
 - *Blue Cross Blue Shield Association Medical Policy Reference Manual. Minimally Invasive Surgery for Snoring, Obstructive Sleep Apnea Syndrome/Upper Airway Resistance Syndrome. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual (June 2007) Surgery 7.01.101*
 - *Blue Cross Blue Shield Association Medical Policy Reference Manual. Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual (January 2008) Medicine 2.01.18*
 - *Blue Cross Blue Shield Association Medical Policy Reference Manual. Surgical Management of Obstructive Sleep Apnea Syndrome/Upper Airway Resistance Syndrome. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual (February 2005); Surgery 7.01.51*
 - *Blue Cross Blue Shield TEC Assessment. 1995 TEC Assessments; Tab 31*
 - *BlueCross BlueShield Association (BCBSA), Technology Evaluation Center. TEC Assessments 2000; Tab 15*
 - *Bridevaux PO, Fitting JW, Fellrath JM, et al. Inter-observer agreement on apnoea hypopnoea index using portable monitoring of respiratory parameters. Swiss Med Wkly* 2007; 137(43-44):602-7
 - *Centers for Medicare & Medicaid Services. CMS Manual System. Pub 100-3, Medicare National Coverage Determination. Continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea; 240.4. Mar 13 2008. Accessed Sep 3, 2008*
 - *Chan J, Edmand J, Koltai P. Obstructive Sleep Apnea in Children, American Family Physician™ Am Fam Physician.* 2004 Mar 1;69(5):1147-54
 - *Chesson AL Jr, Berry RB, Pack A; American Academy of Sleep Medicine; A. Practice parameters for the use of portable monitoring devices in the investigation of suspected*

obstructive sleep apnea in adults. Sleep 2003; 26(7):907-13. Available online at: <http://www.aasmnet.org/PDF/260719.pdf>

- *Collop NA, Anderson WM, Boehlecke B et al; Portable Monitoring Task Fo. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. J Clin Sleep Med 2007; 3(7):737-47. Available at: <http://www.aasmnet.org/jcsm/AcceptedPapers/PMProof.pdf> . Last accessed February 2007*
- *Darrow DH. Surgery for pediatric sleep apnea. Otol Clin N Am. 2007; 40(4):855-875*
- *Farrar J, Ryan J, Oliver E et al. Radiofrequency ablation for the treatment of obstructive sleep apnea: a meta-analysis. Laryngoscope 2008; 118(10):1878-83*
- *Ferguson K, Ono T, Lowe A, Keenan S, Fleetham J. A randomized crossover study of an oral appliance vs. nasal-continuous positive airway pressure in the treatment of mild-moderate obstructive sleep apnea. Chest. 1996;109:1269-75*
- *Ferguson KA, Heighway K, Ruby RR. A randomized trial of laser-assisted uvulopalatoplasty in the treatment of mild obstructive sleep apnea. Am J Respir Crit Care Med 2003; 167(1):15-9*
- *Flemons WW, Littner MR, Rowley JA et al. Home diagnosis of sleep apnea: a systematic review of the literature. An evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. Chest 2003; 124(4): 1543-79*
- *Fogel RB and White DP. Obstructive Sleep Apnea. Adv Intern Med, 2000. 45:351-389*
- *Friedman M, Vidyasagar R, Bliznikas D et al. Patient selection and efficacy of pillar implant technique for treatment of snoring and obstructive sleep apnea/hypopnea syndrome. Otolaryngol Head Neck Surg 2004; 134(2):187-96*
- *Garcia-Diaz E, Quintana-Gallego E, Ruiz A et al. Respiratory polygraphy with actigraphy in the diagnosis of sleep apnea-hypopnea syndrome. Chest 2007; 131(3):725-32*
- *Giles TL, Lasserson TJ, Smith BJ, White J, Wright J, Cates CJ. Continuous positive airway pressure for obstructive sleep apnea in adults. Cochrane Database Syst Rev. 2006 Jul 19;3:CD0011006*
- *Goroll AH, Mulley AG, editors. Approach to the patient with sleep apnea. In: Primary Care Medicine, 5th ed. Lippincott Williams & Wilkins; 2008*
- *Guilleminault C, Stoohs R, Clerk A et al. A cause of daytime sleepiness. The upper airway resistance syndrome. Chest 1993; 104(3):781-7*
- *Ho WK, Wei WI, Chung KF. Managing disturbing snoring with palatal implants: a pilot study. Arch Otolaryngol Head Neck Surg 2004; 130(6):753-8*
- *Hoban TF, Chervin RD. Sleep-related breathing disorders of childhood: description and clinical picture, diagnosis, and treatment approaches. Sleep Med Clin. 2007; 2(3):445-462*
- *Hussain SF, Love L, Burt H et al. A randomized trial of auto-titrating CPAP and fixed CPAP in the treatment of obstructive sleep apnea-hypopnea. Respir Med 2004; 98(4):330-3*

- *Institute for Clinical Systems Improvement (ICSI). Health Care Guideline: Diagnosis and Treatment of Obstructive Sleep Apnea. Sixth Edition. June 2008*
- *Krahn AD, Yee R, Erickson MK et al. Physiologic pacing in patients with obstructive sleep apnea: a prospective, randomized crossover trial. J Am Coll Cardiol 2006; 47(2):379-83*
- *Kuhnel TS, Hein G, Hohenhorst W et al. Soft palate implants: a new option for treating habitual snoring. Eur Arch Otorhinolaryngol 2005; 262(4):277-80*
- *Kushida CA, Littner MR, Hirshkowitz M, Morgenthaler TI, Alessi CA, Bai. Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. Sleep. 2006 Mar 1;29(3):375-80*
- *Kushida CA, Littner MR, Morgenthaler T, Alessi CA, Bailey D, Coleman J. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. Accessed Feb 2, 2008. Available at URL address: <http://www.aasmnet.org/PracticeParameters.aspx?cid=104>*
- *Kushida CA, Morgenthaler TI, Littner MR, Alessi CA, Bailey D, Coleman. Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: an update for 2005. Sleep. 2006 Feb 1;29(2):240-3*
- *Lattimore JDL, Celemjer DS, Wilson I. Obstructive sleep apnea and cardiovascular disease. J Am Coll Cardiol. 2003 May 7;41(9):1429-37*
- *Lim J, Lasserson TJ, Fleetham J et al. Oral appliances for obstructive sleep apnoea. Cochrane Database Syst Rev 2006; (1):CD004435*
- *Littner M, Hirshkowitz M, Davila D et al. 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. Sleep 2002; 25(2):143-7*
- *Littner M, Kushida CA, Hartse K et al. Practice parameters for the use of laser-assisted uvulopalatoplasty: an update for 2000. Sleep 2001; 24(5):603-8*
- *Littner MR, Kushida C, Wise M, Davila DG, Morgenthaler T, Lee-Chiong T. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. Sleep. 2005 Jan 1;28(1):113-121*
- *Mair EA, Day RH. Cautery-assisted palatal stiffening operation. Otolaryngol Head Neck Surg 2000; 122(4):547-56*
- *Marcus CL, et al. Section on Pediatric Pulmonology, Subcommittee on Obstructive Sleep Apnea Syndrome. American Academy of Pediatrics. Clinical Practice Guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. 2002;109(4):704-12*
- *Marcus CL, Omlin KJ, Basinski DJ, et al. Normal polysomnographic values for children and adolescents. AM Rev Resp Dis. 1992; 146:1235-1239*
- *Marklund M, Franklin KA, Sahlin C, et al. The effect of mandibular advancement device on apneas and sleep in patients with obstructive sleep apnea. Chest 1998; 113:707-713*
- *Marrone O, Resta O, Salvaggio A et al. Preference for fixed or automatic CPAP in patients with obstructive sleep apnea syndrome. Sleep Med 2004; 5(3):247-51*
- *Mason: Murray & Nadel's textbook of Respiratory Medicine, 4th ed. Saunders, an Imprint of Elsevier; 2005*

- Maurer JT, Verse T, Stuck BA et al. Palatal implants for primary snoring: short-term results of a new minimally invasive surgical technique. *Otolaryngol Head Neck Surg* 2005; 132(1):125-31
- Morgenthaler T, Alessi C, Friedman L et al. Standards of Practice Committee; American Academy of Sleep Medicine. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. *Sleep* 2007; 30(4):519-29
- Morgenthaler T, Alessi C, Friedman L, Owens J, Kapur V, Boehlecke B, e. Standards of Practice Committee, American Academy o Sleep Medicine. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. *Sleep*. 2007 Apr 1;30(4):519-29
- Mulgrew AT, Fox N, Ayas NT et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Intern Med* 2007; 146(3):157-66
- National Institute for Health and Clinical Evidence (NICE). Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. *Technology Appraisal Guidance 139*. London, UK:NICE;November 2007
- Pang KP, Terris DJ. Modified cautery-assisted palatal stiffening operation: new method for treating snoring and mild obstructive sleep apnea. *Otolaryngol Head Neck Surg* 2007; 136(5):823-6
- Polysomnography Task Force, American Sleep Disorders Association Stand. Practice parameters for the indications for polysomnography and related procedures. *Sleep* 1997; 20(6):406-22
- Reeves-Hoche MK, Hudgel DW, Meck R et al. Continuous versus bilevel positive airway pressure for obstructive sleep apnea. *Am J Respir Crit Care Med* 1995; 151(2 pt 1):443-9
- Schechter MS. American Academy of Pediatrics. Technical report: Diagnosis and management of childhood sleep apnea syndrome. *Pediatrics*. 2002;109(4):e69-e69
- Senn O, Brack T, Russi EW et al. A continuous positive airway pressure trial as a novel approach to the diagnosis of the obstructive sleep apnea syndrome. *Chest* 2006; 129(1):67-75
- Sher AE, Schechtman KB, Piccirillo JF. The efficacy of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep*. 1996 Feb;19(2):156-77
- Simantirakis EN, Schiza SE, Chrysostomakis SI et al. Atrial overdrive pacing for the obstructive sleep apnea-hypopnea syndrome. *N Engl J Med* 2005; 353(24):2568-77
- Somers VK, White DP, Amin R, Abraham WT, Costa F, Culebras A, et al. Sleep apnea and cardiovascular disease: an American Heart Association/American College of Cardiology Foundation Scientific Statement from the American Heart Association Council for High Blood Pressure Research Professional Education Committee, Council on Clinical Cardiology, Stroke Council, and Council on Cardiovascular Nursing. *J Am Coll Cardiol*. 2008 Aug 19;52(8):686-717
- Stammnitz A, Jerrentrup A, Penzel T et al. Automatic CPAP titration with different self-setting devices in patients with obstructive sleep apnoea. *Eur Respir J* 2004; 24(2):273-8

- *Standards of Practice Committee of the American Sleep Disorders Associ. Practice parameters for the use of laser-assisted uvulopalatoplasty. Sleep 1994; 17(8):744-8*
- *Steward DL, Huntley TC, Woodson BT et al. Palate implants for obstructive sleep apnea: multiinstitution, randomized, placebo-controlled study. Otolaryngol Head Neck Surg. 2008; 139(4):506-10*
- *Steward DL, Weaver EM, Woodson BT. A comparison of radiofrequency treatment schemes for obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2004; 130(5):579-85*
- *Steward DL. Effectiveness of multilevel (tongue and palate) radiofrequency tissue ablation for patients with obstructive sleep apnea syndrome. Laryngoscope 2004; 114(12):2073-84*
- *Sundaram S, Bridgman SA, Lim J, Lasserson TJ. Surgery for obstructive sleep apnoea. Cochrane Database Syst Rev. 2005 Oct 19;(4):CD001004*
- *Tauman R, Gulliver TE, Krishna J, et al. Persistence of obstructive sleep apnea syndrome in children after adenotonsillectomy. J Ped. 2006; 149(6): 803-808*
- *Thorpy M, Chesson A, Derderian S, K, Kader G, Millman R, Potolicchio. Practice Parameters for the treatment of obstructive sleep apnea in adults: the efficacy of surgical modifications of the upper airway. Standards of Practice Committee of the American Sleep Disorders Association*
- *Thurnheer R, Bloch KE, Laube I et al; Swiss Respiratory Polygraphy Reg. Respiratory polygraphy in sleep apnea diagnosis. Report of the Swiss respiratory polygraphy registry and systematic review of the literature. Swiss Med Wkly 2007; 137(5-6):97-102*
- *Trikalinos TA, Ip S, Raman G et al. Home diagnosis of obstructive sleep apnea-hypopnea syndrome. AHRQ Technology Assessment Program. Agency for Healthcare Research and Quality, Rockville, MD; August 2007. Available online at <http://www.cms.hhs.gov/determinationprocess/downloads/id48TA.pdf>. Last accessed February 2, 2008*
- *van den Broek E, Richard W, van Tinteren H et al. UPPP combined with radiofrequency thermotherapy of the tongue base for the treatment of obstructive sleep apnea syndrome. Eur Arch Otorhinolaryngol 2008; 265(11):1361-5*
- *Victor LD. Obstructive Sleep Apnea. Am Fam Physician, 1999. 60(8):2279-2286*
- *Walker RP, Grigg-Damberger MM, Gopalsami C et al. Laser-assisted uvulopalatoplasty for snoring and obstructive sleep apnea: Results in 170 patients. Laryngoscope 1995; 105(9 pt 1):938-43*
- *Walker RP, Levine HL, Hopp ML et al. Extended follow-up of palatal implants for OSA treatment. Otolaryngol Head Neck Surg 2007; 137(5):822-7*
- *Walker RP, Levine HL, Hopp ML et al. Palatal implants: a new approach for the treatment of obstructive sleep apnea. Otolaryngol Head Neck Surg 2006; 135(4):549-54*
- *Wassmuth Z, Mair E, Loubé D et al. Cautery-assisted palatal stiffening operation for the treatment of obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2000; 123(1 pt 1):55-60*

- *Whitelaw W, Brant R, Flemons W. Clinical Usefulness of Home Oximetry Compared with Polysomnography for Assessment of Sleep Apnea. Am J Respir Crit Care Med 2005;171:188-93*
- *Woodson BT, Steward DL, Weaver EM et al. A randomized trial of temperature-controlled radiofrequency, continuous positive airway pressure, and placebo for obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2003; 128(6):848-61*

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Orthognathic Surgery

Key/Related Searchable Words

AHI: Apnea/Hypopnea index; average number of apneas and hypopneas per hour of sleep. AHI and RDI may be used interchangeably.

Body Mass Index (BMI) - BMI uses a mathematical formula that takes into account both a person's height and weight to calculate a person's body fat. BMI equals a person's weight in kilograms divided by height in meters squared. ($BMI = \text{kg}/\text{m}^2$).

Diagnostic Audio Recording (SNAP™ Testing) - a diagnostic test proposed for home use which may be self-administered; An audio recording is analyzed for apneic episodes while a patient is sleeping, primarily to help confirm the diagnosis in children. The test sometimes is accompanied by pulse oximetry; the results may be analyzed by a computer; later models of the SNAP Testing Systems contain additional components or channels for the testing of respiratory parameters (air flow, effort, and audio) and additional channels that monitor oxygen saturation and pulse with an additional optional body position channel which would meet the definition of a Type III home portable testing device. However, this test has a poor predictive value if the results are negative.

Epworth Sleepiness Scale (ESS) - a short self-administered questionnaire that asks patients their likelihood of falling asleep in 8 situations ranked from 0 (would never doze) to 3 (high chance of dozing). The maximum score on the ESS is 24 and a score of 10 or below is considered normal.

Excessive Daytime Sleepiness - a condition where a person feels very drowsy during the day, even after getting adequate night time rest, and has a tendency to fall asleep or requires extra effort to avoid sleeping in inappropriate situations, such as at work or driving; also defined as a score greater than or equal to 10 on the Epworth Sleepiness Scale.

Nap Study - a shorter daytime version of a polysomnography sleep study.

Narcolepsy - a neurological condition, where patients experience profound daytime sleepiness; it may also include sudden, periodic, and transient loss of muscle tone associated with extreme emotions, such as laughter or anger (cataplexy).

RDI: Respiratory disturbance index; similar to the apnea-hypopnea index, however, it also includes respiratory events that do not technically meet the definitions of apneas or hypopneas, but do disrupt sleep. Note: AHI and RDI may be used interchangeably.

Sleep Strip - a disposable home screening electronic device with an integrated microprocessor integrated microprocessor that measures the number of times that you stop breathing while you sleep and then determines the presence and severity of sleep apnea.

Upper Airway - the area of the upper respiratory system including the nose, mouth and throat.

Watch PAT - is a self-contained device that is worn on the wrist and uses a non-invasive finger mounted pneu-optical probe to measure the PAT signal. The recorded signals are stored in a removable memory card in the device to be downloaded to a computer for automatic analysis utilizing proprietary algorithms. In addition to the PAT Signal, the watch-PAT 100 records oxygen saturation and actigraphy. A fourth channel, pulse rate, is derived from the PAT Signal.

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
4/03/2009	Medical Policy Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome/UARS (includes Mandibular Repositioning Device) combined with medical Policy Obstructive Sleep Apnea Surgeries-UPPP, LAUP and Somnoplasty (RFVTR) to create a new Medical Policy. Added Medically Necessary (MN), Not Medically Necessary and Investigational indications. Criteria clarified and revised. Literature update and Rationale added. Coding updated.	Medical Policy Committee
06/18/2009	Administrative review	Administrative review
01/19/2010	Coding Update	Administrative Review

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.